VOLUME 47, NUMBER 5

NOVEMBER 1, 2020



ADMINISTRATIVE REGISTER OF KENTUCKY

The submission deadline for this edition of the Administrative Register of Kentucky was noon, October 15, 2020.

MEETING NOTICES

The Administrative Regulation Review Subcommittee is <u>tentatively</u> scheduled to meet on November 9, 2020, at 1:00 p.m. in room 171 Capitol Annex.

ARRS Tentative Agenda - 889 Online agenda updated as needed

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Chapter and Regulation number, as follows:

Title		Chapter	Regulation
806	KAR	050:	155
Cabinet, Department,		Office, Division, Board,	Specific

Board, or Agency

fice, Division, Board, Specific or Major Function Regulation

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Administrative Regulation Review Subcommittee TENTATIVE Meeting Agenda Monday, November 9, 2020 at 1 p.m. Annex Room 171



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201 KAR 002:106. Licensed or permitted facility closures. (Deferred from September)

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- 201 KAR 002:240. Special limited pharmacy permit- Charitable. (Deferred from September)
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Board of Licensure of Marriage and Family Therapists

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202 KAR 007:401. Paramedics. (Amended After Comments)

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302 KAR 050:045. Department's reports to USDA; records retention for three years.

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601 KAR 002:231. Repeal of 601 KAR 002:030. (Deferred from October)

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702 KAR 007:140E. School calendar. ("E" expires 05-09-2021)

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902 KAR 002:210E. Covering the face in response to a declared national or state public health emergency. ("E" expires 05-07-2021)

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902 KAR 045:110. Permits and fees for retail food establishments, vending machine companies, and restricted food concessions. (Amended After Comments)

902 KAR 045:180. Permits and fees for food manufacturing plants, food storage warehouses, salvage processors and distributors, cosmetic manufacturers, and certificate of free sale. (Amended After Comments)

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902 KAR 050:080. Standards of identity and labeling.

902 KAR 050:090. Milk adulteration.

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908 KAR 001:381, Repeal of 908 KAR 001:380, (Deferred from October)

Department for Community Based Services

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921 KAR 003:035 & E. Certification process. ("E" expires 04-25-2021)

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922 KAR 001:500. Educational and training vouchers.

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601 KAR 002:232 & E. Kentucky Ignition Interlock Program. ("E" expires 04-25-2021) (Comments Received; SOC ext., due 11-13-2020)

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902 KAR 008:160 & E. Local health department operations requirements. ("E" expires 05-05-2021) (Comments Received; SOC ext., due 11-13-2020)

902 KAR 008:170 & E. Local health department financial management requirements. ("E" expires 05-05-2021) (Comments Received; SOC ext., due 11-13-2020)

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Milk and Milk Products

902 KAR 050:040. Hauler requirements. (Comments Received; SOC ext., due 11-13-2020)

Department for Behavioral Health, Developmental and Intellectual Disabilities Substance Abuse

908 KAR 001:381. Repeal of 908 KAR 001:380. (Deferred from October) 908 KAR 001:400. Licensing and standards for substance use and misuse prevention. (Comments Received; SOC ext., due 11-13-2020)

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922 KAR 001:450 & E. Eligibility confirmation for tuition waiver. ("E" expires 05-05-2021) (Comments Received; SOC ext., due 11-13-2020)

922 KAR 001:520 & E. Supplements to per diem rates. ("E" expires 4-26-2021) (Comments Received; SOC ext., due 11-13-2020)

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ADMINISTRATIVE REGULATION REVIEW PROCEDURE Overview for Regulations Filed BEFORE noon, July 15, 2019 (See KRS Chapter 13A for specific provisions)

Filing and Publication

Administrative bodies shall file with the Regulations Compiler all proposed administrative regulations, public hearing and comment period information, regulatory impact analysis and tiering statement, fiscal note, federal mandate comparison, and incorporated material information. Those administrative regulations received by the deadline established in KRS 13A.050 shall be published in the Administrative Register.

Public Hearing and Public Comment Period

The administrative body shall schedule a public hearing on proposed administrative regulations, which shall not be held before the 21st day or later than the last workday of the month of publication. Written comments shall also be accepted until the end of the calendar month in which the administrative regulation was published.

The administrative regulation shall include: the place, time, and date of the hearing; the manner in which persons may submit notification to attend the hearing and written comments; that notification to attend the hearing shall be sent no later than 5 workdays prior to the hearing date; the deadline for submitting written comments; and the name, position, mailing address, e-mail address, and telephone and fax numbers of the person to whom notification and written comments shall be sent.

The administrative body shall notify the Compiler, by letter, whether the hearing was held or cancelled and whether written comments were received. If the hearing was held or written comments were received, the administrative body shall file a statement of consideration with the Compiler by the fifteenth day of the calendar month following the month of publication.

A transcript of the hearing is not required unless a written request for a transcript is made, and the person requesting the transcript shall have the responsibility of paying for same. A recording may be made in lieu of a transcript.

Review Procedure

After the public hearing and public comment period processes are completed, the administrative regulation shall be reviewed by the Administrative Regulation Review Subcommittee at its next meeting. After review by the Subcommittee, the administrative regulation shall be referred by the Legislative Research Commission to an appropriate jurisdictional committee for a second review. The administrative regulation shall be considered as adopted and in effect as of adjournment on the day the appropriate jurisdictional committee meets or 30 days after being referred by LRC, whichever occurs first.

ADMINISTRATIVE REGULATION REVIEW PROCEDURE Overview for Regulations Filed AFTER noon, July 15, 2019 (See KRS Chapter 13A for specific provisions)

Filing and Publication

Administrative bodies shall file all proposed administrative regulations with the Regulations Compiler. Filed regulations shall include public hearing and comment period information; a regulatory impact analysis and tiering statement; a fiscal note on state and local government; and, if applicable, a federal mandate comparison and any required incorporated material. Administrative regulations received by the deadline established in KRS 13A.050 shall be published in the Administrative Register.

Public Hearing and Public Comment Period

The administrative body shall schedule a public hearing on a proposed administrative regulation, which shall be held between the 21st and the last workday of the month following the month of publication. Written comments shall also be accepted until the end of the calendar month in which the public hearing was scheduled.

Information about the public comment period shall include: the place, time, and date of the hearing; the manner in which a person may submit written comments or a notification to attend the hearing; a statement specifying that unless a notification to attend the hearing is received no later than 5 workdays prior to the hearing date, the hearing may be cancelled; the deadline for submitting written comments; and the name, position, and contact information of the person to whom notifications and written comments shall be sent.

Public comment periods are at least two months long. For other regulations with open comment periods, please also see last month's Administrative Register of Kentucky.

The administrative body shall notify the Compiler, by letter, whether the hearing was held or cancelled and whether or not written comments were received. If the hearing was held or written comments were received, the administrative body shall file a statement of consideration with the Compiler by the fifteenth day of the calendar month following the close of the public comment period.

Review Procedure

After the public hearing and public comment period processes are completed, the administrative regulation will be tentatively scheduled for review at the next meeting of the Administrative Regulation Review Subcommittee. After review by the subcommittee, the administrative regulation shall be referred by the Legislative Research Commission to an appropriate jurisdictional committee for a second review. If a quorum is present, unless the administrative regulation is deferred or found deficient, the administrative regulation shall be considered in effect upon adjournment of the appropriate jurisdictional committee meets or 90 days after being referred by LRC, whichever occurs first.

EMERGENCY ADMINISTRATIVE REGULATIONS

Emergency regulations filed after 7/15/2019 are automatically set to expire 270 days from the date file d. The 270 days may be extended by one month, if comments were received. Emergency regulations expire upon the conclusion of the 270 days (or 270 days plus the number of days of the requested extension) or upon replacement by an ordinary regulation, whichever occurs first.

STATEMENT OF EMERGENCY 31 KAR 4:193E

This emergency administrative regulation is necessary given that the Kentucky Constitution requires free and fair elections, and specifically because the COVID-19 pandemic has created a state of emergency in the Commonwealth and poses a risk to the health and well-being of voters. See, Governor's Executive Orders 2020-215 and 2020-688. This emergency regulation will allow the Commonwealth to conduct general, special, and local option elections on November 3, 2020, in a manner that reduces the amount of exposure voters, poll workers, and administrators have to possible infection, thereby helping state and federal efforts to slow and stop the spread of the novel coronavirus. This emergency administrative regulation is promulgated pursuant to KRS 13A.190(a)(1) and (4), as well as to be consistent with the Voting Accessibility for the Elderly and Handicapped Act, 52 U.S.C. 20101 et seq. Pursuant to KRS 13A.190(1)(b)(1), this emergency regulation is temporary in nature and will expire as provided in this section. To take effect, it must be ratified by the Governor and Secretary of State through respective executive orders. This emergency administrative regulation will not be replaced by an ordinary administrative regulation.

ANDY BESHEAR, Governor JARED DEARING, Director

STATE BOARD OF ELECTIONS (New Emergency Administrative Regulation)

31 KAR 4:193E. Procedures for November 3, 2020 Elections.

EFFECTIVE: October 2, 2020 RELATES TO: KRS Chapters 39A and 117 STATUTORY AUTHORITY: KRS 39A.100(1)(I) NECESSITY, FUNCTION, AND CONFORMITY:

KRS 39A.100(1)(I) requires the State Board of Elections to establish procedures for election officials to follow when the Governor has declared a state of emergency and the Secretary of State has recommended to the Governor, and the Governor has agreed, that a different time, place, or manner for holding elections is necessary. This emergency administrative regulation outlines the procedures to be undertaken to effectively conduct the November 3, 2020 elections. The following temporary emergency regulations relate to the procedures by which a lawful, registered Kentucky voter may cast a ballot for the elections to be held November 3, 2020. This emergency administrative regulation governs the November 3, 2020 elections only. Neither it, nor any of its component parts, is intended to govern or influence the conduct of any other election. This emergency administrative regulation does not create legal authority or precedent for any election beyond the November 3, 2020 elections.

Section 1. All provisions outlined in this emergency administrative regulation shall apply to the Commonwealth's November 3, 2020 elections only. Any existing administrative regulation promulgated by the State Board of Elections that conflicts with any provision herein is suspended in pertinent part as applied to the November 3, 2020 elections. Any existing statute that directly conflicts with Governor's Executive Order 2020-688, inclusive of the Secretary of State's recommendations as incorporated therein, is deemed suspended in pertinent part, by the authority of the General Assembly consistent with Section 15 of the Kentucky Constitution, as applied to the November 3, 2020 elections. However, no regulation or statute is or shall be deemed as suspended, in whole or in part, unless it directly conflicts with Governor's Executive Order 2020-688, the Secretary of State's recommendations as incorporated therein, or the provisions herein.

Section 2. Definitions. All terms used herein shall have the same definitions as currently stated in the Kentucky Revised Statutes and Kentucky Administrative Regulations unless given a definition here.

(1) The phrase "not able to appear at the polls on election day on account of age, disability or illness," as enacted at KRS 117.085(1)(a)(8) shall be interpreted to mean "of an age, or possessing of a health condition or vulnerability, or potentially in contact with a person of an age, or possessing a health condition or vulnerability, that the voter believes subjects the voter, or other person, to an unacceptable risk of harm from contracting or transmitting the novel coronavirus."

(2) "Disability or illness" as enacted at KRS 117.228(1)(c)(8)(e), shall mean to include "an inability to procure photographic proof of identification due to office closure, temporary work stoppage, or backlog of issuing authorities of such photographic proof of identification, as caused by the COVID-19 pandemic; or, possession of a health condition or vulnerability that the voter believes subjects the voter to unacceptable risk of harm from the novel coronavirus, including unacceptable risk of transmission of the virus from the voter to others."

(3) "Inability to obtain his or her birth certificate or other documents needed to show proof of identification," as enacted at KRS 117.228(1)(c)(8)(b) shall mean to include "the inability to provide a copy of proof of identification possessed by the voter."

(4) "Covered voter," as enacted at KRS 117A.010 shall mean to include "those within the disability community who wish to receive their ballot via electronic means in the same manner as utilized by military and overseas voters."

Section 3. In lieu of in-person absentee voting, described by KRS 117.085, County Clerks shall make in-person voting available to any registered voter of the county during generally available hours coinciding with regular business hours beginning on October 13, 2020. No absentee excuse or application otherwise required by KRS 117.077 or 117.085 shall be required for eligibility to vote early in-person. County Clerks shall make in-person voting available to any registered voter of the county on the three Saturdays before the November 3, 2020 election for a span of at least four (4) hours each Saturday. The location(s) for in-person voting shall be permitted to be outside of the County Clerk's office, so long as voting is conducted in a secured area. County Clerks, with assistance from the State Board of Elections and Secretary of State, shall publicize the location(s) where in-person voting shall occur. During the days of in-person voting, appropriate precautions shall be taken consistent with Centers for Disease Control guidance, and the State Board of Elections, with the assistance of the Governor, shall provide materials to assist in proper sanitization. County Clerks shall implement in-person voting procedures that limit direct contact between individuals, whether poll workers or voters. Such procedures shall promote a method of voting whereby poll workers do not come into contact with voters.

Section 4. County Clerks, taking into account population, geographical impediments, and consistent with the term of Section 5 herein, may reduce the number of sites for in-person voting on November 3, 2020 to the number of secured locations in which the Clerk reasonably believes can: (1) be fully staffed with election officials; and (2) facilitate voting in a manner consistent with Centers for Disease Control guidance, as well as, procedures that limit direct contact between individuals, whether poll workers or voters. Such procedures shall promote a method of voting whereby poll workers do not come into contact with voters. At any site used for voting on November 3, 2020, election officials be empowered to check-in any registered voter in the county, regardless of what precinct the voter is registered in, and counties shall have the flexibility to use the same election equipment across sites. The State Board of Elections, with the assistance of the

Governor, shall provide materials to assist in proper sanitization.

Section 5. No later than September 30, 2020, counties shall present any plan to reduce the number of sites for in-person voting on November 3, 2020 to the State Board of Elections, the Office of the Governor, and the Office of the Secretary of State for approval, and no plan for reduction of November 3, 2020 voting locations shall be implemented without the consent of the State Board of Elections, the Office of the Governor, and the Office of the Governor, and the Office of the Secretary of State. Plans shall include: the address and type of facility for each voting location; the number and type of voting machine or machines to be used at the voting location; the number of poll workers required to fully staff the location. Counties shall be authorized to seek approval of an amended plan at any time before November 2, 2020, to add or reduce locations as demand necessitates.

Section 6. Each county shall establish at least one (1) site for in-person voting on November 3, 2020, which is capable of permitting any registered voter residing in the county to vote at that location. In each county's Section 5 Plan, each such site shall be noted as a "County-wide Voting Center." County Clerks, with assistance from the State Board of Elections and Secretary of State, shall publicize the address of this and all location(s) where in-person voting shall occur on November 3, 2020.

Section 7. The provisions of KRS 117.065(2), requiring that buildings, including schools, constructed, in whole or in part, with tax revenues be available as voting places without cost shall not be deemed to directly conflict with any executive order, administrative regulation, or statute.

Section 8. A voter may deliver an absentee ballot to the office of the County Clerk in the county where the voter is registered, or to a secure drop-off location if one is maintained by the County Clerk in the county where the voter is registered, rather than mailing the ballot via the United States Postal Service. To assist County Clerks in managing the flow of receipt of voter-delivered absentee ballots, the State Board of Elections shall purchase secure drop-boxes and provide them to County Clerks based on request and availability with each requesting county being guaranteed one drop-box at minimum. Any county choosing to use a receptacle for ballot drop-off other than the drop-boxes provided by the State Board of Elections during calendar year 2020, must formally seek the State Board of Elections' approval of the receptacle before any ballot shall be allowed to be deposited inside. Any county choosing to utilize a drop-off receptacle, including those provided by the State Board of Elections, shall inform the State Board of Elections of the number of receptacles being used, the type of each receptacle being used, and the location of each drop-off location. Any receptacle located outside a County Clerk's Office shall be placed in a well-lit, easily accessible location, be bolted down, and be under video surveillance at all times. Any drop-box located inside, shall be under direct supervision of the staff of the County Clerk at all times that it is accessible to the public. Each County Clerk utilizing one or more ballot drop-off receptacle shall empty each receptacle at least once each business day of the County Clerk's Office, and secure the absentee ballots therein in a manner consistent with KRS 117.086(6); however, County Clerks shall empty receptacles more frequently than daily, as needed, so as to reasonably accommodate the volume of voter-delivered absentee ballots.

Section 9. County Clerks shall be permitted to utilize as precinct election officials voters who are registered to vote other than as Democrats or Republicans, and all precinct election officials shall be permitted to work in shifts of less than twelve (12) hours. Notwithstanding KRS 117.045(9), voters who have changed their registration within the last year shall be eligible to serve as an election official for the November 3, 2020 elections. In the appointment of precinct election officials for November 3, 2020, County Clerks shall give preference to precinct election officials who have prior experience as same, whether in prior elections or in

early voting conducted pursuant to this regulation.

Section 10. The State Board of Elections shall ensure that each county is provided access to sufficient election equipment, subject to available funding.

Section 11. As soon as feasible, the State Board of Elections shall make available a secure online portal for the request of an absentee ballot by a registered voter. The requester shall provide personally identifiable information in order to request the absentee ballot. The secure online portal shall have the capacity to ensure verification of the identity of the voter, in a manner not inconsistent with Senate Bill 2, 2020 Regular Session of the Kentucky General Assembly, except as applied herein. Should a voter not have a driver's license record on file with the Kentucky Department of Transportation, the voter may confirm their identity by completing an oath of voter, not inconsistent with the language provided from the Secretary of State, found on the secure online portal. The secure online portal shall transmit the request to the County Clerk of the county in which the requester is registered to vote. The County Clerk shall be responsible for determining if a request is valid and may, at their discretion, fulfill a request believed valid by taking the information of a voter without internet access over the telephone or in person and directly inputting that information into the secure online portal. The County Clerk shall transmit a valid absentee ballot to the registered voter within seven (7) days of receipt or within seven (7) days of ballots being available, no sooner than September 15, 2020. The secure online portal shall close at 11:59 p.m. ET, on October 9, 2020. Notwithstanding the availability of this secure online portal, a registered voter shall still be entitled to request a mail-in absentee ballot using the method of request described in KRS 117.085 until October 9, 2020. From October 10, 2020, through November 3, 2020, only applications for an absentee ballot due to medical emergency, pursuant to KRS 117.077, shall be deemed as valid. An application for an absentee ballot due to a medical emergency need not be notarized and this clause shall not expand the definition or use of the term medical emergency.

Section 12. Postage for all ballots sent by County Clerks to voters and for all ballots sent from voters to County Clerks shall be paid by the State. Intelligent Barcodes shall be utilized for tracking of all mail-in absentee ballots and shall serve in lieu of mail books for County Clerks.

Section 13. Prior to issuance of an absentee ballot to a voter, County Clerks shall highlight with a colored marker each signature blank an absentee-by-mail voter is required by law to sign. All absentee ballots shall be received by the County Clerk of the voter's county of registration by no later than 6:00 p.m., local time, on November 3, 2020, except that, any absentee ballot postmarked on or before November 3, 2020 shall be accepted upon receipt by a County Clerk until 6:00 p.m., local time, November 6, 2020. A ballot delivered by 6:00 p.m., local time, on November 3, 2020 shall not be required to bear a postmark.

Section 14. On or before September 14, 2020, each County Board of Elections shall appoint an absentee ballot processing committee with a minimum of four (4) members, all of whom must be registered voters of that county. Each committee shall have an equal number of registered Democrats and registered Republicans, but membership shall not be restricted to registered members of those parties. One political party shall not compose a majority of a committee unless the role of the committee is assumed by the local County Board of Elections. Each County Board of Elections shall establish, and present to the State Board of Elections for approval, a process for observation of absentee ballot processing and counting, to be conducted in a manner consistent with Centers for Disease Control guidance. The absentee ballot processing committee may meet every day, subject to the needs and requirements of ballot processing, beginning as early as September 21, 2020, to review the absentee ballots cast in the county, but no person shall publicize any tallies

or counts of these ballots, or any partial election results, until 6:00 p.m. local time, on November 3, 2020. Once processed, absentee ballots must be stored in a manner consistent with current statutes and practices.

Section 15. No absentee ballot may be processed and counted unless and until the absentee ballot processing committee verifies the signature on the absentee ballot envelope to match the voter's signature of record, to include the signature on the voter's driver's license or voter registration card. If a signature match cannot be made, or if the voter has committed another absentee ballot error that is subject to remediation, the County Board of Elections, absentee ballot processing committee, or the County Clerk shall make a reasonable effort to contact the voter using the contact information provided by the voter's absentee ballot application, and provide the voter with a timeframe and manner in which the voter may cure the discrepancy. All signature cures must be made by November 9, 2020.

Section 16. Counties shall undertake a good-faith effort to cure all absentee ballot irregularities, when possible, with attempts to cure absentee ballot irregularities starting with a letter generated by the State Board of Elections and mailed to the voter with appropriate instructions. In addition to the letter, counties may, but are not required to, also use email or telephone contact information, if such is provided by the voter, in an attempt to inform the voter of the irregularity.

Section 17. To determine voter intent for ballots imperfectly cast, County Boards of Elections shall take the following universal directives into consideration when reviewing ballot irregularities:

(1) Missing outside signature- DON'T REJECT automatically. If there is an inside signature there is at least one signature for review that will meet substantial compliance.

(2) Missing signature on flap- DON'T REJECT automatically. If there was an outside signature there is at least one signature for review that will meet substantial compliance.

(3) Missing outside signature- DO NOT REJECT automatically, but if the inside flap is missing the signature then REJECT IT.

(4) Signature on outside but missing inside flap: REJECT IT.

(5) If there is a signature that can be matched, but flap is missing: REJECT IT.

(6) Inner envelope not sealed but all the components are present and doesn't appear tampered with: ACCEPT IT.

(7) Detached flap: if it isn't attached but is either inside the white envelope or even inside the yellow envelope it will meet substantial compliance: ACCEPT IT.

(8) The Inner Envelope is missing and the ballot is just in the white envelope: REJECT IT.

(9) Returned or dropped off in just the inner envelope with flap attached and signature present: ACCEPT IT.

(10) Returned in an unofficial outside envelope, if inside envelope, flap and signature are present: ACCEPT IT; If no signature on flap: REJECT IT.

(11) A signature is present, but in wrong location: ACCEPT IT

Section 18. State funds shall procure, at minimum, an additional eight staff members for each county, with the eight largest counties by population receiving more staffing and funding proportionally. All meetings of any absentee ballot processing committees must be posted on the State Board of Elections website at least twenty-four (24) hours prior to the meeting; a schedule of meetings that is updated when changes are made to meeting dates shall satisfy this requirement as long as they are posted in advance of the meeting. At least seven (7) business days prior to November 3, 2020, each County Board of Elections must also post on the State Board of Elections' website: the members of an absentee ballot processing committee; any registered challengers; all plans submitted or approved pursuant to Section 5 of this regulation; and all polling locations with addresses and hours of operation. Any cancellation of a meeting by an absentee ballot processing committee, shall not require twenty-four (24) hour notice.

Section 19. The State Board of Elections and the Secretary of State shall jointly conduct an advertising campaign, subject to available funding, to inform voters of changes to election rules referenced herein and voters' options to vote.

Section 20. The Governor shall take such action as is necessary to provide funds sufficient to cover the increase in cost necessitated by implementation of these regulations, including but not limited to matching state funds against, and in order to secure, the maximum matching federal funds available for pandemicrelated election costs.

Section 21. Voters required to submit an affirmation as described in KRS 117.228(1)(c) shall complete "Voter Affirmation Form" SBE 71, 08/2020. Election Officials required to submit an affirmation as described in KRS 117.228(4) shall complete "Election Official Affirmation Form" SBE 72, 09/2020. All final vote totals must be transmitted via "Certification, Official Count and Record of Election Totals" SBE 49, 08/2020 to the Secretary of State's Office no later than 6:00 p.m., local time, November 10, 2020.

Section 22. Counties shall publicly report results from ballots cast by voters in-person on Election Day, by voters during early voting, and all absentee ballots processed by 6:00 p.m., local time, November 3, 2020. Such reporting shall occur no later than 11:59 p.m. ET, November 3, 2020. A second reporting of all votes tallied shall be submitted by counties before 5:00 p.m. ET, November 6, 2020.

Section 23. If an absentee ballot is delivered by hand to a County Clerk's Office by 6:00 p.m., November 3, 2020 or by the United States Postal Service, bearing a postmark of November 3, 2020 or an earlier date, by 6:00 p.m., November 7, 2020., and is discovered to have been delivered to the wrong County Clerk's Office, it shall be sent by the receiving County Clerk to the correct County Clerk via overnight delivery by the United State Postal Service no later than November 9, 2020. County Clerk shall be the Postal Corporate Express Mail Account, which shall be no cost, and shall inform the Postal Clerk that they were instructed to use the Postal Corporate Express Mail Account under the direction of the Kentuckiana Political Mail Coordinator. Once a voter has requested a mail-in absentee ballot, the voter shall not vote in person unless the voter has failed to receive such requested ballot by October 28, 2020.

Section 24. If a voter has requested, but not received their absentee ballot by October 28, 2020, the voter may appear at a county polling location to vote in person. The election officer shall contact the County Clerk and County Board of Elections who shall determine the voter's eligibility and verify the ballot has not been returned and/or counted. The County Clerk or their designee shall cancel the voter's absentee ballot in the Voter Registration System. Only after the voter's application has been canceled in the Voter Registration System shall the voter be required to sign the supplemental roster, an oath of voter, and be informed that voting more than once in an election is a criminal offense. Each voter who is deemed ineligible to vote may vote a provisional ballot or request a hearing before the County Board of Elections.

Section 25. The deadline for a candidate to seek a recanvass for any special election held on November 3, 2020 shall be extended to 4:00 p.m. ET, on November 10, 2020.

Section 26. The provisions of KRS 117.085(10) shall remain except that the State Board of Elections shall be required to produce to any duly qualified candidate, political party or organization committee or officials thereof, or any committee that advocates or opposes an amendment or public question, for a onetime fee of \$3,500, the names of those voters who have: (1) completed an application for a mail-in absentee ballot; (2) turned in an absentee ballot; and (3) those that have voted in-person before November 3, 2020. Requests from the State Board of Elections for production of such information shall require accompanying payment at the time of first request. The payment of the one-time fee of \$3,500 shall require the State Board of Election to provide updates of the information in a Microsoft Excel spreadsheet format twice weekly to the requestor from August 31, 2020 through November 2, 2020. The information provided by the State Board of Elections shall not be used for any commercial purpose.

Section 27. Should changes in conditions related to the COVID-19 pandemic or the effective administration of the November 3, 2020 election require additional policies or procedures, the State Board of Elections shall be authorized to promulgate further administrative regulations after a public meeting of the State Board of Elections, with contingent approval of both the Governor and the Secretary of State.

Section 28. Incorporated by Reference. (1) The following material is incorporated by reference:

(a) "Certification, Official Count and Record of Election Totals", SBE 49, 08/2020;

(b) "Voter Affirmation Form" SBE 71, 08/2020;

(c) "Election Official Affirmation Form" SBE 72, 09/2020.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the State Board of Elections, 140 Walnut Street, Frankfort, Kentucky Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:40 p.m.

ANDY BESHEAR Governor

JARED DEARING, Executive Director

APPROVED BY AGENCY: October 2, 2020

FILED WITH LRC: October 2, 2020 at 8:00 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this temporary emergency administrative regulation shall be held on December 30, 2020, at 10:00 a.m. ET, at the Office of the State Board of Elections. Individuals interested in being heard at this hearing shall notify this agency in writing by five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing was received by that date, the hearing may be cancelled. This hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted until December 31, 2020. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Taylor Brown, 140 Walnut Street, Frankfort, Kentucky 40601, phone (502) 782-9499, email TaylorA.Brown@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

(1) Provide a brief summary of:

(a) What this administrative regulation does: This emergency administrative regulation outlines the procedures to be undertaken to effectively conduct the November 3, 2020 elections.

(b) The necessity of this administrative regulation: This emergency administrative regulation is necessary given that the Kentucky Constitution requires free and fair elections, yet the COVID-19 pandemic has created a state of emergency in the Commonwealth and poses a risk to the health and well-being of voters.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 39A.100(1)(I) orders the State Board of Elections to establish procedures for election officials to follow when the Governor has declared a state of emergency and the Secretary of State has recommended to the Governor, and the Governor has agreed, that a different time, place, or manner for holding elections is necessary.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This emergency administrative regulation fulfills the mandates of KRS

39A.100(1)(I) and will provide the necessary framework for the Commonwealth's November 3, 2020 given the ongoing state of emergency.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

(b) The necessity of the amendment to this administrative regulation:

(c) How the amendment conforms to the content of the authorizing statutes:

(d) How the amendment will assist in the effective administration of the statutes: This is a new emergency administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This emergency administrative regulation will affect all registered voters in the Commonwealth, along with county fiscal courts, and governmental entities related to the administration of electoral processes.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: It is anticipated that any regulated entities impacted by this emergency administrative regulation will have to take no action fundamentally divergent from those actions already established for the administration of electoral processes.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The State Board of Elections estimates that the implementation of this emergency administrative regulation will cost roughly \$5,240,000 at the state government level. County-level should not exceed those already anticipated by election needs under ordinary circumstances. There are no costs to the individual voters to return a mail-in absentee ballot.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Compliance with this new emergency administrative regulation will benefit the entirety of the Commonwealth in that it will allow for the conduction of elections that minimize the health-risk of all involved during the ongoing state of emergency related to the COVID-19 pandemic.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: The cost of the implementation of this emergency administrative regulation for the State Board of Elections will be minimal as most costs will be borne at the county level or subsidized pursuant to the federal Help America Vote Act (HAVA) and Coronavirus Aid, Relief, and Economic Security (CARES) Act.

(b) On a continuing basis: This will be a temporary emergency administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: A combination of federal, state, and local funds will be used in the implementation and enforcement of this emergency administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: The State Board of Elections believes that the implementation of this emergency administrative regulation can be achieved without an increase in fees or funding by the General Assembly.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: No fees are associated with this emergency administrative regulation.

(9) TIERING: Is tiering applied? Tiering is not used in this emergency administrative regulation as a desired result of the promulgation of this emergency administrative regulation is a uniform procedure for the administration of the November 3, 2020 elections throughout all of the counties in the Commonwealth.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? At the state level, the State Board of Elections and the Secretary of State's Office will be impacted by this emergency administrative regulation. At the local level, office of all County Clerks and all local Boards of Elections will be impacted by this emergency administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. Statutes and regulations either requiring or authorizing this emergency administrative regulation include: KRS 13A.190, KRS 13A.190, and 52 U.S.C. 20101 *et seq.*

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? It is not expected or intended that this emergency administrative regulation will generate any revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? It is not expected or intended that this emergency administrative regulation will generate any revenue.

(c) How much will it cost to administer this program for the first year? The State Board of Elections estimates that the implementation of this emergency administrative regulation will cost roughly \$5,240,000 at the at the state-government level. County-level expenses should not exceed those already anticipated by election needs under ordinary circumstances. There are no costs to the individual voters to return a mail-in absentee ballot.

(d) How much will it cost to administer this program for subsequent years? This emergency administrative regulation is temporary and will not be in force following the administration of the November 3, 2020 elections.

STATEMENT OF EMERGENCY 902 KAR 20:160E

This emergency administrative regulation is being filed concurrently with 907 KAR 15:080E to align with changes the Kentucky Medicaid Program is making to implement new services relating to withdrawal management for chemical dependency treatment center services. As amended, this administrative regulation will implement the licensure requirements to allow for both inpatient and outpatient services to be reimbursable by Medicaid when provided within these facilities. Additional changes implement the licensure requirements for new services relating to service planning, ambulatory withdrawal management, medication assisted treatment, and inpatient chemical dependency treatment. The primary reason for promulgating this administrative regulation as an emergency administrative regulation is to better ensure the availability of a full continuum of care within the Medicaid Program for substance use disorder services pursuant to the American Society of Addiction Medicine's (ASAM) Criteria. Without the authority granted by this administrative regulation, the full continuum of care for substance use disorder established in the ASAM Criteria will not be reimbursable by Medicaid. Nationwide, and within Kentucky, the opioid epidemic has been exacerbated by the ongoing COVID-19 pandemic, and this administrative regulation will give the Department for Medicaid Services (DMS) and Kentucky providers additional vital tools to confront this serious threat to Kentucky citizens. Specifically, this administrative regulation is being filed as an emergency administrative regulation in accordance with KRS 13A.190(1)(a)1., 2., and 4. This emergency administrative regulation is needed pursuant to KRS

13A.190(1)(a)1. in order to thoroughly confront the serious and imminent danger posed to Kentucky citizens by any exacerbation of the opioid epidemic. This emergency administrative regulation is also needed pursuant to KRS 13A.190(1)(a)2. in order to preserve state and federal funding. In order to continue the SUD 1115 Waiver, Kentucky Medicaid is required to establish and maintain the availability of the full spectrum of the ASAM level of care to Kentucky Medicaid members. Failure to fully implement the ASAM criteria may risk continued federal coverage and approval of the SUD 1115 Waiver. If that happens, there would be a loss of federal funding. DMS furthermore expects a modest cost-savings from introducing the ASAM 3.7 level of care and allowing it to be utilized by chemical dependency treatment centers. This emergency administrative regulation is needed pursuant to KRS 13A.190(1)(a)4. to protect human health by increasing access to treatment for substance use disorder (SUD), and to address all aspects of the SUD epidemic within Kentucky. Beyond the immediate imminent danger of any exacerbation of the opioid epidemic, this administrative regulation is necessary to bolster innovative efforts to continue to confront and address the long standing opioid epidemic. This emergency administrative regulation shall be replaced by an ordinary administrative regulation. The ordinary administrative regulation is identical to this emergency administrative regulation.

ANDY BESHEAR, Governor ERIC FRIEDLANDER, Secretary

CABINET FOR HEALTH AND FAMILY SERVICES Office of Inspector General Division of Health Care (Emergency Amendment)

902 KAR 20:160E. Chemical dependency treatment services and facility specifications.

EFFECTIVE October 13, 2020

RELATES TO: KRS 198B.260, 202A.241, 210.005, 216B.010, 216B.015, 216B.105, 216B.990, <u>218A.202</u>, 309.080, <u>309.0831</u>, 309.130, <u>310.021</u>, 311.560, 311.571, 311.840 – 311.862, 314.011(8), 314.042, 319.050, 319.056, 319.064, 319C.010, 320.210(2), 335.080, 335.100, 335.300, 335.500, 42 C.F.R. Part 2, 45 C.F.R. 160, 164, 20 U.S.C. 1400, 29 U.S.C. 701, 42 U.S.C. 290ee-3, 1320d-2 – 1320d-8

STATUTORY AUTHORITY: KRS [216B.010,] 216B.042(1), 216B.105

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 and 216B.105 require the Cabinet for Health and Family Services to regulate health facilities and health services. This administrative regulation establishes licensure requirements for the operation, services, and facility specifications of chemical dependency treatment programs, including programs that [which] elect to provide outpatient behavioral health services for individuals with a substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis.

Section 1. Definitions. (1) "Aftercare" means the process of providing continued services following primary chemical dependency treatment to support and increase gains made during treatment.

(2) "Behavioral health professional" means:

(a) A psychiatrist licensed under the laws of Kentucky to practice medicine or osteopathy, or a medical officer of the government of the United States while engaged in the performance of official duties, who is certified or eligible to apply for certification by the American Board of Psychiatry and Neurology, Inc. or the American Osteopathic Board of Neurology and Psychiatry;

(b) A physician licensed in Kentucky to practice medicine or osteopathy in accordance with KRS 311.571;

(c) A psychologist licensed and practicing in accordance with KRS 319.050;

(d) A certified psychologist with autonomous functioning or licensed psychological practitioner practicing in accordance with

KRS 319.056;

(e) A clinical social worker licensed and practicing in accordance with KRS 335.100;

(f) An advanced practice registered nurse licensed and practicing in accordance with KRS 314.042;

(g) A physician assistant <u>as defined by KRS</u> 311.840(3)[licensed under KRS 311.840 to 311.862];

(h) A <u>licensed</u> marriage and family therapist <u>as defined by</u> [licensed and practicing in accordance with] KRS 335.300(2);

(i) A licensed professional clinical counselor as defined by [licensed and practicing in accordance with] KRS 335.500(3); or

(j) A licensed professional art therapist as defined by KRS 309.130(2).

(3) "Behavioral health professional under clinical supervision" means a:

(a) Psychologist certified and practicing in accordance with KRS 319.056;

(b) Licensed psychological associate licensed and practicing in accordance with KRS 319.064;

(c) Marriage and family <u>therapy[therapist]</u> associate as defined by KRS 335.300(3);

(d) Social worker certified and practicing in accordance with KRS 335.080;

(e) Licensed professional counselor associate as defined by KRS 335.500(4); or

(f) Licensed professional art therapist associate as defined by KRS 309.130(3).

(4) "Certified alcohol and drug counselor" is defined by KRS 309.080(2).

(5) "Governing authority" means the individual, agency, partnership, or corporation that directs and establishes policy concerning the management and operation of a chemical dependency treatment program.

(6) "Interdisciplinary team" means a group of at least four (4) professionals, including a physician, registered nurse, certified chemical dependency counselor, and a person with a master's degree in psychology, social work, or counseling.

(7) "Licensed clinical alcohol and drug counselor" is defined by KRS 309.080(4).

(8) "Licensed clinical alcohol and drug counselor associate" is defined by KRS 309.080(5).

(9) "Peer support specialist" means a paraprofessional who:

(a) Is a registered alcohol and drug peer support specialist in accordance with KRS 309.0831; or

(b)1. Meets the application, training, examination, and supervision requirements of 908 KAR 2:220, 908 KAR 2:230, or 908 KAR 2:240; and

2. Works under the supervision of one (1) of the following:

a. Physician;

b. Psychiatrist;

c. Licensed psychologist;

d. Licensed psychological practitioner;

e. Licensed psychological associate;

f. Licensed clinical social worker;

g. Licensed marriage and family therapist;

h. Licensed professional clinical counselor;

i. Certified social worker;

i. Licensed marriage and family therapy associate;

k. Licensed professional counselor associate;

I. Licensed professional art therapist;

m. Licensed professional art therapist associate;

n. Advanced practice registered nurse;

o. Physician assistant;

p. Certified alcohol and drug counselor; or

q. Licensed clinical alcohol and drug counselor.

(10) "Restraint" means a physical or mechanical device used to restrict the movement of the patient or a portion of the patient's body.

(11) "Substance use disorder" is defined by KRS 222.005(12)[means a cluster of cognitive, behavioral, and physiological symptoms resulting from use of a substance which the individual continues to take despite experiencing substance-related problems as a result, including:

(a) Intoxication;

(b) Withdrawal; or

(c) A substance induced mental health disorder].

(12) "Targeted case manager" means an individual who meets the requirements for a targeted case manager established by 908 KAR 2:260.

Section 2. Scope of Operation and Services. (1) A chemical dependency treatment service shall have a structured inpatient program to provide medical, social, diagnostic, and treatment services to individuals with substance use disorder.

(2) Chemical dependency treatment services shall:

(a) Have a duration of less than thirty (30) days;

(b) Be hospital based or freestanding;

(c) Have eight (8) or more patient beds;

(d) Be under the medical direction of a physician; and

(e) Provide continuous nursing services.

(3) If a chemical dependency treatment program provides outpatient behavioral health services, as <u>established[described]</u> in Section 5 of this administrative regulation, for individuals with a substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis:

(a) The outpatient behavioral health services shall be provided:

1. On a separate floor, in a separate wing, or in a separate building on the campus of the chemical dependency treatment program's inpatient facility; or

2. At an extension off the campus of the chemical dependency treatment program's inpatient facility;

(b) The chemical dependency treatment program shall pay a fee in the amount of \$250 per off-campus extension providing outpatient behavioral health services, submitted to the Office of Inspector General at the time of:

1. Initial licensure, if applicable;

2. The addition of a new extension to the chemical dependency treatment program's license; and

3. Renewal;

(c) Each off-campus extension or on-campus program of outpatient behavioral health services shall be listed on the chemical dependency treatment program's license;

(d) An off-campus extension or a separate building on the campus of the chemical dependency treatment program's inpatient facility where outpatient behavioral health services are provided shall comply with the physical environment requirements of Section 8 of this administrative regulation and be approved by the State Fire Marshal's office prior to:

1. Initial licensure;

2. The addition of the extension or on-campus program of outpatient behavioral health services in a separate building; or

3. A change of location;

(e) The program shall employ directly or by contract a sufficient number of personnel to provide outpatient behavioral health services;

(f) The outpatient behavioral health services program shall have a program director who:

1. May also serve as the chemical dependency treatment program's treatment director described in Section 3(10) of this administrative regulation; and

2. Shall be a:

a. Psychiatrist;

b. Physician;

c. [Certified or] Licensed psychologist or certified psychologist with autonomous functioning;

d. Licensed psychological practitioner;

e. Psychiatric nurse;

f. Advanced practice registered nurse;

g. Licensed professional clinical counselor;

h. Licensed marriage and family therapist;

i. Licensed professional art therapist;

j. Licensed [board certified] behavioral analyst; or

k. Licensed clinical social worker; and

(g) Unless an extension of time is granted pursuant to subsection (4) of this section, the outpatient program shall become accredited by one (1) of the following within one (1) year of adding

outpatient behavioral health services to the chemical dependency treatment program's license:

1. The Joint Commission;

2. The Commission on Accreditation of Rehabilitation Facilities;

3. The Council on Accreditation; or

4. A nationally recognized accreditation organization.

(4)(a) If a chemical dependency treatment services outpatient program has not obtained accreditation within the one (1) year timeframe required by subsection (3)(g) of this section, the program may request a one (1) time only extension to complete the accreditation process.

(b) A request for extension shall:

1. Be submitted in writing to the Office of Inspector General at least sixty (60) days prior to expiration of the one (1) year deadline described in subsection (3)(g) of this section;

2. Include evidence that the program initiated the process of becoming accredited within sixty (60) days of adding outpatient behavioral health services to the program's license and is continuing its efforts to obtain accreditation; and

3. Include an estimated timeframe by which approval of accreditation is anticipated.

(5) A program shall cease providing outpatient behavioral health services if the program fails to:

(a) Become accredited in accordance with subsection (3)(g) of this section;

(b) Request an extension in accordance with subsection (4) of this section, if accreditation has not been obtained; or

(c) Maintain accreditation.

(6) Proof of accreditation shall be provided to the Office of Inspector General upon receiving accreditation and at the time of annual renewal.

Section 3. Administration and Operation. (1) The licensee shall be responsible for compliance with federal, state, and local laws and administrative regulations pertaining to the operation of chemical dependency treatment programs.

(2)(a) The governing authority shall appoint a program administrator who shall have a:

1. Bachelor's degree in a health or human services field;

2. Bachelor's degree in another field supplemented with one

year of work experience in the field of chemical dependency; or
 High school diploma and four (4) years of experience in the field of chemical dependency.

(b) The governing authority shall establish, in writing:

1. Program goals and objectives; and

2. An evaluation plan for annual assessment of the attainment of the goals and objectives.

(3) Program administrator.

(a) The program administrator shall:

Be responsible for the daily management of the facility; and
 Serve as the liaison between the governing authority and

staff members.(b) The program administrator shall keep the governing authority informed of the operations of the facility through reports

and attendance at meetings of the governing authority.

(4) Administrative records and reports.

(a) A medication error, drug reaction, accident, or other incident involving a patient, visitor, or staff member[7] shall be documented in writing, signed by the program administrator and any witness to the event, and placed in an incident file.

(b) Licensure inspection reports, plans of correction, and program evaluations shall be available to the public, upon request, at the facility.

(5) Policies.

(a) Administrative policies. The program shall have a written administrative policy to cover each aspect of the facility's operation, including[as follows]:

1. A description of the organizational structure, staffing, and allocation of responsibility and accountability;

2. A description of referral linkages with other facilities and providers;

 A description of the services included in the program, including outpatient behavioral health services if provided; 4. An expense and revenue accounting system following generally accepted accounting procedures;

5. A volunteer program; and

6. Program evaluation and quality assurance review.

(b) Patient care policy. A written patient care policy shall be developed and shall include a description of:

1. Actions to be taken <u>if[when]</u> a patient is lost, unaccounted for, or otherwise absent without authorization;

2. Provisions for patient visitation and use of telephones;

3. Provision of emergency medical services; and

4. Patient admission and discharge criteria, including the categories of individuals accepted and not accepted by the program.

(c) Patient rights policy. A written policy shall be developed and maintained to enhance patient dignity and to protect human rights. The policy shall assure that each patient or client receiving outpatient behavioral health services shall be[is]:

1. Informed of rules and regulations governing patient conduct and responsibilities, including the procedure for handling grievances;

2. Informed, prior to admission for rehabilitation or receipt of outpatient behavioral health services, of services available and charges for treatment, including charges not covered under Medicare, Medicaid, or other third-party payor;

3. Encouraged and assisted to:

a. Understand and exercise patient rights;

b. Voice grievances; and

c. Recommend changes in policies and services. Upon request by a patient, a grievance or recommendation shall be conveyed to that body within the organization with authority to take corrective action;

4. Presented with the opportunity to participate in the planning of his or her treatment;

5. Informed of the right to refuse to participate in experimental research;

6. Assured confidential treatment of records and presented with the opportunity to approve or refuse release of records to any individual not involved in his or her care, except as required by Kentucky law or third party payment contract; and

7. Treated with consideration, respect, and recognition of personal dignity and individuality, including privacy in treatment and personal health needs.

(6) Personnel.

(a) The governing authority shall:

1. Establish a personnel policy; and

2. Review the personnel policy at least one (1) time annually and update <u>the policy</u> as needed.

(b) There shall be a personnel record for each person employed by the chemical dependency treatment inpatient facility and, if applicable, the outpatient behavioral health services program, which shall include <u>evidence[the following]</u>:

1. [Evidence] Of the results of a tuberculosis test, performed either prior to or within the first week of employment and annually thereafter;

2. [Evidence] Of education, training, and experience, and a copy of current license or certification credentials, if applicable;

3. [Evidence] That the employee received orientation to the facility's written policies within the first week of employment; and

4. [Evidence] Of regular in-service training that[which] corresponds with job duties and includes a list of training and dates completed.

(7) Staffing requirements.

(a) The chemical dependency treatment program shall have personnel sufficient to meet patient needs at the inpatient facility on a twenty-four (24) hour basis.

(b) The number and classification of personnel required shall be based on the number of patients and the individual treatment plans.

(8) Medical director. The chemical dependency treatment program's inpatient facility shall have a medical director who shall:

(a) Be a physician licensed in accordance with KRS 311.571;[+]

(b) Be responsible for the medical aspect of the program; and

(c) Have duties that[which] shall include:

1. Patient admission;

2. Approval of patient treatment plans;

3. Participation in the quality assurance review; and

4. Provision of medical services, personally or by a designated physician, either in-house or on-call, on a twenty-four (24) hour basis.

(9) Interdisciplinary team. The chemical dependency treatment program shall have an interdisciplinary team responsible for:

(a) Developing individual treatment plans;

(b) Developing aftercare plans; and

(c) Conducting quality assurance reviews.

(10) Treatment director. The chemical dependency treatment

program shall have a full time treatment director responsible for:

(a) Coordinating the interdisciplinary team in developing individual treatment plans;

(b) Initiating a periodic review of each patient's treatment plan;

(c) Supervising the maintenance of patient records; and

(d) Coordinating the interdisciplinary team in developing an aftercare plan for each patient to provide continuity of care.

(11) Nursing services within the chemical dependency treatment program's inpatient facility.

(a) Nursing services shall be available on a twenty-four (24) hour basis.

(b) The program shall have at least one (1) full-time registered nurse.

(c) If a registered nurse is not on duty, a licensed practical nurse shall be responsible for the nursing care of patients and a registered nurse shall be on call.

(12) Medical supervision. A physician, or registered nurse under the direction of a physician, shall supervise:

(a) Implementation of the medical aspects of the treatment plan; and

(b) All staff directly involved in patient medical care.

(13) In-service training.

(a) All personnel of the chemical dependency treatment program's inpatient facility or, if applicable, the outpatient behavioral health services program[,] shall participate in ongoing in-service training specific to the employee's job activities.

(b) Training shall include:

1. Thorough job orientation for new personnel; and

2. Regular in-service training emphasizing professional competence and the human relationship necessary for effective health care.

(14) Patient records of the chemical dependency treatment program's inpatient facility.

(a)1. An individual record shall be maintained for each patient.

2. Each entry shall be signed and dated by the person making the entry.

(b) At the time of admission, the following information shall be entered into the patient's record:

1. Name, date of admission, birth date and place, marital status, and Social Security number;

2. Person to contact in case of emergency;

3. Next of kin; and

4. Type and place of employment.

(c) The record shall contain documentation of medical services provided during detoxification and rehabilitation, including the results of physical examinations.

(d)1. The record shall contain the patient's treatment plan <u>establishing[outlining]</u> goals and objectives for the individual during treatment.

2. The record shall also contain documentation of how the plan was implemented and of patient progress in meeting the goals and objectives <u>established[outlined]</u> in the treatment plan.

(e) The record shall contain notation of medication administered, stating the date, time, dosage, and frequency of administration and the name of the person administering each dose.

(f) The record shall contain a discharge summary and a plan for aftercare.

(g) The discharge summary shall be entered in the patient's record within seven (7) days after discharge and shall include:

1. The course and progress of the patient with regard to the

individual treatment plan;

2. General observations of the patient's condition initially, during treatment, and at discharge, and

3. The recommendations and arrangements for further treatment, including prescribed medications and aftercare.

(h) If the patient is referred to another service provider after discharge, and if the patient executes a written release, a copy of the discharge summary shall be [with the patient's permission] sent to the provider with the patient's permission.

(i) After a patient's death or discharge, the completed record shall be placed in an inactive file and <u>be retained for at least the longer of</u>:

1. [Retained for] Six (6) years; or

2. If a minor, three (3) years after the patient reaches the age of majority <u>pursuant to KRS 2.015[under state law, whichever is longest]</u>.

(15) Confidentiality and Security: Use and Disclosure.

(a) The chemical dependency treatment program shall maintain the confidentiality and security of medical records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 13204-2 <u>through</u>[te] 13204-8, and 45 C.F.R. Parts 160 and 164[, as amended], including the security requirements mandated by [subparts A and C of] 45 C.F.R. Part 164, <u>Subparts A and C</u>, or as provided by applicable federal or state law, including 42 U.S.C. 290ee-3, and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

(b) The chemical dependency treatment program may use and disclose medical records. Use and disclosure shall be as established or required by:

1. HIPAA, 42 U.S.C. 1320d-2 <u>through[</u>te] 1320d-8, and 45 C.F.R. Parts 160 and 164; or

2. 42 U.S.C. 290ee-3, and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

(c) This administrative regulation shall not be construed to <u>prohibit[ferbid]</u> the chemical dependency treatment program from establishing higher levels of confidentiality and security than required by HIPAA, 42 U.S.C. 1320d-2 <u>through[te]</u> 1320d-8, and 45 C.F.R. Parts 160 and 164, or 42 U.S.C. 290ee-3, and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

(16) Linkage agreements.

(a) The program shall have linkages through written agreements with providers of other levels of care <u>that could[which may]</u> be medically indicated to supplement the services available in the program.

(b) Linkages shall include a hospital and an emergency medical transportation service in the area.

(17) Quality assurance. The program shall have a quality assurance program that includes an effective mechanism for reviewing and evaluating patient care on a regular basis by the interdisciplinary team.

(18) Medications.

(a) A prescription or nonprescription medication administered to a patient shall be noted in the patient's records with the date, time, and dosage, and signed by the person administering the medication.

(b) Each prescription medication shall be plainly labeled with the:

1. Patient's name;

2. Name of the drug;

3. Strength;

4. Name of pharmacy;

5. Date;

6. Physician name;

7. Caution statement; and

8. Directions for use.

(c)1. A prescription or nonprescription medication shall not be administered to a patient except on the written order of a physician or other practitioner acting within his or her statutory scope of practice.

2. A medication shall be administered by licensed personnel.

(d)1. Medication shall be kept in a locked storage area, which shall be well lighted and of sufficient size to permit storage without crowding.

2. Medication requiring refrigeration shall be kept in a separate locked box in a refrigerator.

3. Medication for external use shall be stored separately from medication administered by mouth or injection.

(e) A medication error or drug reaction shall be reported immediately to the medical director and treatment coordinator and an entry shall be made in the patient's record.

(f) An emergency medical kit, with contents approved by a physician, shall be:

1. Maintained at the facility; and

2. Inspected after use or at least monthly to remove deteriorated and outdated drugs and to ensure completeness of content.

(19) Restraints. Requirements for the use of restraints shall be met pursuant to KRS 202A.241 and 908 KAR 3:010, Section 9.

(20) Activities schedule. A daily schedule of program activities shall be posted in the chemical dependency treatment program's inpatient facility.

Section 4. Provision of Services. (1) <u>Withdrawal management</u> <u>services</u> [Detoxification]. A chemical dependency treatment program's inpatient facility shall provide <u>medically monitored</u> <u>intensive inpatient</u> [medical detoxification] services pursuant to the requirements of 902 KAR 20:111 directly or through another licensed provider for a patient who <u>meets the:</u>

(a) Diagnostic criteria for substance intoxication or withdrawal disorder as established by the most recent version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) for alcohol, tobacco, and other drug use; and

(b) Dimensional criteria for medically monitored intensive inpatient services in accordance with the most recent version of The American Society of Addiction Medicine (ASAM) Criteria [requires detoxification].

(2) Rehabilitation. A chemical dependency treatment program's inpatient facility shall provide:

(a) Medical services as needed, under the supervision of a physician;

(b) Scheduled individual, group, and family counseling;

(c) Psychological testing and evaluation as needed;

(d) Education of the patient on the subject of chemical dependency and related lifestyle issues, including nutrition and communication skills;

(e) Recreational activities with facilities and equipment, consistent with the patient's needs and the therapeutic program;

(f) Referral to other rehabilitative or community service agencies providing services not available through the program; and

(g) Aftercare services provided directly or through arrangement with another agency.

(3) Physical examinations. Within ten (10) days prior to, or three (3) days after, admission to the chemical dependency treatment program's inpatient facility for rehabilitation, a patient shall have a physical examination with tests ordered by a physician.

(4) Psychosocial history.

(a) A patient in a chemical dependency treatment program's inpatient facility shall have a psychosocial history and assessment interview within seventy-two (72) hours after admission for rehabilitation.

(b) The following data shall be collected and recorded in the patient record:

1. History of alcohol and drug use;

2. A determination of current emotional state;

3. Vocational history;

4. Familial relationships; and

5. Educational background.

(5) Treatment plan.

(a) The interdisciplinary team, with the participation of the patient, shall develop an individual treatment plan within four (4) days after admission to the chemical dependency treatment program's inpatient facility for rehabilitation, based on the patient's medical evaluation and psychosocial history and assessment.

(b) The treatment plan shall:

1. Specify the services required for meeting the patient's needs;

2. Identify goals necessary for the patient to achieve, maintain, or reestablish physical health and adaptive capabilities;

3. Establish goals with both long-term and short-term objectives and the anticipated time expected to meet these goals; and

4. Identify the location and frequency of treatment procedures, including referrals for a required service not provided by the program.

(6) The treatment plan shall be reviewed and updated at least weekly for the duration of the inpatient treatment.

(7)(a) The patient's family or significant others shall be involved in the treatment process, if approved by the patient.

(b) An attempt to involve family members or significant others shall be reported in the patient's medical record.

(8) Aftercare plan.

(a)1. A written aftercare plan shall be developed prior to completion of treatment in the chemical dependency treatment program's inpatient facility by the:

a. Interdisciplinary team;

b. Patient; and

c. With the patient's permission, [the] patient's family or significant others.

2. The aftercare plan shall be designed to establish continued contact for the support of the patient.

(b) The aftercare plan shall include methods and procedures to meet patient needs through direct contact or with assistance from other community human services organizations.

(c) If aftercare services are provided directly, review and update of the aftercare plan shall be conducted with the frequency of review determined by the:

1. Interdisciplinary team;

2. Patient; and

3. With the patient's permission, [the] patient's family or significant others.

(d) If the patient is referred to another agency for aftercare services, follow-up shall be conducted to determine if services are being provided.

Section 5. Provision of Outpatient Behavioral Health Services, Plan of Care, and Client Records. (1) Pursuant to Section 2(3) of this administrative regulation, a chemical dependency treatment program may provide one (1) or more of the following outpatient behavioral health services for individuals with a substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis:

(a) Screening, which shall be provided <u>face-to-face or via</u> <u>telehealth</u> by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate to determine the:

1. Likelihood that an individual has a substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis; and

2. Need for an assessment;

(b) Assessment, which shall:

1. Be provided <u>face-to-face or via telehealth</u> by a behavioral health professional, behavioral health professional under clinical supervision, a certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate who gathers information and engages in a process with the client, thereby enabling the professional to:

a. Establish the presence or absence of a substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis;

b. Determine the client's readiness for change;

c. Identify the client's strengths or problem areas <u>that</u>
 <u>could[which may]</u> affect the treatment and recovery processes; and
 d. Engage the client in developing an appropriate treatment relationship;

2. Establish or rule out the existence of a clinical disorder or service need;

3. Include working with the client to develop a plan of care if a clinical disorder or service need is assessed; and

4. Not include psychological or psychiatric evaluations or assessments;

(c) Psychological testing, which shall:

1. Be performed <u>face-to-face or via telehealth</u> by a licensed psychologist, licensed psychological associate, or licensed psychological practitioner; and

2. Include a psychodiagnostic assessment of personality, psychopathology, emotionality, or intellectual disabilities, and interpretation and written report of testing results;

(d) Crisis intervention, which:

1. Shall be a therapeutic intervention for the purpose of immediately reducing or eliminating the risk of physical or emotional harm to the client or another individual;

2. Shall consist of clinical intervention and support services necessary to provide integrated crisis response, crisis stabilization interventions, or crisis prevention activities;

3. Shall be provided:

a. [On-site at the chemical dependency treatment program's facility:

 $\ensuremath{\textbf{b}}\xspace$] As an immediate relief to the presenting problem or threat; and

<u>b.[c.]</u> In a face-to-face, one (1) on one (1) encounter or as a comparable service provided via telehealth;

4. [May include verbal de-escalation, risk assessment, or cognitive therapy;

5.] Shall be provided by a:

a. Behavioral health professional;

b. Behavioral health professional under clinical supervision;

c. Certified alcohol and drug counselor;

d. Licensed clinical alcohol and drug counselor; or

e. Licensed clinical alcohol and drug counselor associate;

5.[6-] Shall be followed by a referral to noncrisis services, if applicable; and

6.[7.] May include:

a. Further service prevention planning, including:

(i) Lethal means reduction for suicide risk; or

(ii) Substance use disorder relapse prevention; or

b. Verbal de-escalation, risk assessment, or cognitive therapy;

(e) Mobile crisis services, which shall:

1. Be available twenty-four (24) hours a day, seven (7) days a week, every day of the year;

2. Be provided for a duration of less than twenty-four (24) hours;

3. Not be an overnight service;

4. Be a multi-disciplinary team based intervention that ensures

access to acute substance use services and supports to:

a. Reduce symptoms or harm; or

b. Safely transition an individual in an acute crisis to appropriate, least restrictive level of care;

5. Involve all services and supports necessary to provide:

a. Integrated crisis prevention;

b. Assessment and disposition;

c. Intervention;

d. Continuity of care recommendations; and

e. Follow-up services;

6. Be provided in a home or community setting by a:

a. Behavioral health professional;

b. Behavioral health professional under clinical supervision;

c. Certified alcohol and drug counselor;

d. Licensed clinical alcohol and drug counselor; or

e. Licensed clinical alcohol and drug counselor associate; and

7. Ensure access to a board certified or board-eligible psychiatrist twenty-four (24) hours a day, seven (7) days a week, every day of the year;

(f) Day treatment, which shall:

1. Be a nonresidential, intensive treatment program designed

for children who: a. Have a substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis;

b. Are under twenty-one (21) years of age; and

c. Are at high risk of out-of-home placement due to a

behavioral health issue;

2. Consist of an organized, behavioral health program of treatment and rehabilitative services for substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis;

3. Have unified policies and procedures that address the organization's philosophy, admission and discharge criteria, admission and discharge process, staff training, and integrated case planning;

4. Include [the following]:

a. Individual outpatient therapy, family outpatient therapy, or group outpatient therapy;

b. Behavior management and social skill training;

c. Independent living skills that correlate to the age and development stage of the client; and

d. Services designed to explore and link with community resources before discharge and to assist the client and family with transition to community services after discharge;

5. Be provided [as follows]:

a. In collaboration with the education services of the local education authority including those provided through 20 U.S.C. 1400 et seq. (Individuals with Disabilities Education Act) or 29 U.S.C. 701 et seq. (Section 504 of the Rehabilitation Act);

b. On school days and during scheduled breaks;

c. In coordination with the child's individual educational plan or Section 504 plan if the child has an individual educational plan or Section 504 plan;

d. By personnel that includes a behavioral health professional, a behavioral health professional under clinical supervision, a certified alcohol and drug counselor, a licensed clinical alcohol and drug counselor, a licensed clinical alcohol and drug counselor associate, or a peer support specialist; and

e. According to a linkage agreement with the local education authority that specifies the responsibilities of the local education authority and the day treatment provider; and

6. Not include a therapeutic clinical service that is included in a child's individualized education plan;

(g) Peer support, which shall:

1. Be provided by a peer support specialist;

2. Be structured and scheduled nonclinical therapeutic activity with a client or group of clients;

3. Promote socialization, recovery, self-advocacy, preservation, and enhancement of community living skills; and

4. Be identified in the client's plan of care <u>developed through a</u> person-centered planning process;

(h) Intensive outpatient program services, which shall:

1. Offer a multi-modal, multi-disciplinary structured outpatient treatment program that is more intensive than individual outpatient therapy, group outpatient therapy, or family outpatient therapy;

2. Be provided at least:

a. Three (3) hours per day at least three (3) days per week for adults; or

b. Six (6) hours per week for adolescents;

3. Include [the following]:

a. Individual outpatient therapy;

b. Group outpatient therapy;

c. Family outpatient therapy unless contraindicated;

d. Crisis intervention; or

e. Psycho-education during which the client or client's family member shall be:

(i) Provided with knowledge regarding the client's diagnosis, the causes of the condition, and the reasons why a particular treatment might be effective for reducing symptoms; and

(ii) Taught how to cope with the client's diagnosis or condition in a successful manner;

4. Include a treatment plan, which shall:

a. Be individualized; and

b. Focus on stabilization and transition to a lower level of care;

5. Be provided by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate;

6. Include access to a board-certified or board-eligible

psychiatrist for consultation;

7. Include access to a psychiatrist, other physician, or advanced practice registered nurse for medication prescribing and monitoring; and

8. Be provided in a setting with a minimum client-to-staff ratio of ten (10) clients to one (1) staff person;

(i) Individual outpatient therapy, which shall:

1. Be provided to promote the:

a. Health and wellbeing of the client; or

b. Recovery from a substance related disorder;

2. Consist of:

a. A face-to-face encounter or telehealth consultation with the client; and

b. A behavioral health therapeutic intervention provided in accordance with the client's plan of care;

3. Be aimed at:

a. Reducing adverse symptoms;

b. Reducing or eliminating the presenting problem of the client; and

c. Improving functioning;

4. Not exceed three (3) hours per day <u>alone or in combination</u> with any other outpatient therapy unless additional time with the client is medically necessary in accordance with 907 KAR 3:130; and

5. Be provided by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate;

(j) Group outpatient therapy, which shall:

1. Be provided to promote the:

a. Health and wellbeing of the client; or

b. Recovery from a substance related disorder;

2. Consist of a face-to-face behavioral health therapeutic intervention provided in accordance with the client's plan of care;

3. Excluding multi-family group therapy, be provided in a group setting of nonrelated individuals, not to exceed twelve (12) individuals in size. For group outpatient therapy, a nonrelated individual means any individual who is not a spouse, significant other, parent or person with custodial control, child, sibling, stepparent, stepchild, step-brother, step-sister, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-inlaw, grandparent, or grandchild;

4. Focus on the psychological needs of the client as evidenced in the client's plan of care;

5. Center on goals including building and maintaining healthy relationships, personal goals setting, and the exercise of personal judgment;

6. Not include physical exercise, a recreational activity, an educational activity, or a social activity;

7. Not exceed three (3) hours per day <u>alone or in combination</u> with any other outpatient therapy [per client] unless additional time is medically necessary in accordance with 907 KAR 3:130;

8. Ensure that the group has a deliberate focus and defined course of treatment;

9. Ensure that the subject of group outpatient therapy shall be related to each client participating in the group; and

10. Be provided by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate who shall maintain individual notes regarding each client within the group in the client's record;

(k) Family outpatient therapy, which shall:

1. Consist of a [face-to-face] behavioral health therapeutic intervention provided <u>face-to-face</u> or via <u>telehealth</u> through scheduled therapeutic visits between the therapist, at least one (1) member of the client's family, and the client unless the client's presence is not required in his or her plan of care;

2. Address issues interfering with the relational functioning of the family;

3. Seek to improve interpersonal relationships within the client's home environment;

4. Be provided to promote the health and wellbeing of the client

or recovery from a substance use disorder;

5. Not exceed three (3) hours per day <u>alone or in combination</u> with any other outpatient therapy [per client] unless additional time is medically necessary in accordance with 907 KAR 3:130; and

6. Be provided by a behavioral health professional, a behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor associate;

(I) Collateral outpatient therapy, which shall consist of a faceto-face <u>or telehealth</u> behavioral health consultation:

1. With a parent, caregiver, or person who has custodial control of a client under the age of twenty-one (21), household member, legal representative, school personnel, or treating professional;

2. Provided by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate; and

3. Provided upon the written consent of a parent, caregiver, or person who has custodial control of a client under the age of twenty-one (21). Documentation of written consent shall be signed and maintained in the client's record;

(m) Screening, brief intervention, and referral to treatment for substance use disorders, which shall:

1. Be provided face-to-face or via telehealth;

<u>2.</u> Be an evidence-based early intervention approach for an individual with non-dependent substance use prior to the need for more extensive or specialized treatment;

3.[2.] Consist of:

a. Using a standardized screening tool to assess the individual for risky substance use behavior;

b. Engaging a client who demonstrates risky substance use behavior in a short conversation, providing feedback and advice; \underline{and}

c. Referring the client to therapy or other services that address substance use if the client is determined to need additional services; and

4.[3-] Be provided by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor associate; [er]

(n) Targeted case management services, which shall:

1. Include services to an:

a. Adult or a child with substance use disorder; or

b. Adult or child with co-occurring mental health or substance use disorder and chronic or complex physical health issues;

2. Be provided by a <u>targeted</u> case manager [as described in subsection (2) or (3) of this section]; and

3. Include the following assistance:

a. Comprehensive assessment and reassessment of client needs to determine the need for medical, educational, social, or other services. The reassessment shall be conducted annually or more often if needed based on changes in the client's condition;

b. Development of a specific care plan <u>that[which]</u> shall be based on information collected during the assessment and revised if needed upon reassessment;

c. Referral and related activities, which may include:

(i) Scheduling appointments for the client to help the individual obtain needed services; or

(ii) Activities that help link the client with medical, social, educational providers, or other programs and services <u>that[which]</u> address identified needs and achieve goals specified in the care plan;

d. Monitoring, which shall be face-to-face and occur no less than once every three (3) months to determine that:

(i) Services are furnished according to the client's care plan;

(ii) Services in the care plan are adequate; and

(iii) Changes in the needs or status of the client are reflected in the care plan; and

e. Contacts with the client, family members, service providers, or others are conducted as frequently as needed to help the client:

(i) Access services;

(ii) Identify needs and supports to assist the client in obtaining services; and

(iii) Identify changes in the client's needs;

(o) Service planning, which shall be provided face-to-face by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate, any of which shall be of the client's choosing to:

<u>1. Assist the client in creating an individualized plan for</u> services and developing measurable goals and objectives needed for maximum reduction of the effects of a substance use disorder or co-occurring disorder;

2. Restore the client's functional level to the client's best possible functional level; and

3. Develop a service plan, which:

a. Shall be directed and signed by the client; and

b. May include:

(i) A mental health advance directive being filed with a local hospital;

(ii) A crisis plan; or

(iii) A relapse prevention strategy or plan; or

(p) Medication assisted treatment with behavioral health therapy, which shall:

1. Exclude methadone-based treatment restricted to licensure in accordance with 908 KAR 1:370 and 908 KAR 1:374;

2. Require an advanced practice registered nurse, a physician, or a physician assistant who prescribes FDA-approved drugs for the treatment of opioid addiction in adult patients to:

a. Document in the patient's record whether or not the patient is compliant with prescribed dosing as evidenced by the results of:

(i) A KASPER report released to the practitioner pursuant to KRS 218A.202(7)(e); and

(ii) Drug testing; and

b. Comply with the prescribing and dispensing standards in 201 KAR 9:270 or 201 KAR 20:065 for FDA-approved drugs used for the treatment of opioid addiction; and

<u>3. Include individual and group outpatient therapy as a service</u> and document monitoring of compliance with recommended nonmedication therapies.

(2) [A case manager who provides targeted case management services to clients with a substance use disorder shall:

(a) Be a certified alcohol and drug counselor, meet the grandfather requirements of 907 KAR 15:040, Section 4(1)(a)3, or have a bachelor's degree in a human services field, including:

1. Psychology;

2. Sociology;

3. Social work;

4. Family studies;

5. Human services;

6. Counseling;

7. Nursing;

8. Behavioral analysis;

Public health;

10. Special education;

11. Gerontology;

12. Recreational therapy;

13. Education;

14. Occupational therapy;

15. Physical therapy;

16. Speech-language pathology;

17. Rehabilitation counseling; or

18. Faith-based education;

(b)1. Have a minimum of one (1) year of full-time employment working directly with adolescents or adults in a human service setting after completion of the requirements described in paragraph (a) of this subsection; or

2. Have a master's degree in a human services field as described in paragraph (a) of this subsection;

(c)1. Have successfully completed case management training in accordance with 908 KAR 2:260; and

2. Successfully complete continuing education requirements in

accordance with 908 KAR 2:260; and

(d) Be supervised by a behavioral health professional who:

1. Has completed case management training in accordance with 908 KAR 2:260; and

2. Has supervisory contact at least two (2) times per month with at least one (1) of the contacts on an individual in person basis.

(3) A case manager who provides targeted case management services to clients with a mental health or substance use disorder and chronic or complex physical health issues shall:

(a) Meet the requirements of subsection (2)(a) of this section;

(b)1. After completion of a bachelor's degree, have a minimum of five (5) years of experience providing service coordination or referring clients with complex behavioral health needs and cooccurring disorders or multi-agency involvement to community based services; or

2. After completion of a master's degree in a human services field as described in subsection (2)(a) of this section, have a minimum of two (2) years of experience providing service coordination or referring clients with complex behavioral health needs and co-occurring disorders or multi-agency involvement to community based services;

(c)1. Have successfully completed case management training in accordance with 908 KAR 2:260; and

2. Successfully complete continuing education requirements in accordance with 908 KAR 2:260; and

(d) For a bachelor's level case manager, be supervised by a behavioral health professional who:

1. Has completed case management training in accordance with 908 KAR 2:260; and

2. Has supervisory contact at least three (3) times per month with at least two (2) of the contacts on an individual in person basis.

(4)] Plan of care.

(a) Each client receiving outpatient behavioral health services from a chemical dependency treatment program shall have an individual plan of care signed by a behavioral health professional.

(b) A plan of care shall:

1. Describe the services to be provided to the client, including the frequency of services;

2. Contain measurable goals for the client to achieve, including the expected date of achievement for each goal;

3. Describe the client's functional abilities and limitations or diagnosis listed in the current edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders;

4. Specify each staff member assigned to work with the client;

5. Identify methods of involving the client's family or significant others if indicated;

6. <u>Establish[Specify]</u> criteria to be met for termination of treatment;

7. Include any referrals necessary for services not provided directly by the chemical dependency treatment program; and

8. State the date scheduled for review of the plan.

(c) The client shall participate to the maximum extent feasible in the development of his or her plan of care, and the participation shall be documented in the client's record.

(d)1. The initial plan of care shall be developed through multidisciplinary team conferences at least thirty (30) days following the first ten (10) days of treatment.

2. The plan of care for individuals receiving intensive outpatient program services shall be reviewed every thirty (30) days thereafter and updated every sixty (60) days or earlier if clinically indicated.

3. Except for intensive outpatient program services, the plan of care for individuals receiving any other outpatient behavioral health service <u>established[described]</u> in subsection (1) of this section shall be reviewed and updated every six (6) months or earlier if clinically indicated.

4. The plan of care and each review and update shall be signed by the participants in the multidisciplinary team conference that developed it.

(3)[(5)] Client Records.

(a) A client record shall be maintained for each individual

receiving outpatient behavioral health services.

(b) Each entry shall be current, dated, signed, and indexed according to the service received.

(c) Each client record shall contain:

1. An identification sheet, including the client's name, address, age, gender, marital status, expected source of payment, and referral source;

2. Information on the purpose for seeking a service;

3. If applicable, consent of appropriate family members or guardians for admission, evaluation, and treatment;

4. Screening information pertaining to the mental health or substance use disorder;

5. If applicable, a psychosocial history;

6. If applicable, staff notes on services provided;

7. If applicable, the client's plan of care;

8. If applicable, disposition;

9. If applicable, assigned status;

10. If applicable, assigned therapists; and

11. If applicable, a termination study <u>restating[recapitulating]</u> findings and events during treatment, clinical impressions, and condition on termination.

Section 6. Compliance with Building Codes, Ordinances, and Regulations; Chemical Dependency Treatment Program's Inpatient Facility. (1) The provisions of this administrative regulation shall not relieve the licensee from compliance with building codes, ordinances, and administrative regulations <u>that[which]</u> are enforced by city, county, or state jurisdictions.

(2) The following shall apply:

(a) Requirements for safety pursuant to the National Fire Protection Association 101, Life Safety Code adopted by the Kentucky Department of Housing, Buildings and Construction;

(b) Requirements for plumbing pursuant to 815 KAR 20:010 through <u>815 KAR 20:195 [20:191];</u> and

(c) Requirements for making buildings and facilities accessible to and usable by persons with disabilities.

(3) The facility shall be approved by the Fire Marshal's Office before a license or license renewal is granted.

(4) The facility shall receive necessary approval from appropriate agencies prior to occupancy and licensure.

(5) Physical and sanitary environment.

(a) The physical plant and overall facility environment shall be maintained to protect the safety and well-being of patients, personnel, and visitors.

(b) A person shall be designated responsible for services and for the establishment of practices and procedures <u>for[in each of the following areas]</u>:

1. Plant maintenance;

2. Laundry operations either on site or off site; and

3. Housekeeping.

(c) The facility buildings, equipment, and surroundings shall be kept in good repair, neat, clean, free from accumulation of dirt and rubbish, and free from foul, stale, or musty odors.

1. An adequate number of housekeeping and maintenance personnel shall be provided.

2. Written housekeeping procedures shall be established for each area, and copies shall be available to personnel.

3. Equipment and supplies shall be provided for cleaning surfaces. The equipment shall be maintained in a safe, sanitary condition.

4. A hazardous cleaning solution, compound, or substance shall be labeled, stored in an approved container, and kept separate from nonhazardous cleaning materials.

5. The facility shall be free from insects, rodents, and their harborage.

6. Garbage and trash shall be stored in closed containers in an area separate from an area used for the preparation or storage of food.

The garbage and trash area shall be cleaned regularly and shall be in good repair.

(d) The facility shall have available at all times a quantity of linen essential to the proper care and comfort of residents.

1. Clean linen and clothing shall be stored in clean, dry, dust-

free areas designated exclusively for this purpose.

2. Soiled linen and clothing shall be placed in suitable bags or closed containers and stored in a separate area ventilated to the exterior of the building.

Section 7. Chemical Dependency Treatment Program's Inpatient Facility Requirements and Special Conditions. (1) Patient rooms. Each patient room shall meet the [following] requirements established in this subsection.[:]

(a) The maximum room capacity shall be six (6) patients.

(b) The minimum room area, exclusive of toilet room, closet, locker, wardrobe, or vestibule, shall be:

1. 100 square feet for a one (1) bed room; and

2. Eighty (80) square feet per bed for multibed rooms.

(c)1. Partitions, cubicle curtains, or placement of furniture shall be used to provide privacy in a multiperson room.

2. Ample closet and drawer space shall be provided for the storage of each patient's personal property.

(d) The placement of a patient in a multibed room shall be appropriate to the age and program needs of the patient.

(2) Lavatory.

(a) In a single or multibed room with a private toilet room, the lavatory may be located in the toilet room.

(b) If two (2) or more patients share a common toilet, a lavatory shall be provided in each patient room.

(3) Centralized toilet area.

(a) If a centralized toilet area is used, the facility shall provide, for each gender on each floor, <u>at least</u> one (1) toilet for each eight
 (8) residents or a major fraction thereof.

(b) Toilets shall be separated by a permanent partition and at least one (1) toilet for each gender shall be designed for wheelchair use.

(4) Patient baths.

(a) There shall be <u>at least</u> one (1) shower stall or one (1) bathtub for each fifteen (15) patients not individually served.

(b) Each bathtub or shower shall provide space for the private use of the fixture and for dressing.

(5) The patient shall be encouraged to take responsibility for maintaining his or her own living quarters and for other day-to-day housekeeping activities of the program, as appropriate to his or her clinical status.

(6) Dietary service.

(a) The facility shall have a dietary department, organized, directed, and staffed to provide quality food service and optimal nutritional care.

1. The dietary service shall be directed on a full-time basis by an individual who, by education or specialized training and experience, is knowledgeable in food service management.

2. The dietary service shall have at least one (1) dietician licensed pursuant to KRS 310.021 to supervise the nutritional aspects of patient care and to approve menus on at least a consultative basis.

3. If food service personnel are assigned a duty outside the dietary department, the duty shall not interfere with the sanitation, safety, or time required for regular dietary assignments.

(b)1. A menu shall be planned, written, and rotated to avoid repetition.

2. Nutritional needs shall be met in accordance with:

a. Recommended dietary allowances of the Food and Nutrition Board of the National Research Council of the National Academy of Sciences; and

b. Physician orders, if applicable.

(c)1. A meal served shall correspond with the posted menu.

2. If a change in the menu is necessary;

a. Substitution shall provide equal nutritive value; and

b. The change shall be recorded on the menu.

3. A menu shall be kept on file for at least thirty (30) days.

(d) Food shall be:

1. Prepared by methods that conserve nutritive value, flavor, and appearance; and

2. Served at the proper temperature.

(e)1. At least three (3) meals shall be served daily with not more than a fifteen (15) hour span between a substantial evening

meal and breakfast.

2. Each meal shall be served at a regular time and a nourishing between-meal or bedtime snack <u>shall be</u> offered.

(f) Food services shall be provided in accordance with 902 KAR 45:005.

Section 8. Physical environment of an off-campus extension or separate building on the campus of the chemical dependency treatment program's inpatient facility where outpatient behavioral health services are provided. (1) Accessibility. The off-campus extension or separate building on the campus of the chemical dependency treatment program's inpatient facility shall meet requirements for making buildings and facilities accessible to and usable by individuals with physical disabilities pursuant to KRS 198B.260 and 815 KAR 7:120.

(2) Physical location and overall environment.

(a) The program shall:

1. Comply with building codes, ordinances, and administrative regulations <u>that[which]</u> are enforced by city, county, or state jurisdictions:

2. Display a sign that can be viewed by the public that contains the facility name, hours of operation, and a street address;

3. Have a publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that shall be operational twenty-four (24) hours per day;

4. Have a reception and waiting area;

5. Provide a restroom; and

6. Have an administrative area.

(b) The condition of the physical location and the overall environment shall be maintained in a manner that assures the safety and well-being of clients, personnel, and visitors.

(3) Prior to occupancy, the facility shall have final approval from appropriate agencies.

ADAM D. MATHER, Inspector General

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 2, 2020

FILED WITH LRC: October 13, 2020 at 12:30 p.m.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact persons: Kara L. Daniel and Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes minimum licensure requirements for the operation of chemical dependency treatment programs, including programs that elect to provide outpatient behavioral health services for individuals with a substance use disorder (SUD) or co-occurring disorder in which SUD is the primary diagnosis.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with KRS 216B.042(1), which requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, including licensure standards and procedures to ensure safe, adequate, and efficient health services. Additionally, this administrative regulation is necessary to comply with KRS 216B.105, which, unless otherwise exempt, prohibits the operation of a health facility without a Cabinet-issued license.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216B.042 by establishing minimum licensure requirements for the operation of chemical dependency treatment programs.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing standards for licensed chemical dependency treatment programs. (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment is being filed concurrently with the Department for Medicaid Services administrative regulation, 907 KAR 15:080, Coverage provisions and requirements regarding chemical dependency treatment center services. Key changes to this administrative regulation, 902 KAR 20:160, are as follows:

Amends Section 1(1)(a) to clarify that a psychiatrist, as included under the definition of "behavioral health professional", may be certified or eligible to apply for certification by the American Osteopathic Board of Neurology;

Updates the definition of "peer support specialist" to include a registered alcohol and drug peer support specialist, and adds clarifying language related to the supervision of peer support specialists;

Adds "targeted case manager" to Section 1, Definitions, and amends Section 5(2) and (3) to delete unnecessarily duplicative language related to case managers because the training requirements and qualifications for targeted case managers are established in 908 KAR 2:260;

Replaces the "detoxification" with "medically monitored intensive inpatient services" and requires the patient to meet the diagnostic criteria for substance intoxication or withdrawal disorder as established by the most recent version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) for alcohol, tobacco, and other drug use, and also meet the dimensional criteria for medically monitored intensive inpatient services in accordance with the most recent version of The American Society of Addiction Medicine (ASAM) Criteria;

Allows for screening, assessment, psychological testing, crisis intervention, individual outpatient therapy, family outpatient therapy, collateral outpatient therapy, and screening, brief intervention, and referral to treatment for SUD to be provided via telehealth;

Removes the requirement for crisis intervention to be provided on-site at the program's facility;

Clarifies the number of hours per week that intensive outpatient services may be provided to adolescents; and

Adds service planning and medication assisted treatment as services that may be provided by a chemical dependency treatment program.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to align with the proposed changes to 907 KAR 15:080 and otherwise address necessary housekeeping changes.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of KRS 216B.042 because it establishes minimum licensure requirements for the operation of chemical dependency treatment centers.

(d) How the amendment will assist in the effective administration of the statutes: This amendment assists in the effective administration of the statutes by establishing standards for licensed chemical dependency treatment centers.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects the three (3) currently licensed chemical dependency treatment centers.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Entities licensed in accordance with this administrative regulation are required to comply with the standards established by this administrative regulation, including the following:

Must operate a structured inpatient program to provide medical, social, diagnostic, and treatment services to individuals with SUD; Must ensure that inpatient services are provided under the medical direction of a physician;

Must provide continuous nursing services;

May provide one (1) or more of the following outpatient behavioral health services: screening, assessment, psychological testing, crisis intervention, mobile crisis services, day treatment, peer support, intensive outpatient program services, individual outpatient therapy, group outpatient therapy, family outpatient therapy, collateral outpatient therapy, screening, brief intervention, and referral to treatment for SUD, targeted case management, service planning, or medication assisted treatment;

Must be in compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the chemical dependency treatment program;

Must have a governing authority;

Must have a program administrator, interdisciplinary team, and treatment director;

Must maintain administrative policies, including patient care, patient rights, and personnel policies;

Must have a program for in-service training;

Must maintain client records in accordance with federal privacy and confidentiality rules;

Must have a process for quality assurance;

Must comply with requirements for administration and storage of medications;

Must post a daily schedule of activities;

Must comply with the requirements for providing medically monitored intensive inpatient services, rehabilitation services, physical examination of the patient, psychosocial history, and development of that patient's treatment plan and aftercare plan;

Must maintain compliance with applicable state and local laws relating to construction, plumbing, safety, and sanitation; and

Must maintain compliance with basic facility requirements for patient rooms, bathrooms, meal service, and overall physical environment.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no additional costs to chemical dependency treatment centers to comply with this amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Licensed chemical dependency treatment centers may enroll in the Kentucky Medicaid Program for reimbursement of covered services provided to Medicaid recipients in need of medically monitored intensive inpatient services, or outpatient services for the treatment of substance use disorder (SUD) or co-occurring disorder in which SUD is the primary diagnosis.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional costs to the cabinet for implementation of this administrative regulation.

(b) On a continuing basis: There are no additional costs to the cabinet for implementation of this administrative regulation on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State general funds and agency monies are used to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish or increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applicable as compliance with this administrative regulation applies equally to all individuals or entities who elect to be regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts the Cabinet for Health and Family Services, Office of Inspector General, and licensed chemical dependency treatment centers.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.042 and 216B.105

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? In accordance with 902 KAR 20:008, Section 3(2), the Cabinet collects a fee of \$1,000 + \$25 per bed from each chemical dependency treatment program. In accordance with this administrative regulation, the Cabinet collects \$250 for each outpatient extension site. These fees are existing provisions and have not been amended in this amendment.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? In accordance with 902 KAR 20:008, Section 3(2), the Cabinet collects a fee of \$1,000 + \$25 per bed from each chemical dependency treatment program. In accordance with this administrative regulation, the Cabinet collects \$250 for each outpatient extension site. These fees are existing provisions and have not been amended in this amendment.

(c) How much will it cost to administer this program for the first year? This amendment imposes no additional costs on the administrative body.

(d) How much will it cost to administer this program for subsequent years? This amendment imposes no additional costs on the administrative body.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): See response above.

Expenditures (+/-): This administrative regulation is anticipated to have minimal fiscal impact to the cabinet.

Other Explanation:

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 42 C.F.R. Part 2, 45 C.F.R. Parts 160, 164, 42 U.S.C. 1320d-2 - 1320d-8, 42 U.S.C. 209ee-3, 20 U.S.C. 1400, 29 U.S.C. 701

2. State compliance standards. KRS 216B.042, 216B.105

3. Minimum or uniform standards contained in the federal mandate. 42 C.F.R. Part 2 prohibits programs from disclosing any information that would identify a person as having or having had substance use disorder, unless that person provides written consent. 45 C.F.R. 160, 164, and 42 U.S.C. 1320d-2 – 1320d-8 establish the HIPAA privacy rules to protect individuals' medical records and other personal health information. 42 U.S.C. 209ee-3 pertains to the confidentiality of patient records. 20 U.S.C. 1400 is the Individuals with Disabilities Education Act. 29 U.S.C. 701 is Section 504 of the Rehabilitation Act.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation does not impose requirements that are more strict than federal laws or regulations.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Not applicable.

STATEMENT OF EMERGENCY 902 KAR 20:440E

This emergency administrative regulation is being filed concurrently with 907 KAR 15:070E to align with changes the Kentucky Medicaid Program is making to implement new services relating to withdrawal management for residential crisis stabilization units. As amended, this emergency administrative regulation will implement the licensure requirements for new services relating to withdrawal management and medication assisted treatment for residential crisis stabilization units. The primary reason for promulgating this administrative regulation as an emergency administrative regulation is to better ensure the availability of a full continuum of care within the Medicaid Program for substance use disorder services pursuant to the American Society of Addiction Medicine's (ASAM) Criteria. Without the authority granted by this administrative regulation, the full continuum of care for substance use disorder established in the ASAM Criteria will not be reimbursable by Medicaid. Nationwide, and within Kentucky, the opioid epidemic has been exacerbated by the ongoing COVID-19 pandemic, and this administrative regulation will give the Department for Medicaid Services (DMS) and Kentucky providers additional vital tools to confront this serious threat to Kentucky citizens. Specifically, this administrative regulation is being filed as an emergency administrative regulation in accordance with KRS 13A.190(1)(a)1., 2., and 4. This emergency administrative regulation is needed pursuant to KRS 13A.190(1)(a)1. in order to thoroughly confront the serious and imminent danger posed to Kentucky citizens by any exacerbation of the opioid epidemic. This emergency administrative regulation is also needed pursuant to KRS 13A.190(1)(a)2. in order to preserve state and federal funding. In order to continue the SUD 1115 Waiver, Kentucky Medicaid is required to establish and maintain the availability of the full spectrum of the ASAM level of care to Kentucky Medicaid members. Failure to fully implement the ASAM criteria may risk continued federal coverage and approval of the SUD 1115 Waiver. If that happens, there would be a loss of federal funding. This emergency administrative regulation is needed pursuant to KRS 13A.190(1)(a)4. to protect human health by increasing access to treatment for substance use disorder (SUD), and to address all aspects of the SUD epidemic within Kentucky. Beyond the immediate imminent danger of any exacerbation of the opioid epidemic, this administrative regulation is necessary to bolster innovative efforts to continue to confront and address the long standing opioid epidemic. This emergency administrative regulation shall be replaced by an ordinary administrative regulation. The ordinary administrative regulation is identical to this emergency administrative regulation.

ANDY BESHEAR, Governor ERIC FRIEDLANDER, Secretary

CABINET FOR HEALTH AND FAMILY SERVICES Office of Inspector General Division of Health Care (Emergency Amendment)

902 KAR 20:440E. Facilities specifications, operation and services; residential crisis stabilization units.

EFFECTIVE: October 13, 2020

RELATES TO: KRS <u>17.500</u>, 200.503(2), 210.005, <u>216B.050</u>, <u>216B.105(2)</u>, <u>309.080(4)</u>, <u>309.0831</u>, <u>309.130(2)</u>, <u>311.571</u>, <u>311.840</u> – <u>311.862</u>, <u>314.042</u>, <u>319.050</u>, <u>319.056</u>, <u>319.064</u>, <u>319C.010</u>, <u>335.080</u>, <u>335.100</u>, <u>335.300</u>, <u>335.500</u>, <u>439.3401</u>, <u>45</u> C.F.R. Parts 160, 164, 42 U.S.C. <u>1320d-2</u> – <u>1320d-8</u>, 42 U.S.C. <u>209ee-3</u>, 42 C.F.R. Part 2

STATUTORY AUTHORITY: KRS 216B.042

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, which includes establishing licensure standards and procedures to ensure safe, adequate, and

efficient health facilities and health services. This administrative regulation establishes minimum licensure requirements for the operation of residential crisis stabilization units <u>that[which]</u> serve at-risk children or children with severe emotional disabilities, at-risk adults or adults with severe mental illness, or individuals with substance use disorder or co-occurring disorders.

Section 1. Definitions. (1) "Behavioral health professional" means:

(a) A psychiatrist licensed under the laws of Kentucky to practice medicine or osteopathy, or a medical officer of the government of the United States while engaged in the performance of official duties, who is certified or eligible to apply for certification by the American Board of Psychiatry and Neurology, Inc. or the American Osteopathic Board of Neurology and Psychiatry;

(b) A physician licensed in Kentucky to practice medicine or osteopathy in accordance with KRS 311.571;

(c) A psychologist licensed and practicing in accordance with KRS 319.050;

(d) A certified psychologist with autonomous functioning or licensed psychological practitioner practicing in accordance with KRS 319.056;

(e) A clinical social worker licensed and practicing in accordance with KRS 335.100;

(f) An advanced practice registered nurse licensed and practicing in accordance with KRS 314.042;

(g) A physician assistant <u>as defined by KRS</u> <u>311.840(3)[licensed under KRS 311.840 to 311.862];</u>

(h) A licensed marriage and family therapist as defined by [licensed and practicing in accordance with] KRS 335.300(2);

(i) A <u>licensed</u> professional clinical counselor <u>as defined by</u> [licensed and practicing in accordance with] KRS 335.500(3); or

(j) A licensed professional art therapist as defined by KRS 309.130(2).

(2) "Behavioral health professional under clinical supervision" means a:

(a) Psychologist certified and practicing in accordance with KRS 319.056;

(b) Licensed psychological associate licensed and practicing in accordance with KRS 319.064;

(c) Marriage and family <u>therapy[therapist]</u> associate as defined by KRS 335.300(3);

(d) Social worker certified and practicing in accordance with KRS 335.080;

(e) Licensed professional counselor associate as defined by KRS 335.500(4); or

(f) Licensed professional art therapist associate as defined by KRS 309.130(3).

(3) "Cabinet" means the Cabinet for Health and Family Services.

(4) "Certified alcohol and drug counselor" is defined by KRS 309.080(2).

(5) "Chemical restraint" means the use of a drug that:

(a) Is administered to manage a resident's behavior in a way that reduces the [safety] risk to the resident or others;

(b) Has the temporary effect of restricting the resident's freedom of movement; and

(c) Is not a standard treatment for the resident's medical or psychiatric condition.

(6) "Child with a severe emotional disability" is defined by KRS 200.503(3).

(7) "Crisis stabilization unit" means a community-based facility that is not part of an inpatient unit and <u>that[which]</u> provides crisis services to no more than <u>sixteen (16)</u> [twelve (12)] clients who require overnight stays.

(8) <u>"Licensed clinical alcohol and drug counselor" is defined by</u> KRS 309.080(4);

(9) "Mechanical restraint" means any device attached or adjacent to a resident's body that he or she cannot easily remove that restricts freedom of movement or normal access to his or her body.

(10) [(9)] "Peer support specialist" means a paraprofessional who:

(a) <u>Is a registered alcohol and drug peer support specialist in</u> accordance with KRS 309.0831; or

(b)1. Meets the application, training, examination, and supervision requirements of 908 KAR 2:220, 908 KAR 2:230, or 908 KAR 2:240; and

2.[(b)] Works under the supervision of one (1) of the following:

a.[1.] Physician;

b.[2.] Psychiatrist;

c.[3.] Licensed psychologist;

d.[4.] Licensed psychological practitioner;

e.[5.] Licensed psychological associate;

f.[6.] Licensed clinical social worker;

g.[7.] Licensed marriage and family therapist;

h.[8.] Licensed professional clinical counselor;

i.[9.] Certified social worker;

<u>j.[10.]</u> Licensed marriage and family <u>therapy[therapist]</u> associate;

k.[11.] Licensed professional counselor associate;

I.[12.] Licensed professional art therapist;

m.[13.] Licensed professional art therapist associate;

n.[14.] Advanced practice registered nurse;

o.[15.] Physician assistant; [or]

p.[16.] Certified alcohol and drug counselor; or

g. Licensed clinical alcohol and drug counselor.

(11) [(10)] "Personal restraint" means the application of physical force without the use of any device for the purpose of restraining the free movement of a resident's body and does not include briefly holding without undue force a resident in order to calm or comfort him or her or holding a resident's hand to safely escort him or her from one (1) area to another.

(12) [(11)] "Seclusion" means the involuntary confinement of a resident alone in a room or in an area from which the resident is physically prevented from leaving.

(13) [(12)] (12) "Serious mental illness", "severe mental illness", or "SMI" means a diagnosis of a major mental disorder as included in the current edition of the Diagnostic and Statistical Manual of Mental Disorders under:

(a) Schizophrenia spectrum and other psychotic disorders;

(b) Bipolar and related disorders;

(c) Depressive disorders; or

(d) Post-traumatic stress disorders (under trauma and stressor related disorders) ["Severe mental illness" means the conditions defined by KRS 210.005(2) and (3)].

(14) [(13)] "Substance use disorder" is defined by KRS 222.005(12)[means a cluster of cognitive, behavioral, and physiological symptoms resulting from use of a substance which the individual continues to take despite experiencing substancerelated problems as a result, including:

(a) Intoxication;

(b) Withdrawal; or

(c) A substance induced mental health disorder].

(15) [(14)] "Time out" means the restriction of a resident for a period of time to a designated area from which the resident is not physically prevented from leaving, for the purpose of providing the resident an opportunity to regain self-control.

Section 2. Licensure Application and Fees. (1) An applicant for initial licensure as a residential crisis stabilization unit shall submit to the Office of Inspector General:

(a) A completed Application for License to Operate a Residential Crisis Stabilization Unit; and

(b) An accompanying initial licensure fee in the amount of \$750, made payable to the Kentucky State Treasurer.

(2) At least sixty (60) calendar days prior to the date of annual renewal, a residential crisis stabilization unit shall submit to the Office of Inspector General:

(a) A completed Application for License to Operate a Residential Crisis Stabilization Unit; and

(b) An annual renewal fee of $500,\ \mathrm{made}$ payable to the Kentucky State Treasurer.

(3)(a) Name change. A residential crisis stabilization unit shall:

1. Notify the Office of Inspector General in writing within ten (10) calendar days of the effective date of a change in the unit's name; and

2. Submit a processing fee of twenty-five (25) dollars.

(b) Change of location. A residential crisis stabilization unit shall not change the location where the unit is <u>operating[operated]</u> until an Application for License to Operate a Residential Crisis Stabilization Unit accompanied by a fee of \$100 is filed with the Office of Inspector General.

(c) Change of ownership.

1. The new owner of a residential crisis stabilization unit shall submit to the Office of Inspector General an Application for License to Operate a Residential Crisis Stabilization Unit accompanied by a fee of \$750 within ten (10) calendar days of the effective date of the ownership change.

2. A change of ownership for a license shall be deemed to occur in accordance with the criteria of 902 KAR 20:008, Section 2(16)[if more than twenty-five (25) percent of an existing residential crisis stabilization unit or capital stock or voting rights of a corporation is purchased, leased, or otherwise acquired by one (1) person from another].

(4) To obtain approval of initial licensure or renew a license to operate a residential crisis stabilization unit, the <u>applicant or</u> licensee shall be in compliance with this administrative regulation and federal, state, and local laws and <u>administrative</u> regulations pertaining to the operation of the unit.

Section 3. [Location. If an alcohol and other drug abuse treatment program licensed pursuant to 908 KAR 1:370 obtains separate licensure under this administrative regulation to operate a residential crisis stabilization unit, the unit shall be located off the campus of any residential treatment program licensed pursuant to 908 KAR 1:370.

Section 4.] Accreditation. (1) Unless an extension is granted pursuant to subsection (2) of this section, an entity licensed under this administrative regulation to operate a residential crisis stabilization unit shall become accredited within one (1) year of initial licensure by [one (1) of the following]:

(a) The Joint Commission;

(b) The Commission on Accreditation of Rehabilitation Facilities;

(c) The Council on Accreditation; or

(d) A nationally recognized accreditation organization.

(2)(a) If a residential crisis stabilization unit has not obtained accreditation in accordance with subsection (1) of this section within one (1) year of initial licensure, the facility may request a one (1) time only extension to complete the accreditation process.

(b) A request for extension shall:

1. Be submitted in writing to the Office of Inspector General at least sixty (60) days prior to the date of annual renewal;

2. Include evidence that the facility initiated the process of becoming accredited within sixty (60) days of initial licensure and is continuing its efforts to obtain accreditation; and

3. Include an estimated timeframe by which approval of accreditation is anticipated.

(3) The cabinet shall revoke the license if the residential crisis stabilization unit fails to [meet one (1) of the following requirements]:

(a)<u>1</u>. Become accredited in accordance with subsection (1) of this section; or

2.a.[(b)] Request an extension in accordance with subsection (2) of this section if accreditation <u>will not be[has not been]</u> obtained within one (1) year of initial licensure; <u>and</u>

b. Become accredited during the extension granted in accordance with subsection (2) of this section; or

(b)[(c)] Maintain accreditation.

(4) Proof of accreditation shall be provided to the Office of Inspector General upon receiving accreditation within one (1) year of initial licensure and at the time of annual renewal <u>established</u> [described] in Section 2(2) of this administrative regulation.

Section <u>4.[5-]</u> Administration and Operation. (1) The licensee shall be legally responsible for:

(a) The residential crisis stabilization unit;

(b) The establishment of administrative policy; and

(c) Ensuring compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the residential crisis stabilization unit.

(2) Executive director. The licensee shall establish lines of authority and designate an executive director who:

(a) May serve in a dual role as the residential crisis stabilization unit's program director established[described] in subsection (5) of this section;

(b) May serve in a dual role as the executive director of a behavioral health services organization (BHSO) or alcohol and other drug treatment entity (AODE) if:

1. The residential crisis stabilization unit and the BHSO or AODE are owned by the same entity; and

2. The residential crisis stabilization unit has a linkage with the BHSO or AODE to assist with continuity of care if needed after discharge from the residential crisis stabilization unit;

(c) Shall be responsible for the administrative management of the residential crisis stabilization unit, including:

1. The total program of the unit in accordance with the unit's written policies; and

2. Evaluation of the unit as it relates to the needs of each resident; and

(d) Shall have a master's degree in business administration or a human services field, or a bachelor's degree in a human services field, including:

1. Social work;

2. Sociology;

3. Psychology;

4. Guidance and counseling;

5. Education;

6. Religion;

7. Business administration;

8. Criminal justice;

9. Public administration;

10. Child care administration:

11. Christian education;

12. Divinity;
 13. Pastoral counseling;

14. Nursing;

15. Public health; or

16. Another human service field related to working with children with severe emotional disabilities or clients with severe mental illness.

(3) An executive director with a master's degree shall have a minimum of two (2) years of prior supervisory experience in a human services program.

(4) An executive director with a bachelor's degree shall have a minimum of two (2) years of prior experience in a human services program plus two (2) years of prior supervisory experience in a human services program.

(5) A residential crisis stabilization unit shall have a program director who:

(a) May serve in a dual role as the program director of a BHSO or AODE if:

1. The residential crisis stabilization unit and the BHSO or AODE are owned by the same entity; and

The residential crisis stabilization unit has a linkage with the BHSO or AODE to assist with continuity of care if needed after discharge from the residential crisis stabilization unit; and

(b) Shall be a:

1. Psychiatrist;

2. Physician:

3. [Certified or] Licensed psychologist or certified psychologist with autonomous functioning;

4. Licensed psychological practitioner;

5. Advanced practice registered nurse:

6. Licensed professional clinical counselor;

7. Licensed marriage and family therapist;

8. Licensed professional art therapist;

9. Licensed [board certified] behavior analyst; or

10. Licensed clinical social worker.

Section 5.[6.] License Procedures. An entity licensed under this administrative regulation to operate a residential crisis stabilization unit shall be subject to the provisions of 902 KAR 20:008, Sections 1, 2, 5, 6, and 7.

Section 6.[7-] Background Checks and Personnel Records. (1) All personnel of a residential crisis stabilization unit shall:

(a) Have a criminal record check performed upon initial hire and every two (2) years through the Administrative Office of the Courts or the Kentucky State Police;

(b) Not have a criminal conviction, or plea of guilty, to a:

1. Sex crime as defined by[specified in] KRS 17.500(8);

2. Violent crime as established[specified] in KRS 439.3401;

3. Criminal offense against a minor as established[specified] in KRS 17.500; or

4. Class A felony; and

(c) Not be listed on the [following]:

1. Central registry established by 922 KAR 1:470;

2. Nurse aide or home health aide abuse registry established by 906 KAR 1:100; or

3. Caregiver misconduct registry established by [922 KAR 5:120E and 922 KAR 5:120.

(2)[(a)] Prior to initial hire, an out-of-state criminal background information check shall be obtained for any applicant recommended for employment in a residential crisis stabilization unit who has resided or resides outside of the Commonwealth.[

(b) A residential crisis stabilization unit may use Kentucky's national background check system established by 906 KAR 1:190 to satisfy the background check requirements of subsections (1) and (2)(a) of this section.]

(3) A residential crisis stabilization unit shall perform annual criminal record and registry checks as established[described] in subsection (1) of this section on a random sample of at least twenty-five (25) percent of all personnel.

(4) A personnel record shall be kept on each staff member and shall contain [the following items]:

(a) Name and address;

(b) Verification of all training and experience, including licensure, certification, registration, or renewals;

(c) Verification of submission to the background check requirements of subsections (1), (2), and (3) of this section;

(d) Performance appraisals conducted no less than annually; and

(e) Employee incident reports.

Section 7.[8.] Quality Assurance and Utilization Review. (1) The residential crisis stabilization unit shall have a quality assurance and utilization review program designed to:

(a) Enhance treatment and care through the ongoing objective assessment of services provided, including the correction of identified problems; and

(b) Provide an effective mechanism for review and evaluation of the service needs of each client.

(2) The need for continuing services shall be evaluated immediately upon a change in a client's service needs or a change in the client's condition to ensure that proper arrangements have been made for:

(a) Discharge:

(b) Transfer; or

(c) Referral to another service provider, if appropriate.

Section 8.[9-] Client Grievance Policy. The residential crisis stabilization unit shall have written policies and procedures governing client grievances, which shall include [the following]:

(1) A process for filing a written client grievance;

(2) An appeals process with time frames for filing and responding to a grievance in writing:

(3) Protection for a client from interference, coercion, discrimination, or reprisal; and

(4) Conspicuous posting of the grievance procedures in a public area to inform a client of:

(a) His or her right to file a grievance;

(b) The process for filing a grievance; and

(c) The address and telephone number of the cabinet's ombudsman. $% \label{eq:constraint}$

Section <u>9.[10.]</u> Services and Staffing. (1) An entity licensed under this administrative regulation to operate a residential crisis stabilization unit shall provide [the following services]:

(a) Screening as established by 907 KAR 15:070, Section 3(2)(a);

(b) Assessment <u>as established by 907 KAR 15:070, Section</u> <u>3(2)(b);</u>

(c) Treatment planning <u>as established by 907 KAR 15:070,</u> Section 3(2)(e);

(d) Individual [outpatient] therapy as established by 907 KAR 15:070, Section 3(2)(c);

(e) Group [outpatient] therapy <u>as established by 907 KAR</u> <u>15:070, Section 3(2)(d)</u>; and

(f) Psychiatric services.

(2) An entity licensed under this administrative regulation to operate a residential crisis stabilization unit may provide:

(a) Family therapy <u>as established by 907 KAR 15:070, Section</u> <u>3(2)(f);</u> or

(b) Peer support by a peer support specialist <u>as established by</u> <u>907 KAR 15:070, Section 3(2)(g)</u>.

(3)(a) Except as provided by paragraph (b) of this subsection, the services identified in subsection (1) and (2)(a) of this section shall be delivered by a behavioral health professional or a behavioral health professional under clinical supervision.

(b) In addition to the professionals identified in paragraph (a) of this subsection, the services identified in subsection (1)(a), (b), (d), and (e) and subsection (2)(a) of this section may be provided by a certified alcohol and drug counselor <u>or licensed clinical alcohol and drug counselor</u>.

(c)1. A residential crisis stabilization unit shall have access to a board-certified or board-eligible psychiatrist twenty-four (24) hours per day, seven (7) days per week.

2. The psychiatrist may serve more than one (1) residential crisis stabilization unit and be available through telehealth consultation.

(d) The psychiatrist shall be available to evaluate, provide treatment, and participate in treatment planning.

(4) If a crisis stabilization program serves adults with a severe mental illness or substance use disorder and children with severe emotional disabilities:

(a) The programs shall not be located on the same campus; and

(b) The children's program shall serve clients:

1. Under the age of eighteen (18); or

2. Up to the age of twenty-one (21) if developmentally appropriate for the client.

(5) A residential crisis stabilization unit shall:

(a) Provide treatment for acute withdrawal <u>as established by</u> 907 KAR 15:070, Section 3(2)(h), if appropriate;

(b) Complete a mental status evaluation and physical health questionnaire of the client upon admission;

(c) Have written policies and procedures for:

1. Crisis intervention; and

2. Discharge planning, which shall begin at the time of admission and aftercare planning processes;

(d) Make referrals for physical health services to include diagnosis, treatment, and consultation for acute or chronic illnesses occurring during the client's stay in the residential crisis stabilization unit or identified during the admission assessment;

(e) Have a description of linkages with behavioral health services organizations licensed under 902 KAR 20:430 or other programs, including entities licensed as an AODE, that [which]:

1. Address identified needs and achieve goals specified in the treatment plan: and

2. Help promote continuity of care after discharge;

(f) Have at least one (1) direct-care staff member assigned direct-care responsibility for:

1. Every four (4) clients during normal waking hours; and

2. Every six (6) clients during normal sleeping hours;

(g) Ensure that administrative management of the unit is

provided by the unit's executive director;

(h) Provide a training program for direct-care staff pertaining to:

1. The care of clients in a <u>residential</u> crisis stabilization unit;

Detection and reporting of abuse, neglect, or exploitation;
 Emergency and safety procedures;

Emergency and safety procedures,
 Behavior management, including de-escalation training;

Denavior management, including de-escalation training
 Physical management procedures and techniques;

6. Suicide prevention and care; and

7. Trauma informed care; and

(i) Assure that each client shall be:

 In need of short-term behavior management and at risk of placement in a higher level of care;

2. Able to take care of his or her own personal needs, if an adult:

3. Medically able to participate in services; and

4. Served in the least restrictive environment available in the community.

Section <u>10.[14.]</u> Client Records. (1) A client record shall be maintained for each individual receiving services.

(2) Each entry shall be current, dated, signed, and indexed according to the service received.

(3) Each client record shall contain:

(a) An identification sheet, including the client's name, address, date of birth, gender, marital status, expected source of payment, and referral source;

(b) Information on the purpose for seeking a service;

(c) If applicable, consent via signature of <u>an</u> appropriate family <u>member or guardian[members or guardians]</u> for admission, evaluation, and treatment;

(d) Mental status evaluation and physical health questionnaire of the client taken upon admission;

(e) Staff notes for all services provided;

(f) Documentation of treatment planning, including diagnosis and all services to be provided; and

(g) Documentation of medication prescribing and monitoring used in treatment.

(4) Ownership.

(a) Client records shall be the property of the residential crisis stabilization unit.

(b) The original client record shall not be removed from the unit except by court order or subpoena.

(c) Copies of a client record or portions of the record may be used and disclosed. Use and disclosure shall be as established by subsection (6) of this section.

(5) Retention of records. After a client's death or discharge, the completed client record shall be placed in an inactive file and <u>be</u> retained for at least the longer of:

(a) [Retained for] Six (6) years; or

(b) If a minor, three (3) years after the client reaches the age of majority <u>pursuant to KRS 2.015[under state law, whichever is the longest]</u>.

(6) Confidentiality and Security: Use and Disclosure.

(a) The residential crisis stabilization unit shall maintain the confidentiality and security of client records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 <u>through[te]</u> 1320d-8, and 45 C.F.R. Parts 160 and 164, [as <u>amended</u>,] including the security requirements mandated by [subparts A and C of] 45 C.F.R. Part 164, <u>Subparts A and C</u>, or as provided by applicable federal or state law, including 42 U.S.C. 290ee-3, and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

(b) The residential crisis stabilization unit may use and disclose client records. Use and disclosure shall be as established or required by:

¹. HIPAA, 42 U.S.C. 1320d-2 <u>through</u>[te] 1320d-8, and 45 C.F.R. Parts 160 and 164; or

2. 42 U.S.C. 290ee-3, and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

(c) A residential crisis stabilization unit may establish higher levels of confidentiality and security than required by HIPAA, 42 U.S.C. 1320d-2 <u>through[te]</u> 1320d-8, and 45 C.F.R. Parts 160 and 164, or 42 U.S.C. 290ee-3, and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

Section <u>11.[42.]</u> Client Rights. (1) A residential crisis stabilization unit shall have written policies and procedures to ensure that the rights of a client are protected, including a statement of rights and responsibilities, which shall be:

(a) Provided at the time of admission:

1. To the client; or

2. If the client is a minor or incapacitated, to the client, client's parent, guardian, or other legal representative;

(b) Read to the client or client's parent, guardian, or other legal representative if requested or if either cannot read;

(c) Written in language that is understandable to the client;

(d) Conspicuously posted in a public area of the facility; and

(e) Cover the [following]:

1. [The] Right to treatment, regardless of race, religion, or ethnicity;

2. [The] Right to recognition and respect of personal dignity in the provision of all treatment and care;

3. [The] Right to be provided treatment and care in the least restrictive environment possible;

4. [The] Right to an individualized plan of care;

5. [The] Right of the client, including the client's <u>parent, guardian</u>, <u>or other legal representative[parents or guardian</u>] if the client is a minor <u>or incapacitated</u>, to participate in treatment planning;

6. [The] Nature of care, procedures, and treatment provided;

7. [The] Right to an explanation of risks, side effects, and benefits of all medications and treatment procedures used;

8. $\left[\underline{\text{The}} \right]$ Right to be free from verbal, sexual, physical, or mental abuse; and

9. [The] Right, to the extent permitted by law, to refuse the specific medications or treatment procedures and the responsibility of the facility if the client refuses treatment, to seek appropriate legal alternatives or orders of involuntary treatment, or in accordance with professional standards, to terminate the relationship with the client upon reasonable notice.

(2) A residential crisis stabilization unit's written policies and procedures concerning client rights shall assure and protect the client's personal privacy within the constraints of his or her plan of care, including:

(a) Visitation by family or significant others in a suitable area of the facility; and

(b) Telephone communications with family or significant others at a reasonable frequency.

(3)(a) If a privacy right is limited, a full explanation shall be given to the client or the client's parent. [or] guardian, or other legal representative if the client is a minor or incapacitated.

(b) Documentation shall be included in the client's record of any privacy limitation.

(4) Information shall be provided to the client, or the client's parent. [er] guardian, or other legal representative if the client is a minor or incapacitated, regarding the use and disposition of special observation and audio visual techniques, which may include [the following]:

(a) One (1) way vision mirror;

(b) Audio recording;

(c) Video tape recording;

(d) Television;

(e) Movie; or

(f) Photographs.

(5)(a) If the residential crisis stabilization unit serves children as <u>established[described]</u> in Section 9[10](4)(b) of this administrative regulation, written policy and procedures shall be developed in consultation with professional and direct-care staff to provide for behavior management of residents, including the use of a time-out room.

(b)1. Behavior management techniques:

a. Shall be explained fully to each client and, if the client is a minor or incapacitated, the client's parent, guardian, or other legal representative; and

b. May include time out or personal restraint.

2. Prone holds, chemical restraint, and mechanical restraint shall be prohibited in a residential crisis stabilization unit.

(c) The unit shall prohibit cruel and unusual disciplinary measures including [the following]:

1. Corporal punishment;

2. Forced physical exercise;

3. Forced fixed body positions;

4. Group punishment for individual actions;

5. Verbal abuse, ridicule, or humiliation;

6. Denial of three (3) balanced nutritional meals per day;

7. Denial of clothing, shelter, bedding, or personal hygiene needs;

8. Denial of access to educational services;

 Denial of visitation, mail, or phone privileges for punishment;
 Exclusion of the resident from entry to his or her assigned living unit; and

11. Personal restraint or seclusion as a punishment or employed for the convenience of staff.

(d) Written policy shall prohibit residents from administering disciplinary measures upon one another and shall prohibit persons other than professional or direct-care staff from administering disciplinary measures to residents.

(6) If personal restraint is used as a safe behavioral management technique, the residential crisis stabilization unit shall have a policy <u>that[which]</u> shall:

(a) <u>Establish[Describe]</u> criteria for appropriate use of personal restraint;

(b) Establish[Describe] documentation requirements; and

(c) Ensure that staff who implement the use of personal restraint shall:

1. Have documented training in the proper use of the procedure used;

2. Be certified in physical management by a nationallyrecognized training program in which certification is obtained through skilled-out testing; and

3. Receive annual training and recertification in crisis intervention and behavior management.

Section <u>12.[13.]</u> Reports of Abuse, Neglect, or Exploitation. (1) A residential crisis stabilization unit shall have written policies <u>that[which]</u> assure:

(a) The reporting of cases of abuse, neglect, or exploitation of adults and children to the cabinet pursuant to KRS Chapters 209 and 620; and

(b) That a resident may file a complaint with the cabinet concerning resident abuse, neglect, or exploitation.

(2) The unit shall have evidence that all allegations of abuse, neglect, or exploitation are thoroughly investigated internally[$_{T}$] and shall prevent further potential abuse while the investigation is in progress.

Section <u>13.[14.]</u> Medication Prescribing and Monitoring in a Residential Crisis Stabilization Unit. (1) Medication prescribing and monitoring shall be under the direction of a licensed psychiatrist, a licensed physician supervised by a psychiatrist, or an APRN certified in psychiatric-mental health nursing practice who meets the requirements established in 201 KAR 20:057.

(2) Prescriptions concerning medication shall not exceed an order for more than five (5) refills.

(3) Medication prescribing and monitoring used in treatment shall be recorded in the staff notes and on a special medications chart in the client record.

(4) A copy of the prescription shall be kept in the client record.

(5) A blood or other laboratory test or examination shall be performed in accordance with accepted medical practice on each client receiving medication prescribed or administered by the residential crisis stabilization unit staff.

(6) Drug supplies shall be stored under proper sanitary, temperature, light, and moisture conditions.

(7) Medication kept by the unit shall be properly labeled.

(8) A medication shall be stored in the originally received container unless transferred to another container by a pharmacist or another person licensed to transfer the medication.

(9) Medication kept in the unit shall be kept in a locked cabinet.

(10) A controlled substance shall be kept under double lock

(for example, in a locked box in a locked cabinet).

(11) There shall be a controlled substances record, in which is recorded:

(a) The name of the client;

(b) The date, time, dosage, balance remaining, and method of administration of each controlled substance;

(c) The name of the prescribing physician or other ordering practitioner acting within the scope of his or her license to practice; and

(d) The name of the nurse who administered it[$_{\tau}$] or staff who supervised the self-administration.

(12) Access to the locked cabinet shall be restricted to a designated medication nurse or other authorized personnel.

(13) Medication to be self-administered shall be made available to the client at the time of administration.

Section <u>14.[15.]</u> Facility Requirements. (1) Living Unit. A living unit shall be located within a single building in which there is at least 120 square feet of space for each resident in the facility.

(2) Bedrooms.

(a) More than four (4) clients shall not sleep in the same[a] bedroom.

(b) A bedroom shall be equipped with a bed for each client.

(c) A bed shall:

1. Be at least thirty-six (36) inches wide and at least five (5) feet in length;

2. Be long and wide enough to accommodate the client's size;

3. Have a mattress cover, two (2) sheets, a pillow, and bed

covering to keep the client comfortable; 4. Be equipped with a support mechanism and a clean mattress; and

5. Be placed so that a client shall not experience discomfort because of proximity to a radiator or heat outlet, or exposure to a draft.

(d) There shall be separate sleeping quarters for males and females.

(e) A client shall not be housed in a room, a detached building, or other enclosure that has not previously been inspected and approved for residential use by the Office of Inspector General and the Department of Housing, Buildings and Construction.

(3) Bathrooms.

(a) For every eight (8) residents, each residential crisis stabilization unit shall have at least one (1):

1. Wash basin with hot and cold water;

2. Bath or shower with hot and cold water; and

3. Flush toilet.

(b) If separate toilet and bathing facilities are not provided, males and females shall not be permitted to use those facilities at the same time.

(4) Living area.

(a) The living area shall provide comfortable seating for all clients housed within the residential crisis stabilization unit.

(b) Each living unit shall be equipped with a:

1. Working sink; and

2. Stove and refrigerator, unless a kitchen is directly available within the same building as the living unit.

(5) There shall be adequate lighting, heating, heated water, and ventilation.

(6) There shall be space for a client to store personal belongings, including a receptacle where personal property may be stored and locked.

(7) The residential crisis stabilization unit shall be kept in good repair, neat, clean, free from accumulations of dirt and rubbish, and free from foul, stale, and musty odors.

(8) The residential crisis stabilization unit shall be kept free from insects and rodents with their harborages eliminated.

(9) The residential crisis stabilization unit shall establish an infection control system <u>that[which]</u> includes training personnel on proper hygiene related to infections prevalent among alcohol and other drug abusers.

(10) Services shall be provided in an area where clients are ensured privacy and confidentiality.

Section $\underline{15.[16.]}$ Facility Specifications. (1) A residential crisis stabilization unit shall:

(a) Be of safe and substantial construction;

(b) Be in compliance with applicable state and local laws relating to zoning, construction, plumbing, safety, and sanitation;

(c) Be approved by the State Fire Marshal's office prior to initial licensure or if the unit changes location; and

(d) Meet requirements for making buildings and facilities accessible to and usable by individuals with physical disabilities pursuant to KRS 198B.260 and 815 KAR 7:120.

(2) A residential crisis stabilization unit shall:

(a) Have a written emergency plan and procedures for meeting potential disasters such as fires or severe weather;

(b) Post the emergency plan conspicuously in a public area of the unit and provide a copy to all personnel;

(c) Provide training for all personnel on how to report a fire, extinguish a small fire, and evacuate a building; and

(d) Practice fire drills monthly, with a written record kept of all practiced fire drills, detailing the date, time, and residents who participated.

Section <u>16.[17.]</u> Denial and Revocation. (1) The cabinet shall deny an Application for License to Operate a Residential Crisis Stabilization Unit if:

(a) Any person with ownership interest in the <u>residential</u> crisis stabilization unit has had previous ownership interest in a health care facility that had its license revoked or voluntarily relinquished its license as the result of an investigation or pending disciplinary action;

(b) Any person with ownership interest in the <u>residential</u> crisis stabilization unit has been discontinued from participation in the Medicaid Program due to fraud or abuse of the program; or

(c) The applicant fails after the initial inspection to submit an acceptable plan of correction or fails to submit an acceptable amended plan of correction within the timeframes required by 902 KAR 20:008, Section 2(13)[(5)].

(2) The cabinet shall revoke a license if it finds that:

(a) In accordance with KRS 216B.105(2), there has been a substantial failure by the residential crisis stabilization unit to comply with the provisions of this administrative regulation;

(b) The residential crisis stabilization unit fails to submit an acceptable plan of correction or fails to submit an acceptable amended plan of correction within the timeframes required by 902 KAR 20:008, Section 2(13)[(5)]; or

(c) The residential crisis stabilization unit is terminated from participation in the Medicaid Program pursuant to 907 KAR 1:671.

(3) The denial or revocation of a residential crisis stabilization unit's license shall be mailed to the applicant or licensee, by certified mail, return receipt requested, or by personal service. Notice of the denial or revocation shall <u>state[set forth]</u> the particular reasons for the action.

(4) The denial or revocation shall become final and conclusive thirty (30) days after notice is given, unless the applicant or licensee, within the thirty (30) day period, files a request in writing for a hearing with the cabinet.

(5) Urgent action to suspend a license.

(a) The cabinet shall take urgent action to suspend a residential crisis stabilization unit's license if the cabinet has probable cause to believe that the continued operation of the unit would constitute an immediate danger to the health, welfare, or safety of its residents.

(b)1. The residential crisis stabilization unit shall be served with notice of the hearing on the urgent suspension to be held no sooner than twenty (20) days from the delivery of the notice.

2. Notice of the urgent suspension shall <u>state[set forth]</u> the particular reasons for the action.

(6) Notice of a hearing on an urgent suspension shall be served on the residential crisis stabilization unit by certified mail, return receipt requested, or by personal service.

(7)(a) Within five (5) working days of completion of the hearing, the cabinet's hearing officer shall render a written decision affirming, modifying, or revoking the urgent suspension.

(b) The urgent suspension shall be affirmed if there is

substantial evidence of an immediate danger to the health, safety, or welfare of the residents.

(8) The decision rendered under subsection (7) of this section shall be a final order of the agency on the matter, and any party aggrieved by the decision may appeal to circuit court.

(9) If the cabinet issues an urgent suspension, the cabinet shall take action to revoke the residential crisis stabilization unit's license pursuant to subsection (3) of this section if:

(a) The facility fails to attend the expedited hearing; or

(b) The decision rendered under subsection (7) of this section affirms that there is substantial evidence of an immediate danger to the health, safety, or welfare of the residents.

(10) Pursuant to KRS 216B.050, the cabinet may compel obedience to its lawful orders.

Section <u>17.[18.]</u> Incorporation by Reference. (1) The OIG 20:440, "Application for License to Operate a Residential Crisis Stabilization Unit", October 2014 edition, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of Inspector General, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

ADAM D. MATHER, Inspector General

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 2, 2020

FILED WITH LRC: October 13, 2020 at 12:30 p.m.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact: persons: Kara L. Daniel or Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes minimum licensure requirements for the operation of residential crisis stabilization units that serve at-risk children or children with severe emotional disabilities, at-risk adults or adults with severe mental illness, or individuals with substance use disorder or co-occurring disorders.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with KRS 216B.042(1), which requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, including licensure standards and procedures to ensure safe, adequate, and efficient health services.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216B.042 by establishing minimum licensure requirements for the operation of residential crisis stabilization units.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing standards for licensed residential crisis stabilization units.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment is being filed concurrently with the Department for Medicaid Services administrative regulation, 907 KAR 15:070, Coverage provisions and requirements regarding services provided by residential crisis stabilization units. Key changes to this administrative regulation, 902 KAR 20:440, are as follows:

Amends Section 1(1)(a) to clarify that a psychiatrist, as included under the definition of "behavioral health professional", may be certified or eligible to apply for certification by the American Osteopathic Board of Neurology; Amends Section 1(7) to allow a crisis stabilization unit to serve sixteen (16) clients rather than twelve (12) clients who require overnight stays;

Adds a definition for "licensed clinical alcohol and drug counselor";

Updates the definition of "peer support specialist" to include a registered alcohol and drug peer support specialist, and allow for peer support specialists to work under the supervision of a licensed clinical alcohol and drug counselor;

Deletes the prohibition against co-locating a residential alcohol and other drug treatment entity (AODE) and a residential crisis stabilization program on the same campus;

Adds language to allow the executive director to serve in a dual role as the executive director of a residential crisis stabilization unit and an AODE if both facilities are owned by the same entity and meet other criteria;

Adds language to allow the program director to serve in a dual role as the program director of a residential crisis stabilization unit and an AODE if both facilities are owned by the same entity and meet other criteria;

Removes language allowing residential crisis stabilization units to use the Kentucky National Background Check Program (NBCP) to satisfy the State-level criminal record check requirements. Use of the NBCP was originally included in this administrative regulation by error, prior to receiving additional information from the Federal Bureau of Investigation, which clarified that the Kentucky State Police relies upon a federal statute, Section 6201 of the Affordable Care Act (ACA), for the submission of fingerprints to the FBI for direct patient access employees in voluntarily participating long-term care settings. Because residential crisis stabilization units are not included in the statutory definition of a "long-term care facility" or otherwise covered under Section 6201 of the ACA, residential crisis stabilization units cannot voluntarily participate in the Kentucky NBCP;

Adds a cross-reference to applicable sections in 907 KAR 15:070 as it relates to the following services provided by residential crisis stabilization units: screening, assessment, treatment planning, individual therapy, group therapy, family therapy, and peer support;

Allows a licensed clinical alcohol and drug counselor to provide screening, assessment, treatment planning, individual therapy, group therapy, and family therapy;

Adds a cross-reference to 907 KAR 15:070, Section 3, if a residential crisis stabilization unit provides treatment for acute withdrawal; and

Adds licensed AODE programs as one of the programs with which residential crisis stabilization units may have a linkage to help promote continuity of care after discharge.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to align with the proposed changes to 907 KAR 15:070.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of KRS 216B.042 because it establishes minimum licensure requirements for the operation of residential crisis stabilization units.

(d) How the amendment will assist in the effective administration of the statutes: This amendment assists in the effective administration of the statutes by establishing standards for licensed residential crisis stabilization units.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects the four (4) currently licensed residential crisis stabilization units.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Entities licensed in accordance with this administrative regulation are required to comply with the standards established by this administrative regulation, including:

State Fire Marshal approval of the facility's location prior to

initial licensure or a change of location;

Accreditation within one (1) year of initial licensure, unless an extension is granted;

Compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the residential crisis stabilization unit;

Designation of an executive director who may also serve as the residential crisis stabilization unit's program director if the individual is a behavioral health professional as defined by Section 1 of this administrative regulation;

Compliance with abuse registry and criminal background check requirements;

Implementation of a process for quality assurance and utilization review;

Implementation of a process for responding to client grievances;

Mandatory delivery of screening, assessment, treatment planning, individual therapy, group therapy, and psychiatric services;

Optional delivery of family therapy and peer support services;

Treatment for acute withdrawal, if appropriate;

Retention of client records;

Implementation of administrative and personnel policies as well as policies that ensure that the rights of clients are protected;

Medication prescribing and monitoring;

Compliance with basic facility requirements for bedrooms, bathrooms, living areas, infection control, and cleanliness; and

Compliance with applicable state and local laws relating to zoning, construction, plumbing, safety, and sanitation as well as emergency plans in the effect of a disaster or severe weather.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no additional costs to residential crisis stabilization units to comply with this amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Licensed residential crisis stabilization units may enroll in the Kentucky Medicaid Program for reimbursement of covered services provided to Medicaid recipients in need of short-term crisis services.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional costs to the cabinet for implementation of this administrative regulation.

(b) On a continuing basis: There are no additional costs to the cabinet for implementation of this administrative regulation on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State general funds and agency monies are used to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish or increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applicable as compliance with this administrative regulation applies equally to all individuals or entities who elect to be regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts the Cabinet for Health and Family Services, Office of Inspector General, and licensed residential crisis stabilization units.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.042

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The Cabinet collects an initial fee of \$750 and annual renewal fee of \$500 from each licensed residential crisis stabilization unit. These fees are existing requirements and are not being amended by this amendment.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will generate an initial licensure fee of \$750 and annual licensing fee of \$500 for each entity licensed as a residential crisis stabilization unit. These fees are existing requirements and are not being amended by this amendment.

(c) How much will it cost to administer this program for the first year? This amendment imposes no additional costs on the administrative body.

(d) How much will it cost to administer this program for subsequent years? This amendment imposes no additional costs on the administrative body.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): See response above.

Expenditures (+/-): This administrative regulation is anticipated to have minimal fiscal impact to the cabinet.

Other Explanation:

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 45 C.F.R. Parts 160, 164, 42 U.S.C. 1320d-2 - 1320d-8, 42 U.S.C. 209ee-3, 42 C.F.R. Part 2

2. State compliance standards. KRS 216B.042

3. Minimum or uniform standards contained in the federal mandate. 45 C.F.R. 160, 164, and 42 U.S.C. 1320d-2 – 1320d-8 establish the HIPAA privacy rules to protect individuals' medical records and other personal health information. 42 U.S.C. 209ee-3 pertains to the confidentiality of patient records. 42 C.F.R. Part 2 prohibits programs from disclosing any information that would identify a person as having or having had substance use disorder, unless that person provides written consent.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation does not impose requirements that are more strict than federal laws or regulations.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Not applicable.

STATEMENT OF EMERGENCY 907 KAR 15:070E

This emergency administrative regulation governs residential crisis stabilization units. As amended, this emergency administrative regulation will implement new services relating to withdrawal management and medication assisted treatment for residential crisis stabilization units. The primary reason for promulgating this administrative regulation as an emergency administrative regulation is to better ensure the availability of a full continuum of care within the Medicaid Program for substance use disorder services pursuant to the American Society of Addiction Medicine's (ASAM) Criteria. Without the authority granted by this administrative regulation, the full continuum of care for substance use disorder established in the ASAM Criteria will not be

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reimbursable by Medicaid. Nationwide, and within Kentucky, the opioid epidemic has been exacerbated by the ongoing COVID-19 pandemic, and this administrative regulation will give the Department for Medicaid Services (DMS) and Kentucky providers additional vital tools to confront this serious threat to Kentucky citizens. Specifically, this administrative regulation is being filed as an emergency administrative regulation in accordance with KRS 13A.190(1)(a)1., 2., and 4. This emergency administrative regulation is needed pursuant to KRS 13A.190(1)(a)1. in order to thoroughly confront the serious and imminent danger posed to Kentucky citizens by any exacerbation of the opioid epidemic. This emergency administrative regulation is also needed pursuant to KRS 13A.190(1)(a)2. in order to preserve state and federal funding. In order to continue the SUD 1115 Waiver, Kentucky Medicaid is required to establish and maintain the availability of the full spectrum of the ASAM level of care to Kentucky Medicaid members. Failure to fully implement the ASAM criteria may risk continued federal coverage and approval of the SUD 1115 Waiver. If that happens, there would be a loss of federal funding. This emergency administrative regulation is needed pursuant to KRS 13A.190(1)(a)4. to protect human health by increasing access to treatment for substance use disorder (SUD), and to address all aspects of the SUD epidemic within Kentucky. Beyond the immediate imminent danger of any exacerbation of the opioid epidemic, this administrative regulation is necessary to bolster innovative efforts to continue to confront and address the long standing opioid epidemic. This emergency administrative regulation shall be replaced by an ordinary administrative regulation. The ordinary administrative regulation is identical to this emergency administrative regulation.

ANDY BESHEAR, Governor ERIC FRIEDLANDER, Secretary

CABINET FOR HEALTH AND FAMILY SERVICES Department for Medicaid Services Division of Policy and Operations (Emergency Amendment)

907 KAR 15:070E. Coverage provisions and requirements regarding services provided by residential crisis stabilization units.

EFFECTIVE: October 13, 2020

RELATES TO: KRS 205.520, <u>21 U.S.C. 823(g)(2)</u>, 42 U.S.C. 1396a(a)(10)(B), 42 U.S.C. 1396a(a)(23)

STATUTÓRY AUTHORITY: KŔS 194A.030(2), 194A.050(1), 205.520(3)

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has a responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed or opportunity presented by federal law to qualify for federal Medicaid funds. This administrative regulation establishes the coverage provisions and requirements regarding Medicaid Program behavioral health services provided by residential crisis stabilization units.

Section 1. General Coverage Requirements. (1) For the department to reimburse for a service covered under this administrative regulation, the service shall be:

(a) Medically necessary; and

(b) Provided:

1. To a recipient; and

2. By a residential crisis stabilization unit that meets the provider participation requirements established in Section 2 of this administrative regulation.

(2)(a) Direct contact between a practitioner and a recipient shall be required for each service.

(b) A service that does not meet the requirement in paragraph (a) of this subsection shall not be covered.

(3) A service shall be:

(a) Stated in the recipient's plan of care; and

(b) Provided in accordance with the recipient's plan of care.

(4) A residential crisis stabilization unit shall establish a plan of care for each recipient receiving services.

Section 2. Provider Participation. (1) To be eligible to provide services under this administrative regulation, a residential crisis stabilization unit shall:

(a) Be currently enrolled in the Kentucky Medicaid Program in accordance with 907 KAR 1:672;

(b) Except as established in subsection (3) of this section, be currently participating in the Kentucky Medicaid Program in accordance with 907 KAR 1:671;

(c) Be licensed as a residential crisis stabilization unit in accordance with 902 KAR 20:440;

(d) Comply with the requirements established in 902 KAR 20:440;

(e) Have:

1. For each service it provides, the capacity to provide the full range of the service as established in this administrative regulation;

2. Demonstrated experience in serving individuals with behavioral health disorders;

3. The administrative capacity to ensure quality of services;

4. A financial management system that provides documentation of services and costs; and

5. The capacity to document and maintain individual case records:

(f) Be a community-based, residential program that offers an array of services including:

1. Screening;

2. Assessment;

3. Treatment planning;

4. Individual [outpatient]-therapy;

5. Group [outpatient] therapy;

6. Psychiatric services;

7. Family [outpatient] therapy at the option of the residential crisis stabilization unit; [or]

8. Peer support at the option of the residential crisis stabilization unit:

<u>9. Withdrawal management if treating substance use disorders:</u> or

10. Medication assisted treatment if treating substance use disorders;

(g) Provide services in order to:

1. Stabilize a crisis and divert an individual from a higher level of care;

2. Stabilize an individual and provide treatment for acute withdrawal, if applicable; and

3. Re-integrate an individual into the individual's community or other appropriate setting in a timely fashion;

(h) Not be part of a hospital;

(i) Be used when an individual:

1. Is experiencing a behavioral health crisis that cannot be safely accommodated within the individual's community; and

2. Needs overnight care that is not hospitalization;

(j) Except as established in subsection (2)(a) of this section, not contain more than sixteen (16) beds;

(k) Except as established in subsection (2)(b) of this section, not be part of multiple units comprising one (1) facility with more than sixteen (16) beds in aggregate;

(I) Agree to provide services in compliance with federal and state laws regardless of age, sex, race, creed, religion, national origin, handicap, or disability;

(m) Comply with the Americans with Disabilities Act (42 U.S.C. 12101 et seq.) and any amendments to the Act;

(n) Have the capacity to employ staff authorized to provide treatment services in accordance with this section and to coordinate the provision of services among team members;

(o) Have the capacity to provide the full range of residential crisis stabilization services as stated in Section 3(2) of this administrative regulation and on a twenty-four (24) hour a day, seven (7) day a week, every day of the year basis;

(p) Have access to a board certified or board-eligible psychiatrist twenty-four (24) hours a day, seven (7) days a week,

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every day of the year; [and]

(q) Have knowledgeable staff regarding mental health, substance use, or co-occurring disorders based on the population being served; and

(r) For the treatment or stabilization of withdrawal management symptoms for substance use disorder or co-occurring disorders, have a planned and structured regimen of twenty-four (24) hour professionally directed evaluation, observation, medical monitoring, and addiction treatment[disorders].

(2) If every recipient receiving services in the:

(a) Single unit is under the age of twenty-one (21) years or over the age of sixty-five (65) years, the limit of sixteen (16) beds established in subsection (1)(j) of this section shall not apply; or

(b) Multiple units is under the age of twenty-one (21) years or over the age of sixty-five (65) years, the limit of sixteen (16) beds established in subsection (1)(k) of this section shall not apply

(3) In accordance with 907 KAR 17:015, Section 3(3), a residential crisis stabilization unit that[which] provides a service to an enrollee shall not be required to be currently participating in the fee-for-service Medicaid Program.

Section 3. Covered Services. (1)(a) Except as specified in the requirements stated for a given service, the services covered may be provided for:

1. A mental health disorder;

2. A substance use disorder; or

3. Co-occurring mental health and substance use disorders.

(b) Residential crisis stabilization services shall be provided in a residential crisis stabilization unit.

(2) Residential crisis stabilization services shall include the services established in this subsection.[:

(a) A screening provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A licensed clinical social worker;

4. A licensed professional clinical counselor:

5. A licensed professional art therapist;

6. A licensed marriage and family therapist;

7. A physician;

8. A psychiatrist;

9. An advanced practice registered nurse; or

10. A behavioral health practitioner under supervision except

for a licensed assistant behavior analyst;

(b) An assessment provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A licensed clinical social worker;

4. A licensed professional clinical counselor;

5. A licensed professional art therapist;

6. A licensed marriage and family therapist;

7. A physician;

8. A psychiatrist;

9. An advanced practice registered nurse;

10. A licensed behavior analyst; or

11. A behavioral health practitioner under supervision;

(c) Individual outpatient therapy or group outpatient therapy provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A licensed clinical social worker;

4. A licensed professional clinical counselor;

5. A licensed professional art therapist;

6. A licensed marriage and family therapist;

7. A physician;

8. A psychiatrist;

9. An advanced practice registered nurse;

10. A licensed behavior analyst: or

11. A behavioral health practitioner under supervision;

(d) Treatment planning provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A licensed clinical social worker;

4. A licensed professional clinical counselor;

5. A licensed professional art therapist;

6. A licensed marriage and family therapist;

7. A physician:

8. A psychiatrist;

9. An advanced practice registered nurse;

10. A licensed behavior analyst; or

11. A behavioral health practitioner under supervision except for a certified alcohol and drug counselor;

(e) Psychiatric services provided by:

1. A psychiatrist; or

2. An APRN; or

(f) At the option of the residential crisis stabilization unit:

1. Family outpatient therapy provided by:

a. A licensed psychologist;

b. A licensed psychological practitioner;

c. A licensed clinical social worker;

d. A licensed professional clinical counselor;

e. A licensed professional art therapist;

f. A licensed marriage and family therapist;

g. A physician;

h. A psychiatrist;

i. An advanced practice registered nurse; or

j. A behavioral health practitioner under supervision except for a licensed assistant behavior analyst; or

2. Peer support provided by a peer support specialist working under the supervision of:

a. An approved behavioral health service provider; or

b. A certified alcohol and drug counselor.

(3) (a) A screening shall:

1. Establish the need for a level of care evaluation to determine the most appropriate and least restrictive service to maintain the safety of the individual who may have a mental health disorder, substance use disorder, or co-occurring disorders;

2. Not establish the presence or specific type of disorder; [and]

3. Establish the need for an in-depth assessment of the number and duration of risk factors including:

a. Imminent danger and availability of lethal weapons;

b. Verbalization of suicidal or homicidal risk;

c. Need of immediate medical attention, including withdrawal management needs;

d. Positive and negative coping strategies;

e. Lack of family or social supports; f. Active psychiatric diagnosis; or

g. Current drug and alcohol use;

4. Be provided face-to-face or via telehealth as appropriate pursuant to 907 KAR 3:170; and

5. Be provided by:

a. An approved behavioral health practitioner; or b. An approved behavioral health practitioner under

supervision. (b) An assessment shall:

treatment relationship;

and service plan; [and]

ASAM Criteria; and

6. Be provided by:

service need;

assessments:

supervision.

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1. Include gathering information and engaging in a process with the individual that enables the practitioner to:

a. Establish the presence or absence of a mental health disorder, a substance use disorder, or co-occurring disorders;

d. Engage the individual in developing an appropriate

2. Establish or rule out the existence of a clinical disorder or

3. Include working with the individual to develop a treatment

4. Not include psychological or psychiatric evaluations or

5. If being made for the treatment of a substance use disorder,

b. An approved behavioral health practitioner under

utilize a multi-dimensional assessment that complies with The

a. An approved behavioral health practitioner; or

b. Determine the individual's readiness for change; c. Identify the individual's strengths or problem areas that may

affect the treatment and recovery processes; and

(c) Individual [outpatient] therapy shall:

1. Be provided to promote the:

a. Health and wellbeing of the individual; or

b. Restoration of a recipient to their best possible functional level[Recovery] from a substance use disorder, a mental health

disorder, or co-occurring disorders;

2. Consist of:

a. A face-to-face, one (1) on one (1) encounter between the provider and recipient; and

b. A behavioral health therapeutic intervention provided in accordance with the recipient's identified crisis treatment plan;

3. Be aimed at:

a. Reducing adverse symptoms;

b. Reducing or eliminating the presenting problem of the recipient; and

c. Improving functioning; [and]

4. Not exceed three (3) hours per day unless additional time is medically necessary; and

5. Be provided by:

a. An approved behavioral health practitioner; or

b. An approved behavioral health practitioner under supervision.

(d)1. Group [outpatient] therapy shall:

a. Be a behavioral health therapeutic intervention provided in accordance with a recipient's identified crisis treatment plan;

b. Be provided to promote the:

(i) Health and wellbeing of the individual; or

(ii) <u>Restoration of a recipient to their best possible functional</u> <u>level[Recovery]</u> from a substance use disorder, a mental health disorder, or co-occurring disorders;

c. Consist of a face-to-face behavioral health therapeutic intervention provided in accordance with the recipient's identified crisis treatment plan;

d. Be provided to a recipient in a group setting:

(i) Of nonrelated individuals; and

(ii) Not to exceed twelve (12) individuals in size;

e. Focus on the psychological needs of the recipients as evidenced in each recipient's crisis treatment plan;

f. Center on goals including building and maintaining healthy relationships, personal goals setting, and the exercise of personal judgment;

g. Not include physical exercise, a recreational activity, an educational activity, or a social activity; and

h. Not exceed three (3) hours per day per recipient unless additional time is medically necessary.

2. The group shall have a:

a. Deliberate focus; and

b. Defined course of treatment.

3. The subject of group outpatient therapy shall relate to each recipient participating in the group.

4. The provider shall keep individual notes regarding each recipient within the group and within each recipient's health record.

5. The group shall be provided by:

a. An approved behavioral health practitioner; or

b. An approved behavioral health practitioner under supervision.

(e)1. Treatment planning shall:

a. Involve assisting a recipient in creating an individualized plan for services needed;

b. Involve restoring a recipient's functional level to the recipient's best possible functional level; and

c. Be performed using a person-centered planning process.

2. A service plan:

a. Shall be directed by the recipient;

b. Shall include practitioners of the recipient's choosing; and

c. May include:

(i) A mental health advance directive being filed with a local hospital;

(ii) A crisis plan; or

(iii) A relapse prevention strategy or plan.

3. A service plan shall be completed by:

a. An approved behavioral health practitioner; or

b. An approved behavioral health practitioner under

supervision.

(f)[1.] Family [outpatient] therapy shall:

<u>1.</u> Consist of a face-to-face behavioral health therapeutic intervention provided:

a. Through scheduled therapeutic visits between the therapist and the recipient and at least one (1) member of the recipient's family; and

b. To address issues interfering with the relational functioning of the family and to improve interpersonal relationships within the recipient's home environment:[-]

2. [Family outpatient therapy shall:]

a. Be provided to promote:

(i) The health and wellbeing of the individual; or

(ii) <u>Restoration of a recipient to their best possible functional</u> <u>level[Recovery]</u> from a substance use disorder, a mental health disorder, or co-occurring disorders; and

b. Not exceed three (3) hours per day per individual unless additional time is medically necessary; and

3. Be provided by:

a. An approved behavioral health practitioner; or

<u>b. An approved behavioral health practitioner under</u> supervision.

(g)1. Peer support services <u>provided by a peer support</u> <u>specialist working under the supervision of an approved behavioral</u> <u>health practitioner</u> shall:

a. Be social and emotional support that is provided by an individual who is experiencing a mental health disorder, a substance use disorder, or co-occurring mental health and substance use disorders to a recipient by sharing a similar mental health disorder, substance use disorder, or co-occurring mental health and substance use disorders in order to bring about a desired social or personal change;

b. Be an evidence-based practice;

c. Be structured and scheduled non-clinical therapeutic activities with an individual recipient or a group of recipients;

d. Be provided by a self-identified consumer, parent, or family member:

(i) Of a child consumer of mental health disorder services, substance use disorder services, or co-occurring mental health disorder services and substance use disorder services; and

(ii) Who has been trained and certified in accordance with 908 KAR 2:220, 908 KAR 2:230, or 908 KAR 2:240;

e. Promote socialization, recovery, self-advocacy, preservation, and enhancement of community living skills for the recipient;

f. Be coordinated within the context of a comprehensive, individualized treatment plan developed through a person-centered planning process;

g. Be identified in each recipient's treatment plan; and

h. Be designed to directly contribute to the recipient's individualized goals as specified in the recipient's treatment plan.

2. To provide peer support services, a residential crisis stabilization unit shall:

a. Employ peer support specialists who are qualified to provide peer support services in accordance with 908 KAR 2:220, 908 2:230, or 908 2:240;

b. [Use an approved behavioral health services provider or certified alcohol and drug counselor to supervise peer support specialists;

e.]Have the capacity to coordinate the provision of services among team members; [and]

<u>c.[</u>d.] Have the capacity to provide on-going continuing education and technical assistance to peer support specialists;

<u>d.</u> Require individuals providing peer support services to recipients to provide no more than thirty (30) hours per week of direct recipient contact; and

e. Require peer support services provided to recipients in a group setting to not exceed eight (8) individuals within any group at one (1) time.

(h)1. Withdrawal management services for substance use disorder shall:

a. Meet the service criteria for medically monitored intensive inpatient services for adults and medically monitored high-intensity inpatient services for adolescents in accordance with The ASAM Criteria; and

b. Comply with services pursuant to the requirements of 902 KAR 20:111.

2. A recipient who is receiving withdrawal management services shall:

a. Meet the current dimensional admissions criteria for withdrawal management level of care as found in The ASAM Criteria; and

b. Not require the full resources of an acute care hospital or a medically managed inpatient treatment program.

3. Withdrawal management services shall be provided by:

a. A physician or psychiatrist;

b. A physician assistant;

c. An advanced practice registered nurse; or

d. Any other approved behavioral health practitioner or nurse with oversight by a physician, advanced practice registered nurse, or a physician assistant.

(i)1. Medication assisted treatment shall be available per patient choice for the treatment of a substance use disorder or cooccurring disorders.

2. Medication assisted treatment shall be provided by a provider who:

<u>a. ls:</u>

(i) A physician licensed to practice medicine under KRS Chapter 311;

(ii) An advanced practice registered nurse (APRN); or

(iii) A physician assistant who has appropriately updated department provider enrollment information;

b. Meets standards in accordance with 201 KAR 9:270 or 201 KAR 20:065;

c. Maintains a current waiver under 21 U.S.C 823(g)(2) to prescribe buprenorphine products; and

d. Has experience and knowledge in addiction medicine.

(3) For those recipients being treated for a substance use

disorder, care coordination shall include at minimum: (a) Referring the recipient to appropriate community services;

(b) Facilitating medical and behavioral health follow-ups;

(c) Linking to appropriate levels of substance use treatment within the continuum in order to provide on-going support; and

(d) Facilitating medication assisted treatment as necessary, per patient choice, if the medication is not offered on-site.

(4) The extent and type of a screening shall depend upon the problem of the individual seeking or being referred for services.

(5) A diagnosis or clinical impression shall be made using terminology established in the most current edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders.

(6) <u>After July 1, 2021, if treating substance use disorders, the</u> <u>facility shall possess an appropriate ASAM level of care</u> <u>certification in accordance with The ASAM Criteria.</u>

(7) The department shall not reimburse for a service billed by or on behalf of an entity or individual who is not a billing provider.

Section 4. Additional Limits and Non-covered Services or Activities. (1) The following services or activities shall not be covered under this administrative regulation:

(a) A service provided to:

1. A resident of:

a. A nursing facility; or

b. An intermediate care facility for individuals with an intellectual disability;

2. An inmate of a federal, local, or state:

a. Jail;

b. Detention center; or

c. Prison; or

3. An individual with an intellectual disability without documentation of an additional psychiatric diagnosis;

(b) Psychiatric or psychological testing for another agency, including a court or school, that does not result in the individual receiving psychiatric intervention or behavioral health therapy from the residential crisis stabilization unit;

(c) A consultation or educational service provided to a recipient

or to others;

(d) A telephone call, an email, a text message, or other electronic contact that does not meet the requirements stated in the definition of "face-to-face";

(e) Travel time;

(f) A field trip;

(g) A recreational activity;

(h) A social activity; or

(i) A physical exercise activity group.

(2) Residential crisis stabilization services shall not include:

(a) Room and board;

(b) Educational services;

(c) Vocational services;

(d) Job training services;

(e) Habilitation services;

(f) Services to an inmate in a public institution pursuant to 42 C.F.R. 435.1010;

(g) Services to an individual residing in an institution for mental diseases pursuant to 42 C.F.R. 435.1010;

(h) Recreational activities;

(i) Social activities; or

(j) Services required to be covered elsewhere in the state plan.

(3)(a) A consultation by one (1) provider or professional with another shall not be covered under this administrative regulation.

(b) A third party contract shall not be covered under this administrative regulation.

Section 5. No Duplication of Service. (1) The department shall not reimburse for a service provided to a recipient by more than one (1) provider, of any program in which the service is covered, during the same time period.

(2) For example, if a recipient is receiving a residential crisis stabilization service from a community mental health center, the department shall not reimburse for the same service provided to the same recipient during the same time period by a residential crisis stabilization unit.

Section 6. Records Maintenance, Documentation, Protection, and Security. A residential crisis stabilization unit shall maintain a current health record for each recipient in accordance with 902 KAR 20:440.

Section 7. Medicaid Program Participation Compliance. (1) A residential crisis stabilization unit shall comply with:

(a) 907 KAR 1:671;

(b) 907 KAR 1:672; and

(c) All applicable state and federal laws.

(2)(a) If a residential crisis stabilization unit receives any duplicate payment or overpayment from the department, regardless of reason, the residential crisis stabilization unit shall return the payment to the department.

(b) Failure to return a payment to the department in accordance with paragraph (a) of this subsection may be:

1. Interpreted to be fraud or abuse; and

 $\ensuremath{\text{2. Prosecuted}}$ in accordance with applicable federal or state law.

(3)(a) When the department makes payment for a covered service and the residential crisis stabilization unit accepts the payment:

1. The payment shall be considered payment in full;

2. A bill for the same service shall not be given to the recipient; and

3. Payment from the recipient for the same service shall not be accepted by the residential crisis stabilization unit.

(b)1. A residential crisis stabilization unit may bill a recipient for a service that is not covered by the Kentucky Medicaid Program if the:

a. Recipient requests the service; and

b. Residential crisis stabilization unit makes the recipient aware in advance of providing the service that the:

(i) Recipient is liable for the payment; and

(ii) Department is not covering the service.

2. If a recipient makes payment for a service in accordance

with subparagraph 1. of this paragraph, the:

a. Residential crisis stabilization unit shall not bill the department for the service; and

b. Department shall not:

 $({\rm i})$ Be liable for any part of the payment associated with the service; and

(ii) Make any payment to the residential crisis stabilization unit regarding the service.

(4)(a) The signature of the residential crisis stabilization unit's staff or representative shall indicate that the residential crisis stabilization unit attests that any claim associated with a service is valid and submitted in good faith.

(b) Any claim and substantiating record associated with a service shall be subject to audit by the:

1. Department or its designee;

2. Cabinet for Health and Family Services, Office of Inspector General or its designee;

3. Kentucky Office of Attorney General or its designee:

4. Kentucky Office of the Auditor for Public Accounts or its designee; or

5. United States General Accounting Office or its designee.

(c) If a residential crisis stabilization unit receives a request from the department or its designee to provide a claim, related information, related documentation, or record for auditing purposes, the residential crisis stabilization unit shall provide the requested information to the department within the timeframe requested by the department.

(d)1. All services provided shall be subject to review for recipient or provider <u>fraud or</u> abuse; and <u>compliance with this</u> administrative regulation and state and federal law.

2. Willful abuse by a residential crisis stabilization unit shall result in the suspension or termination of the residential crisis stabilization unit from Medicaid Program participation.

Section 8. Third Party Liability. A residential crisis stabilization unit shall comply with KRS 205.622.

Section 9. Use of Electronic Signatures. (1) The creation, transmission, storage, and other use of electronic signatures and documents shall comply with the requirements established in KRS 369.101 to 369.120.

(2) A residential crisis stabilization unit that chooses to use electronic signatures shall:

(a) Develop and implement a written security policy that shall:

1. Be adhered to by each of the residential crisis stabilization unit's employees, officers, agents, or contractors;

2. Identify each electronic signature for which an individual has access; and

3. Ensure that each electronic signature is created, transmitted, and stored in a secure fashion;

(b) Develop a consent form that shall:

1. Be completed and executed by each individual using an electronic signature;

2. Attest to the signature's authenticity; and

3. Include a statement indicating that the individual has been notified of his or her responsibility in allowing the use of the electronic signature; and

(c) Provide the department, immediately upon request, with:

1. A copy of the residential crisis stabilization unit's electronic signature policy;

2. The signed consent form; and

3. The original filed signature.

Section 10. Auditing Authority. The department shall have the authority to audit any:

(1) Claim;

(2) Medical record; or

(3) Documentation associated with any claim or medical record.

Section 11. Federal Approval and Federal Financial Participation. The department's coverage of services pursuant to this administrative regulation shall be contingent upon:

(1) Receipt of federal financial participation for the coverage; and

(2) Centers for Medicare and Medicaid Services' approval for the coverage.

Section 12. Appeals. (1) An appeal of an adverse action by the department regarding a service and a recipient who is not enrolled with a managed care organization shall be in accordance with 907 KAR 1:563.

(2) An appeal of an adverse action by a managed care organization regarding a service and an enrollee shall be in accordance with 907 KAR 17:010.

LISA LEE, Commissioner

APPROVED BY AGENCY: September 9, 2020

FILED WITH LRC: October 13, 2020 at 12:40 p.m.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Persons: Jonathan Scott and Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the coverage provisions and requirements regarding Medicaid Program behavioral health services provided by residential crisis stabilization units (RCSUs).

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with federal mandates. Section 1302(b)(1)(E) of the Affordable Care Act mandates that "essential health benefits" for Medicaid programs include "mental health and substance use disorder services, including behavioral health treatment" for all recipients. 42 U.S.C. 1396a(a)(23) is known as the freedom of choice of provider mandate. This federal law requires the Medicaid Program to "provide that (A) any individual eligible for medical assistance (including drugs) may obtain such assistance from any institution, agency, community pharmacy or person, gualified to perform the service or services required (including an organization which provides such services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services.' 42 U.S.C. 1396a(a)(10)(B) requires the Medicaid Program to ensure that services are available to Medicaid recipients in the same amount, duration, and scope.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by complying with federal mandates and enhancing and ensuring Medicaid recipients' access to behavioral health services.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will assist in the effective administration of the authorizing statutes by complying with federal mandates and enhancing and ensuring Medicaid recipients' access to behavioral health services.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments to this administrative regulation combine a previously separate description of who may perform a service and a description of the service itself. In addition, the amendments implement additional requirements relating to withdrawal management and medication assisted treatment, including a requirement that the services be conducted in accordance with the ASAM Criteria.

(b) The necessity of the amendment to this administrative regulation: These amendments are necessary to comply with existing OIG administrative regulations, implement an SUD 1115 waiver, and provide additional formatting improvements.

(c) How the amendment conforms to the content of the authorizing statutes: The amendments conform to the content of

the authorizing statutes by implementing an SUD 1115 waiver.

(d) How the amendment will assist in the effective administration of the statutes: The amendments will assist in the effective administration of the statutes by providing additional clarity and requirements relating to residential crisis stabilization units.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: There are currently fifteen (15) entities that are providing residential crisis stabilization unit (RCSU) services under this administrative regulation. Medicaid recipients who qualify for behavioral health services provided by an RCSU will also be affected by this administrative regulation.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment. Facilities and providers may need to comply with the ASAM Criteria in order to provide certain services.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). The entities referenced in paragraph (a) could experience administrative costs associated with enrolling with the Medicaid Program.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3). The entities referenced in paragraph (a) will benefit by receiving Medicaid Program reimbursement, and the benefit of providing additional services. Behavioral health professionals authorized to provide services in a residential crisis stabilization unit will benefit by having more employment opportunities in Kentucky. Medicaid recipients in need of behavioral health services will benefit from an expanded base of providers from which to receive these services.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: DMS does not anticipate additional costs in implementing this administrative regulation.

(b) On a continuing basis: DMS does not anticipate additional costs in implementing this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under the Social Security Act, Title XIX and matching funds of general fund appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment. Neither an increase in fees nor funding is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any fees.

(9) Tiering: Is tiering applied? Tiering is not applied as the policies apply equally to the regulated entities.

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 42 U.S.C. 1396a(a)(10)(B) and 42 U.S.C. 1396a(a)(30)(A).

2. State compliance standards. KRS 205.520(3) states: "Further, it is the policy of the Commonwealth to take advantage of all federal funds that may be available for medical assistance. To qualify for federal funds the secretary for health and family services may by regulation comply with any requirement that may be imposed or opportunity that may be presented by federal law. Nothing in KRS 205.510 to 205.630 is intended to limit the secretary's power in this respect."

KRS 205.6311 requires the Department for Medicaid Services

to "promulgate administrative regulations . . . to expand the behavioral health network to allow providers to provide services within their licensure category."

3. Minimum or uniform standards contained in the federal mandate. 42 U.S.C. 1396a(a)(10)(B) requires the Medicaid Program to ensure that services are available to Medicaid recipients in the same amount, duration, and scope. Expanding the provider base will help ensure Medicaid recipient access to services statewide and reduce or prevent the lack of availability of services due to demand exceeding supply in any given area. Medicaid reimbursement for services is required to be consistent with efficiency, economy and quality of care and be sufficient to attract enough providers to assure access to services. 42 U.S.C. 1396a(a)(30)(A) requires Medicaid state plans to: "...provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4)) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area."

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? The administrative regulation does not impose stricter than federal requirements.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. The administrative regulation does not impose stricter than federal requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services will be affected by the amendment to this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.010(1), 194A.030(2), 194A.050(1), 205.520(3), 205.6311, 42 U.S.C. 1396a(a)(10)(B), and 42 U.S.C. 1396a(a)(30)(A).

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The amendment is not expected to generate revenue for state or local government.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The amendment is not expected to generate revenue for state or local government.

(c) How much will it cost to administer this program for the first year? DMS does not expect any additional costs in administering these amendments during the first year.

(d) How much will it cost to administer this program for subsequent years? DMS does not expect any additional costs in administering these amendments during subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

STATEMENT OF EMERGENCY 907 KAR 15:080E

This emergency administrative regulation governs chemical dependency treatment center services. As amended, this administrative regulation will allow for both inpatient and outpatient services to be reimbursable by Medicaid when provided within these facilities. Additional changes implement new services relating to service planning, ambulatory withdrawal management, medication assisted treatment, and inpatient chemical dependency treatment. The primary reason for promulgating this administrative regulation as an emergency administrative regulation is to better ensure the availability of a full continuum of care within the Medicaid Program for substance use disorder services pursuant to the American Society of Addiction Medicine's (ASAM) Criteria. Without the authority granted by this administrative regulation, the full continuum of care for substance use disorder established in the ASAM Criteria will not be reimbursable by Medicaid. Nationwide, and within Kentucky, the opioid epidemic has been exacerbated by the ongoing COVID-19 pandemic, and this administrative regulation will give the Department for Medicaid Services (DMS) and Kentucky providers additional vital tools to confront this serious threat to Kentucky citizens. Specifically, this administrative regulation is being filed as an emergency administrative regulation in accordance with KRS 13A.190(1)(a)1., 2., and 4. This emergency administrative regulation is needed pursuant to KRS 13A.190(1)(a)1. in order to thoroughly confront the serious and imminent danger posed to Kentucky citizens by any exacerbation of the opioid epidemic. This emergency administrative regulation is also needed pursuant to KRS 13A.190(1)(a)2. in order to preserve state and federal funding. In order to continue the SUD 1115 Waiver, Kentucky Medicaid is required to establish and maintain the availability of the full spectrum of the ASAM level of care to Kentucky Medicaid members. Failure to fully implement the ASAM criteria may risk continued federal coverage and approval of the SUD 1115 Waiver. If that happens, there would be a loss of federal funding. DMS furthermore expects a modest cost-savings from introducing the ASAM 3.7 level of care and allowing it to be utilized by chemical dependency treatment centers. This emergency administrative regulation is needed pursuant to KRS 13A.190(1)(a)4. to protect human health by increasing access to treatment for substance use disorder (SUD), and to address all aspects of the SUD epidemic within Kentucky. Beyond the immediate imminent danger of any exacerbation of the opioid epidemic, this administrative regulation is necessary to bolster innovative efforts to continue to confront and address the long standing opioid epidemic. This emergency administrative regulation shall be replaced by an ordinary administrative regulation. The ordinary administrative regulation is identical to this emergency administrative regulation.

ANDY BESHEAR, Governor ERIC FRIEDLANDER, Secretary

CABINET FOR HEALTH AND FAMILY SERVICES Department for Medicaid Services Division of Policy and Operations (Emergency Amendment)

907 KAR 15:080E. Coverage provisions and requirements regarding [outpatient] chemical dependency treatment center services.

EFFECTIVE: October 13, 2020

RELATES TO: KRS 205.520, <u>205.622</u>, <u>309.0831</u>, <u>21</u> U.S.C. <u>823(g)(2)</u>, <u>42</u> U.S.C. 1396a(a)(10)(B), 1396a(a)(23), <u>42</u> C.F.R. <u>435.1010</u>

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3)

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has a responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed or opportunity presented by federal law to qualify for federal Medicaid funds. This administrative regulation establishes the coverage provisions and requirements regarding Medicaid Program outpatient and inpatient chemical dependency treatment center services.

Section 1. General Coverage Requirements. (1) For the department to reimburse for a service covered under this administrative regulation, the service shall be:

(a) Medically necessary; and

(b) Provided:

1. To a recipient; and

2. By a chemical dependency treatment center that meets the provider participation requirements established in Section 2 of this administrative regulation.

(2)(a) <u>Direct</u>[Face-to-face] contact between a practitioner and a recipient shall be required for each service except for:

1. Collateral outpatient therapy for a recipient under the age of twenty-one (21) years if the collateral outpatient therapy is in the recipient's plan of care;

2. A family outpatient therapy service in which the corresponding current procedural terminology code establishes that the recipient is not present; or

3. A psychological testing service comprised of interpreting or explaining results of an examination or data to family members or others in which the corresponding current procedural terminology code establishes that the recipient is not present.

(b) A service that does not meet the requirement in paragraph (a) of this subsection shall not be covered.

(3) A billable unit of service shall be actual time spent delivering a service in <u>an[a face-to-face]</u> encounter.

(4) A service shall be:

(a) Stated in the recipient's plan of care; and

(b) Provided in accordance with the recipient's plan of care.

(5)(a) A chemical dependency treatment center shall establish a plan of care for each recipient receiving services from a chemical dependency treatment center.

(b) A plan of care shall meet the treatment plan requirements established in 902 KAR 20:160.

Section 2. Provider Participation. (1)(a) To be eligible to provide services under this administrative regulation, a chemical dependency treatment center shall:

1. Be currently enrolled as a provider in the Kentucky Medicaid Program in accordance with 907 KAR 1:672;

2. Except as established in subsection (2) of this section, be currently participating in the Kentucky Medicaid Program in accordance with 907 KAR 1:671;

3. Be licensed as a chemical dependency treatment center to provide outpatient <u>and inpatient</u> behavioral health services in accordance with 902 KAR 20:160; and

4. Have:

a. For each service it provides, the capacity to provide the full range of the service as established in this administrative regulation;

b. Documented experience in serving individuals with mental health, substance use, or co-occurring[behavioral health] disorders;

c. The administrative capacity to ensure quality of services;

d. A financial management system that provides

documentation of services and costs; and e. The capacity to document and maintain individual health

records. (b) The documentation referenced in paragraph (a)4.b. of this subsection shall be subject to audit by:

1. The department or its designee;

2. The Cabinet for Health and Family Services, Office of Inspector General;

3. A managed care organization, if the chemical dependency treatment center is enrolled in its network;

4. The Centers for Medicare and Medicaid Services;

5. The Kentucky Office of the Auditor of Public Accounts; or

6. The United States Department of Health and Human

Services, Office of the Inspector General.

(2) In accordance with 907 KAR 17:015, Section 3(3), a chemical dependency treatment center that[which] provides a service to an enrollee shall not be required to be currently participating in the fee-for-service Medicaid Program.

(3) A chemical dependency treatment center shall:

(a) Agree to provide services in compliance with federal and state laws regardless of age, sex, race, creed, religion, national origin, handicap, or disability; and

(b) Comply with the Americans with Disabilities Act (42 U.S.C. 12101 et seq.) and any amendments to the act.

(4)(a) Except as provided by paragraph (b) of this subsection, chemical dependency treatment center shall possess accreditation, within one (1) year of initial enrollment, by one (1) of the following:

1. The Joint Commission;

2. The Commission on Accreditation of Rehabilitation Facilities; The Council on Accreditation; or

4. A nationally recognized accreditation organization.

(b) The department shall grant a one (1) time extension to a

chemical dependency treatment center that requests a one (1) time extension to complete the accreditation process, if the request is submitted at least ninety (90) days prior to expiration of provider enrollment.

Section 3. Covered Services.

(1) Reimbursement shall not be available for services performed within a chemical dependency treatment program by a:

(a) Licensed behavior analyst;

(b) Licensed assistant behavior analyst;

(c) Registered behavior technician; or

(d) Community support associate.

(2) The services covered may be provided for a substance use disorder or co-occurring disorders.

(3)[(2)] The [following] services listed in this subsection shall be covered under this administrative regulation in accordance with the requirements established in this subsection.[:

(a) A screening, crisis intervention, or intensive outpatient program service provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A certified psychologist with autonomous functioning;

4. A licensed clinical social worker;

5. A licensed professional clinical counselor;

6. A licensed professional art therapist;

7. A licensed marriage and family therapist;

8. A physician;

9. A psychiatrist;

10. An advanced practice registered nurse;

11. A licensed psychological associate working under the supervision of a board-approved licensed psychologist;

12. A certified psychologist working under the supervision of a board-approved licensed psychologist;

A licensed clinical alcohol and drug counselor in accordance with Section 11 of this administrative regulation; or

14. A behavioral health practitioner under supervision, except for a licensed assistant behavior analyst;

(b) An assessment provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A certified psychologist with autonomous functioning;

4. A licensed clinical social worker;

5. A licensed professional clinical counselor;

6. A licensed professional art therapist;

7. A licensed marriage and family therapist;

8. A physician;

9. A psychiatrist:

10. An advanced practice registered nurse;

11. A licensed behavior analyst;

12. A licensed psychological associate working under the supervision of a board-approved licensed psychologist;

13. A certified psychologist working under the supervision of a board-approved licensed psychologist;

14. A licensed clinical alcohol and drug counselor in accordance with Section 11 of this administrative regulation; or

15. A behavioral health practitioner under supervision:

(c) Psychological testing provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A certified psychologist with autonomous functioning;

4. A licensed psychological associate working under the supervision of a board-approved licensed psychologist; or

5. A certified psychologist working under the supervision of a

board-approved licensed psychologist;

(d) Day treatment or mobile crisis services provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner; 3. A certified psychologist with autonomous functioning;

4. A licensed clinical social worker;

5. A licensed professional clinical counselor;

6. A licensed professional art therapist;

7. A licensed marriage and family therapist;

8. A physician; A psychiatrist;

10. An advanced practice registered nurse;

11. A licensed psychological associate working under the

supervision of a board-approved licensed psychologist;

12. A certified psychologist working under the supervision of a board-approved licensed psychologist;

13. A licensed clinical alcohol and drug counselor in accordance with Section 11 of this administrative regulation;

14. A behavioral health practitioner under supervision, except for a licensed assistant behavior analyst: or

15. A peer support specialist working under the supervision of an approved behavioral health services provider;

(e) Peer support provided by a peer support specialist working under the supervision of an approved behavioral health services provider:

(f) Individual outpatient therapy, group outpatient therapy, or collateral outpatient therapy provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A certified psychologist with autonomous functioning;

4. A licensed clinical social worker;

5. A licensed professional clinical counselor;

6. A licensed professional art therapist;

7. A licensed marriage and family therapist;

8. A physician;

9. A psychiatrist;

10. An advanced practice registered nurse;

11. A licensed behavior analyst;

12. A licensed psychological associate working under the supervision of a board-approved licensed psychologist;

13. A certified psychologist working under the supervision of a board-approved licensed psychologist;

14. A licensed clinical alcohol and drug counselor in accordance with Section 11 of this administrative regulation; or

15. A behavioral health practitioner under supervision;

(g) Family outpatient therapy provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A certified psychologist with autonomous functioning;

11. A licensed psychological associate working under the

12. A certified psychologist working under the supervision of a

13. A licensed clinical alcohol and drug counselor in

14. A behavioral health practitioner under supervision, except

accordance with Section 11 of this administrative regulation; or

4. A licensed clinical social worker;

board-approved licensed psychologist;

5. A licensed professional clinical counselor;

6. A licensed professional art therapist;

7. A licensed marriage and family therapist;

10. An advanced practice registered nurse;

supervision of a board-approved licensed psychologist;

8. A physician; 9. A psychiatrist;

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for a licensed assistant behavior analyst; or

(h) A screening, brief intervention, and referral to treatment for a substance use disorder or SBIRT provided by:

1. A licensed psychologist;

- 2. A licensed psychological practitioner:
- 3. A certified psychologist with autonomous functioning;

4. A licensed clinical social worker;

5. A licensed professional clinical counselor;

6. A licensed professional art therapist;

7. A licensed marriage and family therapist;

8. A physician;

9. A psychiatrist;

10. An advanced practice registered nurse;

11. A licensed psychological associate working under the supervision of a board-approved licensed psychologist;

12. A certified psychologist working under the supervision of a board-approved licensed psychologist;

13. A licensed clinical alcohol and drug counselor in accordance with Section 11 of this administrative regulation; or

14. A behavioral health practitioner under supervision, except for a licensed assistant behavior analyst.

(3)](a) A screening shall:

1. Determine the likelihood that an individual has a substance use disorder.

2. Not establish the presence or specific type of disorder; [and]

3. Establish the need for an in-depth assessment;

4. Be provided face-to-face or via telehealth as appropriate pursuant to 907 KAR 3:170; and

5. Be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(b) An assessment shall:

1. Include gathering information and engaging in a process with the individual that enables the practitioner to:

a. Establish the presence or absence of a substance use disorder;

b. Determine the individual's readiness for change;

c. Identify the individual's strengths or problem areas that may affect the treatment and recovery processes; and

d. Engage the individual in developing[the development of] an appropriate treatment relationship;

2. Establish or rule out the existence of a clinical disorder or service need:

3. Include working with the individual to develop a plan of care; [and]

4. Not include psychological or psychiatric evaluations or assessments;

5. Utilize a multidimensional assessment that complies with the most current edition of The ASAM Criteria to determine the most appropriate level of care;

6. Be provided face-to-face or via telehealth as appropriate pursuant to 907 KAR 3:170; and

7. Be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(c) Psychological testing shall:

1. Include[:

psychodiagnostic assessment of personality, a.l а psychopathology, emotionality, or intellectual disabilities;

2. Include an[and b.] interpretation and a written report of testing results;

3. Be face-to-face or via telehealth as appropriate pursuant to 907 KAR 3:170; and

4. Be provided by:

a. A licensed psychologist;

b. A certified psychologist with autonomous functioning;

c. A licensed psychological practitioner;

d. A certified psychologist under supervision; or

e. A licensed psychological associate under supervision[and

2. Be performed by an individual who has met the requirements of KRS Chapter 319 related to the necessary credentials to perform psychological testing].

(d) Crisis intervention:

1. Shall be a therapeutic intervention for the purpose of immediately reducing or eliminating the risk of physical or emotional harm to:

a. The recipient; or

b. Another individual;

2. Shall consist of clinical intervention and support services necessary to provide integrated crisis response, crisis stabilization interventions, or crisis prevention activities for individuals;

3. Shall be provided:

a. [On-site in the facility where the outpatient behavioral health services are provided;

b.]As an immediate relief to the presenting problem or threat; and

b.[c.] In a one (1) on one (1)[face-to-face, one-on-one] encounter between the provider and the recipient, which is delivered either face-to-face or via telehealth if appropriate pursuant to 907 KAR 3:170;

4. Shall be followed by a referral to non-crisis services if applicable; [and]

5. May include:

a. Further service prevention planning including[that includes]:

(i) Lethal means reduction for suicide risk; or

(ii) Substance use disorder relapse prevention; or

b. Verbal de-escalation, risk assessment, or cognitive therapy; and

6. Shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(e) Mobile crisis services shall:

1. Be available twenty-four (24) hours per day, seven (7) days per week, every day of the year;

2. Be provided for a duration of less than twenty-four (24) hours;

Not be an overnight service;

4.[Ensure access to a board-certified or board-eligible psychiatrist twenty-four (24) hours per day, seven (7) days per week, every day of the year;

3. Be provided for a duration of less than twenty-four (24) hours:

4. Not be an overnight service;

5.] Be a face-to-face, multi-disciplinary team-based intervention in a home or community setting that ensures access to substance use disorder services and supports to:

a. Reduce symptoms or harm; or

b. Safely transition an individual in an acute crisis to the appropriate least restrictive level of care;

5.[6.] Involve all services and supports necessary to provide:

a. Integrated crisis prevention;

b. Assessment and disposition;

c. Intervention;

d. Continuity of care recommendations; and

e. Follow-up services;

Include access to a board-certified or board-eligible psychiatrist twenty-four (24) hours a day, seven (7) days a week,

every day of the year; and 7. Be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section;

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section; or

c. A peer support specialist who:

(i) Is under the supervision of an approved behavioral health practitioner, as limited by subsection (1) of this section; and

(ii) Provides support services for a mobile crisis service[faceto-face in a home or community setting].

(f)1. Day treatment shall be a non-residential, intensive treatment program for an individual under the age of twenty-one (21) years who has:

a. A substance use disorder; and

b. A high risk of out-of-home placement due to a behavioral health issue.

2. Day treatment shall:

a. Be face-to-face;

<u>b.</u> Consist of an organized, behavioral health program of treatment and rehabilitative services;

c.[b.] Include:

(i) Individual outpatient therapy, family outpatient therapy, or group outpatient therapy;

(ii) Behavior management and social skills training;

(iii) Independent living skills that correlate to the age and developmental stage of the recipient; or

(iv) Services designed to explore and link with community resources before discharge and to assist the recipient and family with transition to community services after discharge; and

d.[c.] Be provided:

(i) In collaboration with the education services of the local education authority including those provided through 20 U.S.C. 1400 et seq. (Individuals with Disabilities Education Act) or 29 U.S.C. 701 et seq. (Section 504 of the Rehabilitation Act);

(ii) On school days and <u>during</u> [on non-instructional weekdays during the school year including]scheduled school breaks;

(iii) In coordination with the recipient's individualized educational plan or Section 504 plan if the recipient has an individualized educational plan or Section 504 plan; and

(iv) [Under the supervision of a licensed or certified approved behavioral health services provider or a behavioral health practitioner working under clinical supervision; and

(v)] With a linkage agreement with the local education authority that specifies the responsibilities of the local education authority and the day treatment provider.

3. To provide day treatment services, a chemical dependency treatment center shall have:

a. The capacity to employ staff authorized to provide day treatment services in accordance with this section and to coordinate the provision of services among team members; and

b. Knowledge of substance use disorders <u>and co-occurring</u> <u>disorders.</u>

4. Day treatment shall not include a therapeutic clinical service that is included in a child's individualized education <u>program or</u> <u>Section 504</u> plan.

5. Day treatment shall be provided by:

 a. An approved behavioral health practitioner, as limited by subsection (1) of this section;

<u>subsection (1) of this section;</u> <u>b. An approved behavioral health practitioner under</u> <u>supervision, as limited by subsection (1) of this section; or</u>

c. A peer support specialist who:

(i) Is under the supervision of an approved behavioral health practitioner, as limited by subsection (1) of this section; and

(ii) Provides support services for a day treatment service.

(g)1. Peer support services shall:

a. Be emotional support that is provided by:

(i) An individual who has been trained and certified in accordance with 908 KAR 2:220 [or 907 KAR 2:240]and who is experiencing or has experienced a substance use disorder to a recipient by sharing a similar substance use disorder in order to bring about a desired social or personal change;

(ii) A parent <u>or other family member</u>, who has been trained and certified in accordance with 908 KAR 2:230, of a child having or who has had a substance use disorder to a parent or family member of a child sharing a similar substance use disorder in order to bring about a desired social or personal change;[er]

(iii) <u>An individual who has been trained and certified in</u> accordance with 908 KAR 2:240 and identified as experiencing a <u>substance use disorder</u> [A family member who has been trained and certified in accordance with 908 KAR 2:230 of a child having or who has had a substance use disorder to a parent or family member of a child sharing a similar substance use disorder in order to bring about a desired social or personal change]; or

(iv) A registered alcohol and drug peer support specialist who has been trained and certified in accordance with KRS 309.0831 and is a self-identified consumer of substance use disorder services who provides emotional support to others with substance use disorder to achieve a desired social or personal change;

b. Be an evidence-based practice;

c. Be structured and scheduled non-clinical therapeutic activities with an individual recipient or a group of recipients;

d. Be provided face-to-face;

e. Promote socialization, recovery, self-advocacy, preservation, and enhancement of community living skills for the recipient;

f. Except for the engagement into substance use disorder treatment through an emergency department bridge clinic, [e-] be coordinated within the context of a comprehensive, individualized plan of care developed through a person-centered planning process;

<u>g.[f.]</u> Be identified in each recipient's plan of care; and

<u>h.[g.]</u> Be designed to contribute directly to the recipient's individualized goals as specified in the recipient's plan of care.

2. To provide peer support services, a chemical dependency treatment center shall:

a. Have demonstrated:

(i) The capacity to provide peer support services for the behavioral health population being served including the age range of the population being served; and

(ii) Experience in serving individuals with behavioral health disorders;

b. Employ peer support specialists who are qualified to provide peer support services in accordance with 908 KAR 2:220, 908 KAR 2:230,[er] 908 KAR 2:240, or KRS 309.0831;

c. Use an approved behavioral health <u>practitioner[services</u> provider] to supervise peer support specialists;

d. Have the capacity to coordinate the provision of services among team members; [and]

e. Have the capacity to provide on-going continuing education and technical assistance to peer support specialists;

f. Require individuals providing peer support services to recipients to provide no more than thirty (30) hours per week of direct recipient contact; and

<u>g. Require peer support services provided to recipients in a group setting to not exceed eight (8) individuals within any group at one (1) time.</u>

(h)1. Intensive outpatient program services shall:

a. Be an alternative to or transition from <u>a higher level of care</u> for a substance use disorder or co-occurring disorders[inpatient hospitalization or partial hospitalization for a substance use disorder];

b. Offer a multi-modal, multi-disciplinary structured outpatient treatment program that is significantly more intensive than individual outpatient therapy, group outpatient therapy, or family outpatient therapy;

c. <u>Meet the service criteria, including the components for</u> support systems, staffing, and therapies outlined in the most current edition of The ASAM Criteria for intensive outpatient level of care services;

d. Be provided face-to-face;

e. Be provided at least three (3) hours per day at least three (3) days per week <u>for adults:</u>

f. Be provided at least six (6) hours per week for adolescents; and

<u>g.[d.]</u> Include:

(i) Individual outpatient therapy, group outpatient therapy, or family outpatient therapy unless contraindicated;

(ii) Crisis intervention; or

(iii) Psycho-education <u>related to identified goals in the</u> recipient's treatment plan.

2. During psycho-education, the recipient or recipient's family member shall be:

a. Provided with knowledge regarding the recipient's diagnosis, the causes of the condition, and the reasons why a particular treatment might be effective for reducing symptoms; and

b. Taught how to cope with the recipient's diagnosis or condition in a successful manner.

3. An intensive outpatient program services treatment plan

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shall:

a. Be individualized; and

b. Focus on stabilization and transition to a lesser level of care.

4. To provide intensive outpatient program services, a chemical dependency treatment center shall have:

a. Access to a board-certified or board-eligible psychiatrist for consultation;

b. Access to a psychiatrist, physician, or advanced practice registered nurse for medication prescribing and monitoring;

c. Adequate staffing to ensure a minimum recipient-to-staff ratio of ten (10) recipients to one (1) staff person;

d. The capacity to provide services utilizing a recognized intervention protocol based on nationally accepted treatment principles; and

e. The capacity to employ staff authorized to provide intensive outpatient program services in accordance with this section and to coordinate the provision of services among team members.

5. Intensive outpatient program services shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(i) Individual outpatient therapy shall:

1. Be provided to promote the:

a. Health and wellbeing of the recipient; and

b. Restoration of a recipient to their best possible functional

level from substance use disorder or co-occurring disorders[Recipient's recovery from a substance use disorder];

2. Consist of:

a. A face-to-face <u>encounter or via telehealth as appropriate</u> <u>pursuant to 907 KAR 3:170 that is a one (1) on one (1) encounter</u> <u>between the provider and recipient[, one-on-one encounter</u> <u>between the provider and recipient]</u>; and

b. A behavioral health therapeutic intervention provided in accordance with the recipient's identified plan of care;

3. Be aimed at:

a. Reducing adverse symptoms;

b. Reducing or eliminating the presenting problem of the recipient; and

c. Improving functioning; [and]

4. Not exceed three (3) hours per day <u>alone or in combination</u> with any other outpatient therapy per recipient unless additional time is medically necessary; and

5. Be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

<u>b. An approved behavioral health practitioner under</u> supervision, as limited by subsection (1) of this section.

(j)1. Group outpatient therapy shall:

a. Be a behavioral health therapeutic intervention provided in accordance with a recipient's identified plan of care;

b. Be provided to promote the:

(i) Health and wellbeing of the individual[recipient]; and

(ii) <u>Restoration of a recipient to their best possible functional</u> level from a substance use disorder or co-occurring

disorders[Recipient's recovery from a substance use disorder];

c. Consist of a face-to-face behavioral health therapeutic intervention provided in accordance with the recipient's identified plan of care;

d. Be provided to a recipient in a group setting:

(i) Of nonrelated individuals except for multi-family group therapy; and

(ii) Not to exceed twelve (12) individuals in size;

e. Focus on the psychological needs of the recipients as evidenced in each recipient's plan of care;

f. Center on goals, including building and maintaining healthy relationships, personal goals setting, and the exercise of personal judgment;

g. Not include physical exercise, a recreational activity, an educational activity, or a social activity; and

h. Not exceed three (3) hours per day <u>alone or in combination</u> with any other outpatient therapy per recipient unless additional time is medically necessary. 2. The group shall have a:

a. Deliberate focus; and

b. Defined course of treatment.

3. The subject of group outpatient therapy shall relate to each recipient participating in the group.

4. The provider shall keep individual notes regarding each recipient <u>within[of]</u> the group and within each recipient's health record.

5. Group outpatient therapy shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(k)1. Family outpatient therapy shall consist of a face-to-face <u>or</u> <u>appropriate telehealth</u>, <u>pursuant to 907 KAR 3:170</u>, behavioral health therapeutic intervention provided:

a. Through scheduled therapeutic visits between the therapist and the recipient and at least one (1) member of the recipient's family; and

b. To address issues interfering with the relational functioning of the family and to improve interpersonal relationships within the recipient's home environment.

2. A family outpatient therapy session shall be billed as one (1) service regardless of the number of individuals (including multiple members from one (1) family) who participate in the session.

3. Family outpatient therapy shall:

a. Be provided to promote the:

(i) Health and well-being of the <u>individual[recipient];</u> or

(ii) <u>Restoration of a recipient to their best possible functional</u> <u>level</u> from a substance use disorder or co-occurring <u>disorder[Recipient's recovery from a substance use disorder]</u>; and

b. Not exceed three (3) hours per day <u>alone or in combination</u> with any other outpatient therapy per <u>recipient[individual]</u> unless additional time is medically necessary.

4. Family outpatient therapy shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(I)1. Collateral outpatient therapy shall:

a. Consist of a face-to-face <u>or appropriate telehealth, provided</u> <u>pursuant to 907 KAR 3:170,</u> behavioral health consultation:

(i) With a parent or caregiver of a recipient, household member of a recipient, <u>legal representative of a recipient[recipient's</u> representative], school <u>personnel[staff person]</u>, treating professional, or other person with custodial control or supervision of the recipient; and

 $(\ensuremath{\text{ii}})$ That is provided in accordance with the recipient's plan of care; and

b. Not be reimbursable if the therapy is for a recipient who is at least twenty-one (21) years of age.

2. Written consent by a parent or custodial guardian to discuss a recipient's treatment with any person other than a parent or legal guardian shall be signed and filed in the recipient's health record[Consent given to discuss a recipient's treatment with any person other than a parent or legal guardian shall be signed by the recipient or recipient's representative and filed in the recipient's health record].

3. Collateral outpatient therapy shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(m)1. Screening, brief intervention, and referral to treatment for a substance use disorder shall:

<u>a. Be provided face-to-face or via telehealth as appropriate</u> according to 907 KAR 3:170;

<u>b.[1-]</u> Be an evidence-based early-intervention approach for an individual with non-dependent substance use [in order] to provide an effective strategy for intervention prior to the need for more extensive or specialized treatment; and

c.[2.] Consist of:

(i)[a.] Using a standardized screening tool to assess an

individual for risky substance use behavior;

(ii)[b-] Engaging a recipient, who demonstrates risky substance use behavior, in a short conversation and providing feedback and advice[to the recipient]; and

(iii)[c.] Referring a recipient to additional substance use disorder services if the recipient is determined to need additional services to address [the recipient's] substance use.

2. A screening and brief intervention that does not meet criteria for referral to treatment may be subject to coverage by the department.

3. A screening, brief intervention, and referral to treatment for a substance use disorder shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(n)1. Service planning shall:

a. Be provided face-to-face;

b. Involve assisting a recipient in creating an individualized plan for services and developing measurable goals and objectives needed for maximum reduction of the effects of a substance use disorder or co-occurring disorders:

c. Involve restoring a recipient's functional level to the recipient's best possible functional level; and

d. Be performed using a person-centered planning process.

2. A service plan:

a. Shall be directed and signed by the recipient;

b. Shall include practitioners of the recipient's choosing; and

c. May include:

(i) A mental health advance directive being filed with a local hospital;

(ii) A crisis plan; or

(iii) A relapse prevention strategy or plan.

3. Service planning shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(o)1. Ambulatory withdrawal management services shall:

a. Be provided face-to-face for recipients with a substance use disorder or co-occurring disorders;

<u>b. Be incorporated into a recipient's care as appropriate</u> according to the continuum of care described in the most current version of The ASAM Criteria; and

c. Be in accordance with the most current version of The ASAM Criteria for ambulatory withdrawal management levels in an outpatient setting.

2. A recipient who is receiving ambulatory withdrawal management services shall:

a. Meet the most current edition of diagnostic criteria for substance withdrawal management found in the Diagnostic and Statistical Manual of Mental Disorders; and

<u>b. Meet the current dimensional admissions criteria for</u> withdrawal management level of care as found in The ASAM Criteria.

3. Ambulatory withdrawal management services shall be provided by:

a. A physician;

b. A psychiatrist;

c. A physician assistant;

d. An advanced practice registered nurse; or

e. Any other approved behavioral health practitioner with oversight by a physician, advanced practice registered nurse, or a physician assistant, as limited by subsection (1) of this section.

(p)1. Medication assisted treatment shall be provided by an authorized prescribing provider who:

<u>a. ls:</u>

(i) A physician licensed to practice medicine under KRS Chapter 311;

(ii) An advanced practice registered nurse (APRN); or

(iii) A physician assistant who has appropriately updated department provider enrollment information;

b. Meets standards in accordance with 201 KAR 9:270 or 201

KAR 20:065;

c. Maintains a current waiver under 21 U.S.C. 823(g)(2) to prescribe buprenorphine products; and

d. Has experience and knowledge in addiction medicine.

2. Medication assisted treatment with behavioral health therapies shall:

a. Be co-located within the same practicing site as the practitioner with a waiver pursuant to subparagraph 1.b. of this paragraph or be conducted via telehealth as appropriate according to 907 KAR 3:170; or

<u>b. Be conducted with agreements in place for linkage to</u> <u>appropriate behavioral health treatment providers who specialize in</u> <u>substance use disorders and are knowledgeable in</u> <u>biopsychosocial dimensions of alcohol or other substance use</u> <u>disorder, such as:</u>

(i) An approved behavioral health practitioner, as limited by subsection (1) of this section; or

(ii) A multi-specialty group or behavioral health provider group pursuant to 907 KAR 15:010.

3. A medication assisted treatment program shall:

a. Assess the need for treatment including:

(i) A full patient history to determine the severity of the patient's substance use disorder; and

 (ii) Identifying and addressing any underlying or co-occurring diseases or conditions, as necessary;

b. Educate the patient about how the medication works, including:

(i) The associated risks and benefits; and

(ii) Overdose prevention;

c. Evaluate the need for medically managed withdrawal from substances;

d. Refer patients for higher levels of care if necessary; and

<u>e. Obtain informed consent prior to integrating pharmacologic</u> or nonpharmacologic therapies.

4. Medication assisted treatment shall be provided by:

a. A physician;

b. A psychiatrist;

c. An advanced practice registered nurse; or

<u>d</u>. An approved behavioral health practitioner, as limited pursuant to subsection (1) of this section, or approved behavioral health practitioner under supervision, as limited pursuant to subsection (1) of this section, to provide counseling, behavioral therapies, and other support components with experience and knowledge in addiction medicine.

(q)1. An inpatient chemical dependency treatment program shall:

a. Be a structured inpatient program to provide medical, social, diagnostic, and treatment services to individuals with substance use disorder or co-occurring disorders;

<u>b. Be provided face-to-face, twenty-four (24) hours per day,</u> seven (7) days per week, 365 days a year with continuous nursing services and under the medical direction of a physician:

c. Meet the service criteria for medically monitored intensive inpatient services using The ASAM Criteria; and

d. Include the following services:

(i) Screening;

- (ii) Assessment;
- (iii) Service planning;
- (iv) Psychiatric services;
- (v) Individual therapy;
- (vi) Family therapy;
- (vii) Group therapy;
- (viii) Peer support;

(ix) Medication assisted treatment; or

(x) Medically monitored inpatient withdrawal management, as established pursuant to subparagraph 2. of this paragraph.

2. Medically monitored inpatient withdrawal management services provided in an inpatient chemical dependency treatment center shall:

a. Meet the service criteria for medically monitored inpatient withdrawal management services using the current edition of The ASAM Criteria; and

b. Comply with services pursuant to the requirements of 902

KAR 20:111.

3. For a recipient in an inpatient chemical dependency treatment program, care coordination shall include at minimum:

a. Facilitating medication assisted treatment for recipients as necessary, per recipient choice;

b. Referral to appropriate community services;

c. Facilitation of medical and behavioral health follow ups; and

d. Linking the recipient to the appropriate level of substance

use treatment within the continuum to provide ongoing supports. 4. Inpatient chemical dependency treatment services shall be provided in accordance with 902 KAR 20:160, Sections 4 and 7.

5. Length-of-stay for chemical dependency treatment services shall be person-centered and according to an individually designed plan of care that is consistent with this administrative regulation and the licensure of the facility and practitioner.

<u>6.a. Except as established in clause b. or c. of this</u> subparagraph, the physical structure in which inpatient chemical dependency treatment services is provided shall:

(i) Have between nine (9) and sixteen (16) beds; and

(ii) Not be part of multiple units comprising one (1) facility with more than sixteen (16) beds in aggregate.

b. If every recipient receiving services in the physical structure is under the age of twenty-one (21) years or over the age of sixtyfive (65) years, the limit of sixteen (16) beds established in clause a. of this subparagraph shall not apply.

c. The limit of sixteen (16) beds established in clause a. of this subparagraph shall not apply if the facility possesses the appropriate inpatient ASAM certification to provide chemical dependency treatment center services, with the exception that:

(i) Each currently enrolled chemical dependency treatment center shall be granted a one (1) time provisional certification that expires July 1, 2021, unless extended by the department; or

(ii) A federal waiver, or other change to controlling federal law that allows for the availability of federal financial participation, shall be available for this clause to be operational.

<u>7. Inpatient chemical dependency treatment services shall not</u> include:

a. Room and board;

b. Educational services;

c. Vocational services;

d. Job training services;

e. Habilitation services;

f. Services to an inmate in a public institution pursuant to 42 C.F.R. 435.1010;

g. Services to an individual residing in an institution for mental diseases pursuant to 42

C.F.R. 435.1010;

h. Recreational activities;

i. Social activities; or

j. Services required to be covered elsewhere in the Medicaid state plan.

8. To provide inpatient chemical dependency treatment services, the program shall:

a. Have the capacity to employ staff authorized to provide services in accordance with this section and to coordinate the provision of services among team members:

b. Be licensed as a chemical dependency treatment services and facility in accordance with 902 KAR 20:160; and

c. After July 1, 2021, possess an appropriate ASAM Level of Care Certification for medically monitored intensive inpatient services in accordance with The ASAM Criteria.

9.a. Inpatient chemical dependency treatment shall be provided by:

(i) An approved behavioral health practitioner, except as provided pursuant to subsection (1) of this section; or

(ii) An approved behavioral health practitioner under supervision, except as provided pursuant to subsection (1) of this section.

b. Support services for inpatient chemical dependency shall be provided by a peer support specialist under the supervision of an approved behavioral health practitioner.

(4)[The extent and type of a screening shall depend upon the nature of the problem of the individual seeking or being referred for

services.

(5) A diagnosis or clinical impression shall be made using terminology established in the most current edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental DisordersTM.

(6)] The department shall not reimburse for a service billed by or on behalf of an entity or individual who is not a billing provider.

Section 4. Additional Limits and Non-covered Services or Activities. (1)(a) Except as established in paragraph (b) of this subsection, unless a diagnosis is made and documented in the recipient's health record within three (3) visits, the service shall not be covered.

(b) The requirement established in paragraph (a) of this subsection shall not apply to:

1. Mobile crisis services;

2. Crisis intervention;

3. A screening; or

4. An assessment.

(2) The department shall not reimburse for both a screening and <u>a screening</u>, <u>brief intervention and referral to treatment</u> (<u>SBIRT)[an SBIRT]</u> provided to a recipient on the same date of service.

(3) The following services or activities shall not be covered under this administrative regulation:

(a) A service provided to:

1. A resident of:

a. A nursing facility; or

b. An intermediate care facility for individuals with an intellectual disability;

2. An inmate of a federal, local, or state:

a. Jail;

b. Detention center; or

c. Prison; or

3. An individual with an intellectual disability without documentation of an additional psychiatric diagnosis;

(b) A consultation or educational service provided to a recipient or to others;

(c) A telephone call, an email, a text message, or other electronic contact that does not meet the requirements stated in the definition of "face-to-face" established in 907 KAR 15:005, Section 1(21). Contact that is not reimbursable under this paragraph may be permissible if it is conducted in the course of a telehealth service permitted pursuant to 907 KAR 3:170 or this administrative regulation, as applicable[(14)];

(d) Travel time;

(e) A field trip;

(f) A recreational activity;

(g) A social activity; or

(h) A physical exercise activity group.

(4)(a) A consultation by one (1) provider or professional with another shall not be covered under this administrative regulation except as established in Section 3(3)(I)1 of this administrative regulation.

(b) A third-party contract shall not be covered under this administrative regulation.

(5) A billing supervisor arrangement between a billing supervisor and <u>an approved[a]</u> behavioral health practitioner under supervision shall not:

(a) Violate the clinical supervision rules or policies of the respective professional licensure boards governing the billing supervisor and the <u>approved</u> behavioral health practitioner under supervision; or

(b) Substitute for the clinical supervision rules or policies of the respective professional licensure boards governing the billing supervisor and the <u>approved</u> behavioral health practitioner under supervision.

Section 5. No Duplication of Service. (1) The department shall not reimburse for a service provided to a recipient by more than one (1) provider, of any program in which the same service is covered, during the same time period.

(2) For example, if a recipient is receiving a behavioral health

service from an independent behavioral health provider, the department shall not reimburse for the same service provided to the same recipient during the same time period by a chemical dependency treatment center.

Section 6. Records Maintenance, Documentation, Protection, and Security. (1) A chemical dependency treatment center shall maintain a current health record for each recipient.

(2) A health record shall document each service provided to the recipient including the date of the service and the signature of the individual who provided the service.

(3) A health record shall:

(a) Include:

1. An identification and intake record including:

a. Name;

b. Social Security number;

c. Date of intake;

d. Home (legal) address;

e. Health insurance or Medicaid participation information;

f. If applicable, the referral source's name and address;

g. Primary care physician's name and address;

h. The reason the individual is seeking help including the presenting problem and diagnosis;

i. Any physical health diagnosis, if a physical health diagnosis exists for the individual, and information regarding:

(i) Where the individual is receiving treatment for the physical health diagnosis; and

(ii) The physical health provider's name; and

j. The name of the informant and any other information deemed necessary by the chemical dependency treatment center in order to comply with the requirements of:

(i) This administrative regulation;

(ii) The chemical dependency treatment center's licensure board;

(iii) State law; or

(iv) Federal law;

2. Documentation of the:

a. Screening;

b. Assessment, if an assessment was performed; and

c. Disposition, if a disposition was performed;

3. A complete history including mental status and previous treatment;

4. An identification sheet;

5. A consent for treatment sheet that is accurately signed and dated; and

6. The individual's stated purpose for seeking services; and

(b) Be:

1. Maintained in an organized central file;

2. Furnished upon request:

a. To the Cabinet for Health and Family Services; or

b. For an enrollee, to the managed care organization in which the recipient is enrolled or has been enrolled in the past;

3. Made available for inspection and copying by:

a. Cabinet for Health and Family Services' personnel; or

b. Personnel of the managed care organization in which the recipient is enrolled if applicable;

4. Readily accessible; and

5. Adequate for the purpose of establishing the current treatment modality and progress of the recipient if the recipient received services beyond a screening.

(4) Documentation of a screening shall include:

(a) Information relative to the individual's stated request for services; and

(b) Other stated personal or health concerns if other concerns are stated.

(5)(a) A chemical dependency treatment center's <u>service</u> notes regarding a recipient shall:

1. Be made within forty-eight (48) hours of each service visit; [and]

2. Indicate if the service was provided face-to-face or via telehealth for outpatient services; and

3. Describe the:

a. Recipient's symptoms or behavior, reaction to treatment,

and attitude;

b. Behavioral health practitioner's intervention;

c. Changes in the plan of care if changes are made; and

- d. Need for continued treatment if deemed necessary.
- (b)1. Any edit to notes shall:
- a. Clearly display the changes; and

b. Be initialed and dated by the person who edited the notes.

2. Notes shall not be erased or illegibly marked out.

(c)1. Notes recorded by <u>an approved[a]</u> behavioral health practitioner [working] under supervision shall be co-signed and dated by the supervising professional within thirty (30) days.

2. If services are provided by <u>an approved[a]</u> behavioral health practitioner [working]under supervision, there shall be a monthly supervisory note recorded by the supervising professional <u>that[which]</u> reflects consultations with the <u>approved</u> behavioral health practitioner working under supervision concerning the:

a. Case; and

b. Supervising professional's evaluation of the services being provided to the recipient.

(6) Immediately following a screening of a recipient, the practitioner shall perform a disposition related to:

(a) A provisional diagnosis;

(b) A referral for further consultation and disposition, if applicable; or

(c)1. If applicable, termination of services and referral to an outside source for further services; or

2. If applicable, termination of services without a referral to further services.

(7) Any change to a recipient's plan of care shall be documented, signed, and dated by the rendering practitioner and by the recipient or recipient's representative.

(8)(a) Notes regarding services to a recipient shall:

1. Be organized in chronological order;

2. Be dated;

3. Be titled to indicate the service rendered;

4. State a starting and ending time for the service; and

5. Be recorded and signed by the rendering practitioner and include the professional title (for example, licensed clinical social worker) of the provider.

(b) Initials, typed signatures, or stamped signatures shall not be accepted.

(c) Telephone contacts, family collateral contacts not covered under this administrative regulation, or other non-reimbursable contacts shall:

1. Be recorded in the notes; and

Not be reimbursable.

(9)(a) A termination summary shall:

1. Be required, upon termination of services, for each recipient who received at least three (3) service visits; and

2. Contain a summary of the significant findings and events during the course of treatment including the:

a. Final assessment regarding the progress of the individual toward reaching goals and objectives established in the individual's plan of care;

b. Final diagnosis of clinical impression; and

c. Individual's condition upon termination and disposition.

(b) A health record relating to an individual who has been terminated from receiving services shall be fully completed within ten (10) days following termination.

(10) If an individual's case is reopened within ninety (90) days of terminating services for the same or related issue, a reference to the prior case history with a note regarding the interval period shall be acceptable.

(11)(a) Except as established in paragraph (b) of this subsection, if a recipient is transferred or referred to a health care facility or other provider for care or treatment, the transferring chemical dependency treatment center shall, within ten (10) business days of awareness of the transfer or referral, transfer the recipient's records in a manner that complies with the records' use and disclosure requirements as established in or required by:

1.a. The Health Insurance Portability and Accountability Act;

b. 42 U.S.C. 1320d-2 to 1320d-8; and

c. 45 C.F.R. Parts 160 and 164; or

2.a. 42 U.S.C. 290ee-3; and

b. 42 C.F.R. Part 2.

(b) If a recipient is transferred or referred to a residential crisis stabilization unit, a psychiatric hospital, a psychiatric distinct part unit in an acute care hospital, a Level I psychiatric residential treatment facility, a Level II psychiatric residential treatment facility, or an acute care hospital for care or treatment, the transferring chemical dependency treatment center shall, within forty-eight (48) hours of the transfer or referral, transfer the recipient's records in a manner that complies with the records' use and disclosure requirements as established in or required by:

1.a. The Health Insurance Portability and Accountability Act;

b. 42 U.S.C. 1320d-2 to 1320d-8; and

c. 45 C.F.R. Parts 160 and 164; or

2.a. 42 U.S.C. 290ee-3; and

b. 42 C.F.R. Part 2.

(12)(a) If a chemical dependency treatment center's Medicaid Program participation status changes as a result of voluntarily terminating from the Medicaid Program, involuntarily terminating from the Medicaid Program, a licensure suspension, or death of an owner or deaths of owners, the health records of the chemical dependency treatment center shall:

1. Remain the property of the chemical dependency treatment center; and

2. Be subject to the retention requirements established in subsection (13) of this section.

(b) A chemical dependency treatment center shall have a written plan addressing how to maintain health records in the event of death of an owner or deaths of owners.

(13)(a) Except as established in paragraph (b) or (c) of this subsection, a chemical dependency treatment center shall maintain a health record regarding a recipient for at least six (6) years from the last date of the service or until any audit dispute or issue is resolved beyond six (6) years.

(b) After a recipient's death or discharge from services, a provider shall maintain the recipient's record for the longest of the following periods:

1. Six (6) years unless the recipient is a minor; or

2. If the recipient is a minor, three (3) years after the recipient reaches the age of majority under state law.

(c) If the Secretary of the United States Department of Health and Human Services requires a longer document retention period than the period referenced in paragraph (a) of this subsection, pursuant to 42 C.F.R. 431.17, the period established by the secretary shall be the required period.

(14)(a) A chemical dependency treatment center shall comply with 45 C.F.R. Part 164.

(b) All information contained in a health record shall:

1. Be treated as confidential;

2. Not be disclosed to an unauthorized individual; and

3. Be disclosed to an authorized representative of:

a. The department;

b. Federal government; or

c. For an enrollee, the managed care organization in which the enrollee is enrolled.

(c)1. Upon request, a chemical dependency treatment center shall provide to an authorized representative of the department, federal government, or managed care organization if applicable, information requested to substantiate:

a. Staff notes detailing a service that was rendered;

b. The professional who rendered a service; and

c. The type of service rendered and any other requested information necessary to determine, on an individual basis, whether the service is reimbursable by the department or the managed care organization, if applicable.

2. Failure to provide information referenced in subparagraph 1. of this paragraph shall result in denial of payment for any service associated with the requested information.

Section 7. Medicaid Program Participation Compliance. (1) A chemical dependency treatment center shall comply with:

(a) 907 KAR 1:671;

(b) 907 KAR 1:672; and

(c) All applicable state and federal laws.

(2)(a) If a chemical dependency treatment center receives any duplicate payment or overpayment from the department or a managed care organization, regardless of reason, the chemical dependency treatment center shall return the payment to the department or managed care organization in accordance with 907 KAR 1:671.

(b) Failure to return a payment to the department or managed care organization in accordance with paragraph (a) of this subsection may be:

1. Interpreted to be fraud or abuse; and

2. Prosecuted in accordance with applicable federal or state law.

(3)(a) When the department makes payment for a covered service and the chemical dependency treatment center accepts the payment:

1. The payment shall be considered payment in full;

2. A bill for the same service shall not be given to the recipient; and

3. Payment from the recipient for the same service shall not be accepted by the chemical dependency treatment center.

(b)1. A chemical dependency treatment center may bill a recipient for a service that is not covered by the Kentucky Medicaid Program if the:

a. Recipient requests the service; and

b. Chemical dependency treatment center makes the recipient aware in writing in advance of providing the service that the:

(i) Recipient is liable for the payment; and

(ii) Department is not covering the service.

2. If a recipient makes payment for a service in accordance with subparagraph 1. of this paragraph, the:

a. Chemical dependency treatment center shall not bill the department for the service; and

b. Department shall not:

(i) Be liable for any part of the payment associated with the service; and

(ii) Make any payment to the chemical dependency treatment center regarding the service.

(4)(a) A chemical dependency treatment center shall attest by the chemical dependency treatment center's staff's or representative's signature that any claim associated with a service is valid and submitted in good faith.

(b) Any claim and substantiating record associated with a service shall be subject to audit by the:

1. Department or its designee;

2. Cabinet for Health and Family Services, Office of Inspector General, or its designee;

3. Kentucky Office of Attorney General or its designee;

4. Kentucky Office of the Auditor for Public Accounts or its designee;

5. United States General Accounting Office or its designee; or

6. For an enrollee, managed care organization in which the enrollee is enrolled.

(c)1. If a chemical dependency treatment center receives a request from the:

a. Department to provide a claim, related information, related documentation, or record for auditing purposes, the chemical dependency treatment center shall provide the requested information to the department within the timeframe requested by the department; or

b. Managed care organization in which an enrollee is enrolled to provide a claim, related information, related documentation, or record for auditing purposes, the chemical dependency treatment center shall provide the requested information to the managed care organization within the timeframe requested by the managed care organization.

2.a. The timeframe requested by the department or managed care organization for a chemical dependency treatment center to provide requested information shall be:

(i) A reasonable amount of time given the nature of the request and the circumstances surrounding the request; and

(ii) A minimum of one (1) business day.

b. A chemical dependency treatment center may request a

longer timeframe to provide information to the department or a managed care organization if the chemical dependency treatment center justifies the need for a longer timeframe.

(d)1. All services provided shall be subject to review for recipient or provider <u>fraud or</u> abuse, <u>and compliance with this</u> administrative regulation and state and federal law.

2. Willful abuse by a chemical dependency treatment center shall result in the suspension or termination of the chemical dependency treatment center from Medicaid Program participation in accordance with 907 KAR 1:671.

Section 8. Third Party Liability. A chemical dependency treatment center shall comply with KRS 205.622.

Section 9. Use of Electronic Signatures. (1) The creation, transmission, storage, and other use of electronic signatures and documents shall comply with the requirements established in KRS 369.101 to 369.120.

(2) A chemical dependency treatment center that chooses to use electronic signatures shall:

(a) Develop and implement a written security policy that shall:

1. Be adhered to by each of the chemical dependency treatment center's employees, officers, agents, or contractors;

2. Identify each electronic signature for which an individual has access; and

3. Ensure that each electronic signature is created, transmitted, and stored in a secure fashion;

(b) Develop a consent form that shall:

1. Be completed and executed by each individual using an electronic signature;

2. Attest to the signature's authenticity; and

3. Include a statement indicating that the individual has been notified of his or her responsibility in allowing the use of the electronic signature; and

(c) Provide the department, immediately upon request, with:

1. A copy of the chemical dependency treatment center's electronic signature policy;

2. The signed consent form; and

3. The original filed signature.

Section 10. Auditing Authority. The department or managed care organization in which an enrollee is enrolled shall have the authority to audit any:

(1) Claim;

(2) Health record; or

(3) Documentation associated with any claim or health record.

Section 11. Federal Approval and Federal Financial Participation. (1) The department's reimbursement of services pursuant to this administrative regulation shall be contingent upon:

(a) Receipt of federal financial participation for the coverage; and

(b) Centers for Medicare and Medicaid Services' approval for the coverage.

(2) The reimbursement of services provided by a licensed clinical alcohol and drug counselor or licensed clinical alcohol and drug counselor associate shall be contingent and effective upon approval by the Centers for Medicare and Medicaid Services.

Section 12. Appeals. (1) An appeal of an adverse action by the department regarding a service and a recipient who is not enrolled with a managed care organization shall be in accordance with 907 KAR 1:563.

(2) An appeal of an adverse action by a managed care organization regarding a service and an enrollee shall be in accordance with 907 KAR 17:010.

LISA LEE, Commissioner

ERIC FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 2, 2020

FILED WITH LRC: October 13, 2020 at 12:40 p.m.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Persons: Jonathan Scott and Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the coverage provisions and requirements regarding Medicaid Program outpatient and inpatient chemical dependency treatment center (CDTC) services.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with federal mandates. Section 1302(b)(1)(E) of the Affordable Care Act mandates that "essential health benefits" for Medicaid programs include "mental health and substance use disorder services, including behavioral health treatment" for all recipients.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by complying with federal mandates and enhancing and ensuring Medicaid recipients' access to behavioral health services.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will assist in the effective administration of the authorizing statutes by complying with federal mandates and enhancing and ensuring Medicaid recipients' access to behavioral health services.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments to this administrative regulation combine a previously separate description of who may perform a service and a description of the service itself. This series of amendments also includes a reference to the defined terms "approved behavioral health practitioner" and "approved behavioral health practitioner under supervision" from 907 KAR 15:005 instead of a listing of each provider in each service. This provides for more transparency and compactness in the administrative regulation. The administrative regulation has also clarified the use of telehealth in several places. Additional requirements relating to mobile crisis services include requiring access to a board-certified or board eligible psychiatrist at all times, and allowing for the use of peer support specialists. Day treatment services include additional requirements relating to staff qualifications. Peer support specialist services are amended to further allow and enhance the use of emergency department bridge clinics. In addition, peer support specialist services are now required to only be 30 hours per week of direct recipient contact and group peer support services are not allowed to exceed 8 individuals within any group at one time. Intensive outpatient program services are required to comply with the most recent service criteria of the ASAM Criteria, and additional clarification is given about how the services are to be provided to adults and adolescents. The amendments also include new services and requirements relating to "service planning", "ambulatory withdrawal management", "medication assisted treatment", and "inpatient chemical dependency treatment".

(b) The necessity of the amendment to this administrative regulation: These amendments are necessary to comply with existing OIG administrative regulations, implement an SUD 1115 waiver, require compliance with the ASAM Criteria, and provide additional formatting improvements.

(c) How the amendment conforms to the content of the authorizing statutes: The amendments conform to the content of the authorizing statutes by implementing an SUD 1115 waiver.

(d) How the amendment will assist in the effective administration of the statutes: The amendments will assist in the effective administration of the statutes by providing additional clarity and requirements relating to chemical dependency treatment centers.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: Entities licensed as chemical

dependency treatment centers (CDTCs), behavioral health professionals authorized to provide services in CDTCs, and Medicaid recipients who receive services in CDTCs will be affected by the administrative regulation. Currently there are 3 CDTC licenses issued by the state.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment. Entities that qualify as chemical dependency treatment centers and who wish to provide services to Medicaid recipients will need to enroll with the Medicaid Program as prescribed in the Medicaid provider enrollment regulation (complete an application and submit it to DMS) and sign agreements with managed care organizations if the individual wishes to provide services to Medicaid recipients who are enrolled with a managed care organization.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). The entities referenced in paragraph (a) could experience administrative costs associated with enrolling with the Medicaid Program.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3). The entities referenced in paragraph (a) will benefit by receiving Medicaid Program reimbursement for providing behavioral health services to Medicaid recipients. Behavioral health professionals authorized to provide services in a chemical dependency treatment center will benefit by having more employment opportunities in Kentucky. Medicaid recipients in need of behavioral health services will benefit from an expanded base of providers from which to receive these services.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: DMS anticipates potential savings of more than \$4.6 million due to the availability of a level of care that is less expensive than hospitalization via the introduction of inpatient chemical dependency treatment centers.

(b) On a continuing basis: DMS anticipates potential savings of more than \$4.6 million due to the availability of a level of care that is less expensive than hospitalization via the introduction of inpatient chemical dependency treatment centers.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under the Social Security Act, Title XIX and matching funds of general fund appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment. Neither an increase in fees nor funding is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any fees.

(9) Tiering: Is tiering applied? Tiering is not applied as the policies apply equally to the regulated entities.

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. Section 1302(b)(1)(E) of the Affordable Care Act, 42 U.S.C. 1396a(a)(10)(B), and 42 U.S.C. 1396a(a)(23).

2. State compliance standards. KRS 205.520(3) states: "Further, it is the policy of the Commonwealth to take advantage of all federal funds that may be available for medical assistance. To qualify for federal funds the secretary for health and family services may by regulation comply with any requirement that may be imposed or opportunity that may be presented by federal law. Nothing in KRS 205.510 to 205.630 is intended to limit the secretary's power in this respect."

3. Minimum or uniform standards contained in the federal mandate. Substance use disorder services are federally mandated for Medicaid programs. Section 1302(b)(1)(E) of the Affordable Care Act mandates that "essential health benefits" for Medicaid programs include "mental health and substance use disorder services, including behavioral health treatment." 42 U.S.C. 1396a(a)(23) is known as the freedom of choice of provider mandate. This federal law requires the Medicaid Program to "provide that (A) any individual eligible for medical assistance (including drugs) may obtain such assistance from any institution, agency, community pharmacy or person, qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services. Medicaid recipients enrolled with a managed care organization may be restricted to providers within the managed care organization's provider network. The Centers for Medicare and Medicaid Services (CMS) - the federal agency that oversees and provides the federal funding for Kentucky's Medicaid Program has expressed to the Department for Medicaid Services (DMS) the need for DMS to expand its substance use disorder provider base to comport with the freedom of choice of provider requirement. 42 U.S.C. 1396a(a)(10)(B) requires the Medicaid Program to ensure that services are available to Medicaid recipients in the same amount, duration, and scope as available to other individuals (non-Medicaid). Expanding the provider base will help ensure Medicaid recipient access to services statewide and reduce or prevent the lack of availability of services due to demand exceeding supply in any given area.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? The administrative regulation does not impose stricter than federal requirements.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. The administrative regulation does not impose stricter than federal requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services will be affected by the amendment to this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.030(2), 194A.050(1), 205.520(3).

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The amendment is not expected to generate revenue for state or local government.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The amendment is not expected to generate revenue for state or local government.

(c) How much will it cost to administer this program for the first year? DMS anticipates potential savings of more than \$4.6 million due to the availability of a level of care that is less expensive than hospitalization via the introduction of inpatient chemical dependency treatment centers.

(d) How much will it cost to administer this program for subsequent years? DMS anticipates potential savings of more than \$4.6 million due to the availability of a level of care that is less expensive than hospitalization via the introduction of inpatient

chemical dependency treatment centers. Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

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ADMINISTRATIVE REGULATIONS AS AMENDED BY PROMULGATING AGENCY AND REVIEWING SUBCOMMITTEE

ARRS = Administrative Regulation Review Subcommittee IJC = Interim Joint Committee

AGRICULTURAL EXPERIMENT STATION (As Amended at ARRS, October 13, 2020)

smcmurry@uky.edu.

12 KAR 4:075. Licenses and fertilizer product registration.

RELATES TO: KRS 250.366(16), (26), 250.371 – 250.461 STATUTORY AUTHORITY: KRS 250.371, 250.421

NECESSITY, FUNCTION, AND CONFORMITY: KRS 250.371 authorizes the Kentucky Agricultural Experiment Station Director to promulgate administrative regulations for product registration and licensing of custom mix blending facilities. KRS 250.421 requires the director to promulgate administrative regulations necessary to implement KRS 250.371 through 250.451. This administrative regulation establishes requirements for fertilizer product registration and licensing.

Section 1. Definitions.

(1) "Registrant" means the person who registers fertilizer.

(2) "Licensee" means the person who is licensed to distribute fertilizer.

Section 2. An applicant for registration shall complete and submit to the Fertilizer Regulatory Program:

(1) Application for Registration of Farm Fertilizer, Form RS-29-01 Farm Fertilizer;

(2) Application for Registration of Specialty Fertilizer, Form RS-29-03 Specialty Fertilizer (10 Pounds or Less).

(a) In accordance with KRS 250.371(1), a fifty (50) dollar registration fee shall accompany form RS-29-03; and

(b) In accordance with KRS 250.381(4) a fifty (50) dollar inspection fee shall accompany form RS-29-03; or[-]

(3) Application for Registration of Specialty Fertilizer, Form RS-29-04. Specialty Fertilizer (Packages Greater Than 10 Pounds). In accordance with KRS 250.371(1), a fifty (50) dollar registration fee shall accompany the submitted application form.

Section 3. An applicant for licensing shall complete and submit to the Fertilizer Regulatory Program:

(1) Application for Custom Mix Fertilizer Blending, Form RS-29-02 Bulk Fertilizer License; or

(2) Application for Custom Mix Specialty Fertilizer Blending, Form RS-29-05 Bulk Specialty Fertilizer License. In accordance with KRS 250.371(4), a one-hundred (100) dollar license fee shall accompany the submitted application form.

Section 4. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Application for Registration of Farm Fertilizer", Form RS-29-01, October 2019;

(b) "Application for Registration of Specialty Fertilizer", Form RS-29-03, October 2019;

(c) "Application for Registration of Specialty Fertilizer", Form RS-29-04, October 2019;

(d) "Application for Custom Mix Fertilizer Blending", Form RS-29-02, October 2019; and

(e) "Application for Custom Mix Specialty Fertilizer Blending", Form RS-29-05, October 2019.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Division of Regulatory Services, University of Kentucky, 103 Regulatory Services Building, Lexington, Kentucky 40546-0275, Monday through Friday, 8 a.m. to 4:30 p.m.

CONTACT PERSON: Stephen McMurry, Fertilizer and Seed Program Director, University of Kentucky Division of Regulatory Services, 103 Regulatory Services Building, Lexington, Kentucky 40546, phone (859) 218-2440, fax (859) 257-9478, email

AGRICULTURAL EXPERIMENT STATION (As Amended at ARRS, October 13, 2020)

12 KAR 4:080. Plant <u>nutrient[nutrients]</u> <u>guarantees and</u> <u>labeling</u>.

RELATES TO: KRS 250.366(7), 250.371 – 250.451

STATUTORY AUTHORITY: KRS 250.366(7), 250.421

NECESSITY, FUNCTION, AND CONFORMITY: <u>KRS</u> 250.366(7) authorizes the Kentucky Agricultural Experiment Station Director to promulgate administrative regulations for the inspection and analysis of plant nutrient guarantees. KRS 250.421 requires the director to promulgate administrative regulations necessary to implement KRS 250.371 through 250.451. This administrative regulation establishes requirements for plant nutrient labeling requirements.

Plant Nutrient Guarantees. Plant nutrients, Section 1. additional to nitrogen, phosphorus, and potassium, referenced by fertilizer labeling or information provided with a fertilizer shall be registered and guaranteed pursuant to this administrative regulation. Except guarantees for water-soluble nutrients labeled for ready-to-use foliar fertilizers, ready-to-use specialty liquid fertilizers, hydroponic or continuous liquid feed programs and guarantees for potting soils, garden soils, lawn soils, and any other growing media product labeled with a fertilizer guaranteed analysis, the minimum elemental percentages shall be as established in the Table established this in section[paragraph].

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Element	Percent
Calcium (Ca)	1.00[00]
Magnesium (Mg)	0.50[00]
Sulfur (S)	1.00[00]
Boron (B)	0.02[00]
Chlorine (Cl)	0.10[00]
Cobalt (Co)	0.0005
Copper (Cu)	0.05[00]
Iron (Fe)	0.10[00]
Manganese (Mn)	0.05[00]
Molybdenum (Mo)	0.0005
Nickel (Ni)	<u>0.0010</u>
Sodium (Na)	0.10[00]
Zinc (Zn)	0.05[00]

(1) Guarantees and claims shall not be referenced by fertilizer labeling or information provided with a fertilizer for elements other than those established in the Table established in this section[subsection].

(2) Except for nitrogen, phosphorus, and potassium, if present and that shall be listed first, guaranteed elements referenced by fertilizer labeling or information provided with a fertilizer shall be listed in the order established in the Table established in this section[subsection].

(3) The elements established in this **section[subsection]** shall be guaranteed on their elemental basis and are the only ones that **shall[will]** be accepted.

(4) Sources of the elements guaranteed and proof of availability shall be provided upon request.

Section 2. Fertilizer Labels.

(1) Fertilizer labels or information provided with a fertilizer shall be legible and conspicuous and shall include:

(a) Net Weight; [and]

(b) Brand and grade, except grade shall not be required if

primary nutrients are not claimed; [and]

(c) Under the heading of Guaranteed Analysis;[:]

<u>Total Nitrogen (N)</u>	<u>%</u>
Available Phosphate (P205)	<u>%</u>
Soluble Potash (K ₂ O)	<u>%</u>
Other Nutrients, Elemental Basis	<u>%</u>
1 If the percentage is zero, the putrient shall be	a maitte al fue ma

1. If the percentage is zero, the nutrient shall be omitted from the statement, except in nutrient guarantee breakdowns.

2. If the chemical forms of nitrogen are claimed, the form shall be guaranteed in the format established in the Table established in this subparagraph, and the percentages of the individual forms shall add up to the total nitrogen percentage. Implied order of the forms of nitrogen is not intended.

	Total Nitrogen (N)	%				
%	Ammoniacal Nitrogen					
%	Nitrate Nitrogen					
<u>%</u>	Water Insoluble Nitrogen					
<u>%</u>	Urea Nitrogen					
%	Other Recognized and Determinable					
	Forms of Nitrogen					

(d) The source or sources of the guaranteed elements that, if shown on the fertilizer labeling or information provided with a fertilizer, shall be listed below the completed guaranteed analysis statement; and

(e) Name and address of registrant or licensee.

(2) For packaged products, Fertilizer Labels shall:

(a) Appear on the front or back of the package;

(b) Occupy at least the upper third of a side of a package; or

(c) Be printed on a tag and attached to the package.

(3) If the chemical form of a plant nutrient is guaranteed, the percentage for each component shall be shown before the name of the form, as in the following example:

Total Nitrogen (N)	<u>34%</u>
17% Nitrate Nitrogen	
17% Ammoniacal Nitrogen	
Magnesium (Mg)	<u>2.0%</u>
1% Water Soluble Magnesium (Mg)	
<u>Sulfur (S)</u>	<u>10.0%</u>
5% Free Sulfur (S)	
5% Combined Sulfur (S)	
Iron (Fe)	<u>2.0%</u>
2% Chelated Iron (Fe)	

Section 3. Beneficial Substances and Beneficial Compounds. (1) Beneficial substances or beneficial compounds guarantees shall be listed below the guaranteed analysis statement under one (1) of the following headings; "Also Contains Beneficial Substances", "Also Contains Beneficial Compounds", or "Also Contains NonPlant Food Ingredients."[-]

(2) The percentage for each beneficial substance or beneficial compound shall be shown after the name of the form, as in the following examples:

<u>(a)</u> A	A lso	C	0	nta	ains	Beneficial	Substances	(Com	poun	ds)	

Beneficial Substance	% or acceptable units
Purpose Statement:	
(b) Also Contains NonPlant Fo	od Ingredients
Beneficial Substance	% or acceptable units
Purpose Statement:	

(3) For the beneficial substance, Silicon, the guarantee shall be "Soluble Silicon (*Si*)." The method of determination of Soluble Silicon shall be from the Journal of AOAC International, Volume 96, No.2, 2013.

Section 4. The term of "percentage" by symbol or word, when used on fertilizer labeling shall represent only the amount of individual plant nutrients in relation to the total product by weight.

Section 5. Incorporation by Reference.

(1) "Journal of AOAC International", Volume 96, No. 2, 2013, "A 5-Day Method for Determination of Soluble Silicon Concentrations in Nonliquid Fertilizer Materials Using a Sodium Carbonate-Ammonium Nitrate Extractant Followed by Visible Spectroscopy with Heteropoly Blue Analysis: Single-Laboratory Validation", **2013**, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Division of Regulatory Services, University of Kentucky, 103 Regulatory Services Building, Lexington, Kentucky 40546-0275, Monday through Friday, 8 a.m. to 4:30 p.m.[To prescribe in detail when and how plant nutrients in addition to nitrogen, phosphorus and potassium shall be registered and guaranteed.

Section 1. Plant nutrients in addition to nitrogen, phosphorus and potassium when mentioned in any form or manner shall be registered and shall be guaranteed. Guarantees shall be made on the elemental basis. Sources of the elements guaranteed and proof of availability shall be provided the director upon request. Except guarantees for those water soluble nutrients labeled for hydroponic or continuous liquid feed programs, and guarantees for potting soils, the minimum percentages which will be accepted for registration are as follows:

Section 2. Guarantees or claims for the plant nutrients listed in Section 1 of this administrative regulation are the only ones which will be accepted. Proposed labels and directions for the use of the fertilizer shall be furnished with the application for registration upon request. Any of the elements listed in Section 1 of this administrative regulation which are guaranteed shall appear in the order listed and shall immediately follow guarantees for the primary nutrients of nitrogen, phosphorus and potassium if present.]

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AGRICULTURAL EXPERIMENT STATION (As Amended at ARRS, October 13, 2020)

12 KAR 4:130. Investigational allowances.

RELATES TO: KRS 250.366(19), 250.391(3), 250.396(1), (2), 250.401

STATUTORY AUTHORITY: KRS 250.421

NECESSITY, FUNCTION, AND CONFORMITY: <u>KRS 250.421</u> requires the director to promulgate administrative regulations necessary to implement KRS 250.361 through 250.461. This administrative regulation establishes [To prescribe] scientifically sound and fair investigational allowances as a basis for declaring a fertilizer sample deficient in its guaranteed analyses and to detail the calculation of the index value of a fertilizer.

Section 1. A fertilizer shall be deemed deficient if the analysis of an official sample for any primary nutrient is below the guarantee by an amount exceeding the values in the <u>table established in</u> this sectionIfollowing scheduleI.

-	and deciding conclusion.					
	Guaranteed	Total	Available	Soluble		
	percent	Nitrogen	Phosphate	Potash (K ₂ O)		
		(N)	(P ₂ O ₅) percent*	percent*		
		percent*		-		
	05 or less	0.37	0.65	0.39		
	06	0.47	0.71	0.47		
	07	0.59	0.77	0.56		
	08	0.72	0.82	0.63		
	09	0.81	0.86	0.70		
	10	0.89	0.89	0.76		
	12	1.03	0.95	0.87		
	14	1.18	1.02	0.96		
	16	1.29	1.12	1.05		
	18	1.43	1.19	1.12		
	20	1.57	1.32	1.18		

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22	1.62	1.39	1.22
24	1.65	1.46	1.26
26	1.66	1.53	1.29
28	1.58	1.59	1.33
30	1.28	1.67	1.36
32 or more	1.28	1.67	1.36

For guarantees not listed, calculate the appropriate value by interpolation.

*For these investigational allowances to be applicable, the procedures recommended by AOAC International for obtaining samples, preparation and analysis shall be used. These are described in the 15th Edition (1990) of the Official Methods of Analysis of the AOAC International. In evaluating replicate data, Table 19, page 935, Journal of the Association of Official Analytical Chemists, Volume 49, No. 5, October, 1966, shall be followed. [The above materials are hereby incorporated by reference and are available for inspection and copying at 103 Regulatory Services Building, University of Kentucky, Lexington, Kentucky, during regular business hours of 8 a.m. to 5 p.m., Monday through Friday.]

Section 2. A fertilizer shall be deemed deficient in the overall index value if the overall index value is less than ninety-seven (97) percent.

(1) The overall index value **<u>shall be</u>[is]** calculated by comparing the value guaranteed with the value found. Unit values of the nutrients used shall be those referred to in KRS 250.401.

(2) Overall index value. Example of calculation for a 10-10-10 grade found to contain ten and one-tenth (10.1) percent Total Nitrogen (N), ten and two-tenths (10.2) percent Available Phosphate (P_2O_5) and ten and one-tenth (10.1) percent Soluble Potash (K_2O). Nutrient unit values **shall be[are]** assumed to be three (3) dollars per unit N, two (2) dollars per unit (P_2O_5), and one (1) dollar per unit K_2O .

10.0 units N	x3=	10.0
10.0 units P ₂ O ₅	x2=	20.0
10.0 units K ₂ O	x1=	10.0
Commercial Value Guaranteed =		60.0
10.0 units of N	x3=	30.3
10.2 units of P ₂ O ₅	x2=	20.4
10.1 units K ₂ O	x1=	10.1
Commercial Value Found =		60.8
Overall Index Value = 100(60.8/60.	00) = 10	01.3%

Section 3. Secondary and minor elements shall be deemed deficient if the analysis of an official sample for any of these elements is below the guarantee by an amount exceeding the values in the <u>table established in this section.[following</u> schedule:]

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Element	Investigational Allowance			
Calcium)	0.2 unit + 5% of guarantee			
Magnesium)	0.2 unit + 5% of guarantee			
Sulfur)	0.2 unit + 5% of guarantee			
Boron)	0.003 unit + 15% of guarantee			
Molybdenum)	0.0001 unit + 30% of guarantee			
Chlorine)	0.005 unit + 10% of guarantee			
Copper)	0.005 unit + 10% of guarantee			
Iron)	0.005 unit + 10% of guarantee			
Manganese)	0.005 unit + 10% of guarantee			
Sodium)	0.005 unit + 10% of guarantee			
Zinc)	0.005 unit + 10% of guarantee			
The maximum allowance [when] calculated in accordance				
with this table[to the above] shall be one (1) unit (1				
percent).				

Section 4. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "15th Edition (1990) of the Official Methods of Analysis of the AOAC International", **1990; and[.]**

(b) "Table 19, page 935, Journal of the Association of Official Analytical Chemists, Volume 49, No. 5", October, 1966 (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Division of Regulatory Services, University of Kentucky, 103 Regulatory Services Building, Lexington, Kentucky 40546-0275, Monday through Friday, 8 a.m. to 4:30 p.m.

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AGRICULTURAL EXPERIMENT STATION (As Amended at ARRS, October 13, 2020)

12 KAR 4:140. Monetary penalties.

RELATES TO: KRS 250.396(1), (2) STATUTORY AUTHORITY: KRS 250.421

NECESSITY, FUNCTION, AND CONFORMITY: <u>KRS 250.421</u> requires the director to promulgate administrative regulations necessary to implement KRS 250.361 through 250.461. This administrative regulation establishes [To prescribe] the specific method of calculating the monetary penalties required by the fertilizer law.

Section 1. Penalties for deficiencies in Total Nitrogen (N), Available Phosphate (P_2O_5), soluble potash (K_20), and index value shall be calculated <u>based on the table established in this</u> section <u>Ifrom the following schedule:</u>]

<u>section.[hrom-the-following-schedule:</u>]				
Number of Investigational Allowances Below Guarantee	Penalty Schedule			
<2	Equal to the monetary value of the deficiency			
>2 <3	Two (2) times the monetary value of the deficiency			
>3	Three (3) times the monetary value of the deficiency			

Section 2. Minimum standards and overages of primary nutrients <u>may[are allowed to]</u> reduce penalties calculated in Section 1 of this administrative regulation for fertilizer with index values equal to or greater than ninety-seven (97) percent on the basis of the <u>table established in this section.[following schedula:]</u>

scheuule.	
Number of Investigational	Penalty Adjustments
Allowances Below Guarantee	
No more than one (1) deficiency	Penalty adjusted to zero
that is less than or equal to two	
(2) investigational allowances	
No more than one (1) deficiency	Value of overages may
that is greater than two (2) but	adjust up to 100% of the
less than three (3) investigational	value of the deficiencies
allowances	
Two (2) deficiencies that are less	Value of overages may
than three (3) investigational	adjust up to 75% of the
allowances; or, no more than one	value of the deficiencies
(1) deficiency that is equal to or	
greater than three (3) but less	
than four (4) investigational	
allowances	

Section 3. <u>If[When]</u> a fertilizer is subject to a penalty from both a primary nutrient deficiency and an index value deficiency, only the larger penalty shall apply <u>and[; however, in no case shall]</u> the penalty <u>shall not</u> exceed the total value of the fertilizer.

Section 4. Penalties for deficiencies in secondary and minor elements and for excess chlorine in tobacco fertilizer shall be calculated <u>as established in this section[from the following</u> schedule].

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(1) Deficiencies.					
Number	of	Investigational	Penalty Schedule		
Allowance	es Belo	ow Guarantee			
<2			Equal to the monetary		
			value of the deficiency		
>2			Two (2) times the monetary		
			value of the deficiency		
(0) Even a ship da takana fartilizara. Tha investigation of					

(2) Excess chlorine in tobacco fertilizers. The investigational allowance for maximum chlorine shall be five-tenths (0.5) percent.

Number of Investigational Allowances Above Maximum Chlorine Guarantee	Penalty Schedule
<2	Equal to the difference in the soluble potash (for tobacco) unit value and the nontobacco soluble potash unit value
>2	Two (2) times the difference in the soluble potash (for tobacco) unit value and the nontobacco soluble potash unit value

Section 5. Any penalty assessed under Section 1 of this administrative regulation shall be added to any penalty assessed under Section 4 of this administrative regulation, and the total shall be paid by the registrant to the consumer of the lot of fertilizer represented by the sample within three (3) months after the date of notice from the director, receipts taken therefore and **[promptly]** forwarded to the director.

(1) If **a[said]** consumer cannot be found, the amount of the penalty payments shall be paid to the Kentucky Agricultural Experiment Station within three (3) months after the date of the notice from the director to the registrant and set aside for purchase of equipment for the sampling, handling, analyzing, and reporting of results of analyses of official samples and for the education of the Kentucky fertilizer industry on the newest methods in manufacturing blended fertilizers.

(2) If the lot of fertilizer is on hand at a retail location the penalty payments assessed under this section shall be used to reduce the retail price of the fertilizer if it is to be relabeled and sold.

Section 6. [In no case shall] The total of the penalties assessed under this administrative regulation shall not exceed the retail value of the fertilizer.

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AGRICULTURAL EXPERIMENT STATION (As Amended at ARRS, October 13, 2020)

12 KAR 4:170. Maximum chlorine guarantees for tobacco fertilizers.

RELATES TO: KRS 250.366(7), <u>250.376,</u> 250.411(1) STATUTORY AUTHORITY: KRS 250.421

NECESSITY, FUNCTION, AND CONFORMITY: KRS 250.421 requires the director of the Kentucky Agricultural Experiment Station to enforce the provisions of KRS 250.371 <u>through[te]</u> 250.451 and to promulgate and enforce administrative regulations necessary to implement KRS 250.371 <u>through[te]</u> 250.451. This administrative regulation establishes the specific format and conditions for maximum chlorine guarantee for tobacco fertilizers, which is necessary for production of quality tobacco.

Section 1. [(1) Until January 1, 2001, bagged tobacco fertilizer sold for or represented for use on field crop tobacco, shall, in addition to the other guarantees specified by 12 KAR Chapter 4, state a maximum chlorine guarantee not to exceed two and five tenths (2.5) percent in the following format:

Chlorine (ĆI), Maximum 2.5 percent

(2) The maximum chlorine guarantee shall be prominently and conspicuously placed below the Guaranteed Analysis required by 12 KAR 4:090.

(3) On or after January 1, 2001, the provisions of Section 2 of this administrative regulation shall apply to bagged tobacco fortilizer.

Section 2.] (1) [Except as provided by Section 1 of this administrative regulation, all] <u>All</u> fertilizers sold for or represented for use on field crop tobacco, shall, in addition to the other guarantees <u>established[specified]</u> by 12 KAR Chapter 4, state a maximum chlorine guarantee not to exceed fifty (50) pounds chlorine per acre (equivalent to 100 pounds of muriate of potash per acre) in the following format:

Chlorine (Cl), Maximum 50 lb./acre

(2) The maximum chlorine guarantee shall be prominently and conspicuously displayed on the label as required by KRS 250.376.

(3) The invoice, shipping ticket, or bag label shall:

(a) State the rate of application expressed as pounds or tons of the blended fertilizer per acre;

(b) State clearly that the fertilizer is for use on tobacco; and

(c) Give directions for use to include a maximum application rate so that no more than fifty (50) pounds of chlorine <u>shall be[is]</u> applied per acre.

(4) The provisions of this administrative regulation shall not apply to fertilizers for use on plant beds.

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EDUCATION AND WORKFORCE DEVELOPMENT CABINET Education Professional Standards Board (As Amended at ARRS, October 13, 2020)

16 KAR 3:090. Certifications for advanced educational leaders.

RELATES TO: KRS 161.020, 161.027, 161.028, 161.030 STATUTORY AUTHORITY: KRS <u>161.020</u>, 161.027, 161.028, 161.030

NECESSITY, FUNCTION, AND CONFORMITY: KRS 161.020 requires that a teacher or other professional school personnel hold a certificate of legal qualification for the respective position to be issued upon completion of a program of preparation prescribed by the Education Professional Standards Board. An educator preparation provider shall be approved for offering the preparation program corresponding to a particular certificate on the basis of standards and procedures established by the Education Professional Standards Board. This administrative regulation establishes the preparation and certification programs for all advanced educational leaders.

Section 1. Definitions.

(1) "Advanced Educational Leader" means school principal, school superintendent, director of special education, instructional supervisor, or director of pupil personnel.

(2) "Level I" means the standards-based program of studies designed for minimal preparation to serve in the specific Advanced Educational Leader position.

(3) "Level II" means the standards-based program of studies to attain the first five (5) year renewal of the certificate for the specific Advanced Educational Leader position.

(4) "Qualified applicant" means an applicant who holds the appropriate certification for the position unless the superintendent of the employing school district has documented evidence that the applicant is unsuitable for appointment.

Section 2. Programs of Preparation for Advanced Educational Leaders.

(1) Prerequisites for admission for all programs of preparation for Advanced Educational Leadership certifications shall include:

(a) Qualifications for a Kentucky teaching certificate;

(b) Admission to the preparation program on the basis of criteria developed by the Educator Preparation Provider pursuant to 16 KAR 5:010;

(c) Rank II; and

(d) Completion of at least three (3) years of full-time, documented teaching experience in a public school or a nonpublic school which meets the state performance standards as established in KRS 156.160 or which has been accredited by a regional or national accrediting association.

(2) Preparation programs for Advanced Educational Leaders shall be consistent with the Professional Standards for Educational Leadership.

Section 3. Assessment Prerequisites for Advanced Educational Leaders.

(1) Until December 1, 2020, an applicant for advanced educational leadership-school principal, or a career and technical school principal, shall complete the <u>School Leaders Licensure</u> <u>Assessment (6011)[following tests]</u> and attain the minimum score of 160.[specified for each test:

(a) School Leaders Licensure Assessment (6011) - 160; and

(b) The Kentucky Specialty Test of Instructional and Administrative Practices (1015) -158.]

(2) After December 1, 2020, all applicants for certification for advanced educational leadership, or a career and technical school principal, shall attain the specified minimum score on the School Leaders Licensure Assessment (6990). [An applicant for advanced educational leadership-school principal, or a career and technical school principal, shall also be required to take the Kentucky Specialty Test of Instructional and Administrative Practices (1015) and attain the minimum score of 158.]

(3) The Education Professional Standards Board shall determine the specified minimum score for the School Leaders Licensure Assessment (6990).

(4) The Education Professional Standards Board shall specify the passing score for Advanced Educational Leaders on the School Leaders Licensure Assessment (6990). The order shall be posted to the website for the Education Professional Standards Board.

(5) Until December 1, 2020, an applicant for advanced educational leadership-school principal, or a career and technical school principal, may substitute a passing score on the School Leaders Licensure Assessment (6990) for the requirement of <u>subsection (1)</u> [paragraph (1)(a)] of this section.

(6) An applicant for certification for advanced educational leadership, or a career and technical school principal, shall only be required to pass the School Leaders Licensure Assessment once. The applicant shall not be required to pass the assessment if <u>he or</u> <u>she pursues</u> [they pursue] additional certification for advanced educational leadership or career and technical school principal.

(7) The successful completion of the School Leaders Licensure Assessment shall not be required for an applicant who has:

(a) Two (2) years of experience as a certified advanced educational leader in another state; and

(b) Successfully completed a nationally administered test in the area of educational leadership and administration.

(8) An applicant shall take the required assessments on a date established by the Educational Testing Service. An applicant shall authorize that test results be forwarded to the Education Professional Standards Board by the Educational Testing Service.

(9) An applicant shall seek information regarding the dates and location of the test and make application for the appropriate examination prior to the deadline established and sufficiently in advance of anticipated employment to permit test results to be received by the Education Professional Standards Board and processed in the normal certification cycle.

(10) An applicant shall pay all fees assessed by the Educational Testing Service.

(11) An applicant who fails to achieve a minimum score on a required test as specified in this section shall be permitted to retake the test during a regularly scheduled test administration.

(12) A temporary certificate issued in accordance with KRS 161.027(6)(a) shall not be extended for an applicant who does not successfully complete the assessments within the year.

(13) For an applicant applying for a certificate under KRS 161.027(6)(b), the school superintendent of the employing district shall submit a request that shall include an affirmation that the applicant pool consisted of three (3) or less applicants who met the requirements for selecting a principal.

(14) The temporary certificate issued in accordance with KRS 161.027(6)(b) shall not be extended beyond the one (1) year period.

(15) On an annual or biennial basis, the Education Professional Standards Board shall collect and analyze data provided by the Educational Testing Service through score and institution reports which permit evaluation of the examination prerequisites covered by this administrative regulation.

Section 4. Level I and Level II Certification.

(1) The initial professional certificate for all Advanced Educational Leaders, with the exception of School Superintendent, shall be Level I certification.

(2) Application for the professional certificate for the specific Advanced Educational Leader certification shall be made on a Form CA-1.

(3) The initial professional certification for the specific Advanced Educational Leader shall be:

(a) Issued for a duration of five (5) years upon the successful completion of a Level I program approved by the Education Professional Standards Board pursuant to 16 KAR 5:010; and

(b) Renewed subsequently for five (5) year periods.

1. The first renewal shall require the completion of a Level II program approved by the Education Professional Standards Board pursuant to 16 KAR 5:010.

2. Each five (5) year renewal thereafter shall require the completion of:

a. Two (2) years of experience in the corresponding Advanced Educational Leader position;

b. Three (3) semester hours of additional graduate credit or the equivalent related to the corresponding Advanced Educational Leader position; or

c. Forty-two (42) hours of approved training selected from programs approved for the Kentucky Effective Instructional Leadership Training Program.

(4) If a lapse in certification occurs for lack of completion of the Level II preparation, the certification may be reissued for a five (5) year period upon successful completion of the Level II preparation.

(5) If a lapse in Level II certification occurs for lack of completion of the renewal requirements, the certificate may be reissued after the completion of an additional six (6) semester hours of graduate study or the equivalent appropriate to the program.

(6) Graduate level credit earned in the Level I and Level II preparation programs may be eligible for consideration of Rank I classification pursuant to 16 KAR 8:010, "Plan I" or "Plan II".

Section 5. School Superintendent.

(1) In addition to the requirements of Section 2 of this administrative regulation, prerequisites for admission to the program of preparation for Advanced Educational Leadership-School Superintendent shall include:

(a) Except as provided in paragraph (b) of this subsection, completion of the Levels I and II preparation and certification for the position of school principal or supervisor of instruction; or

(b) For a candidate who completed preparation for principal prior to 1988, completion of the assessments for administration.

(2) Each accredited educator preparation provider shall have a formal application procedure for admission to a superintendent preparation program, which shall include [the following]:

(a) A written letter of recommendation from a supervisor or an education agency representative attesting to the applicant's

suitability for school leader;

(b) An admissions portfolio which documents that the applicant demonstrates [the following]:

1. The ability to improve student achievement;

2. Knowledge of school laws related to school finance, school operations, and personnel matters;

3. The ability to implement curriculum, instruction, and assessment;

4. A commitment to ongoing professional growth;

5. Effective communication skills; and

6. The ability to build relationships, foster teamwork, and develop networks; and

(c) Proof the applicant has completed a master's degree program.

(3) Each superintendent preparation program shall utilize a clinical model which requires candidates to:

(a) Work in diverse school and district central office settings;

(b) Solve problems based on the school district's needs;

(c) Develop a mentoring plan for each candidate; and

(d) Design a method to assess the effectiveness of a candidate's clinical experience.

(4) A superintendent preparation program shall require all candidates to complete a capstone project to be presented to a panel of program faculty and practicing school administrators prior to completion of the program.

(5) The professional certificate for Advanced Educational Leader- School Superintendent shall be issued to an applicant who has completed:

(a) An approved program of preparation as required by Section 2 of this administrative regulation and pursuant to 16 KAR 5:010;

(b) The assessment requirements in Section 3 of this administrative regulation; and

(c) At least two (2) years of experience in a position of school principal, supervisor of instruction, guidance counselor, director of pupil personnel, director of special education, school business administrator, local district coordinator of vocational education, or a coordinator, administrator, or supervisor of district-wide services. Other administrative experience may be substituted for this requirement with the approval of the Education Professional Standards Board.

(6) Application for the professional certificate for Advanced Educational Leader - School Superintendent shall be made on a Form CA-1.

(7) The professional certificate for Advanced Educational Leader- School Superintendent shall be valid for the position of school superintendent or assistant superintendent.

Section 6. Supervisor of Instruction. The professional certificate for Advanced Educational Leader- Supervisor of Instruction shall be issued, in accordance with Section 4 of this administrative regulation, to an applicant who has completed the approved program of preparation, which corresponds to the certificate at an educator preparation provider approved under the standards and procedures established in 16 KAR 5:010 and Section 2 of this administrative regulation, and obtained at least the minimum passing score on the School Leadership Licensure Assessment.

Section 7. Director of Pupil Personnel.

(1) The professional certificate for Advanced Educational Leader- Director of Pupil Personnel Services shall be issued, in accordance with Section 4 of this administrative regulation, to an applicant who has completed the approved program of preparation, which corresponds to the certificate at an educator preparation provider approved under the standards and procedures established in 16 KAR 5:010 and Section 2 of this administrative regulation, and obtained at least the minimum passing score on the School Leadership Licensure Assessment.

(2) If a qualified applicant for director of pupil personnel services is not available as attested by the local school superintendent, the superintendent, on behalf of the local board of education, may request a one (1) year probationary certificate for a director of pupil personnel services who has:

(a) A valid Kentucky classroom teaching certificate;

(b) A Rank II;

(c) Three (3) years of successful teaching experience; and

(d) Been admitted to the preparation program for the professional certificate for Advanced Educational Leader- Director of Pupil Personnel Services.

(3) Application for the one (1) year probationary certificate for a director of pupil personnel services shall be made on Form CA-40.

(4) Each annual renewal of the probationary certificate for director of pupil personnel services shall require completion of an additional nine (9) semester hours selected from the approved program.

Section 8. Director of Special Education.

(1) The professional certificate for Advanced Educational Leader- Director of Special Education shall be issued, in accordance with Section 4 of this administrative regulation, to an applicant who has completed the approved program of preparation, which corresponds to the certificate at an educator preparation provider approved under the standards and procedures established in 16 KAR 5:010 and Section 2 of this administrative regulation, and obtained at least the minimum passing score on the School Leadership Licensure Assessment.

(2) The candidate may have three (3) years of full-time experience as a school psychologist, but shall have a minimum of one (1) year as a teacher of exceptional children or school psychologist to meet the requirements of Section 2(1)(a) of this administrative regulation.

(3) The candidate may qualify for a Kentucky school psychologist certificate in lieu of the requirements of Section 2(1)(a) of this administrative regulation.

(4) Each person whose job description includes supervising, directing, administering, or coordinating special education programs, at the district-wide level shall be required to hold:

(a) Endorsement for director of special education;

(b) Professional certificate for director of special education;

(c) Endorsement for supervisor of special education;

(d) Endorsement for teacher consultant for special education;

(e) Certificate valid for supervisor of instruction for persons serving in that position on July 14, 1992, as provided by KRS 157.250; or

(f) Valid certificate possessing the code ADSE for approval of director of special education.

(5) If a qualified applicant is not available for the position of director of special education, the superintendent, on behalf of the local board of education, may request a professional certificate for director of special education for a two (2) year period for an applicant who has:

(a) A valid Kentucky certificate for teachers of exceptional children;

(b) A Rank II;

(c) Three (3) years of full-time experience teaching exceptional children;

(d) Completed a course in special and regular education case law; and

(e) Been admitted to the preparation program for the professional certificate for director of special education.

(6) Application for the two (2) year certificate for a director of special education shall be made on Form CA-28.

(7) The applicant shall complete the total curriculum for the professional certificate for director of special education by September 1 of the year of expiration.

Section 9. Principal.

(1) In addition to the requirements of Section 2 of this administrative regulation, prerequisites for admission to the program of preparation for Advanced Educational Leadership-School Principal shall include:

(a) A written statement documenting the candidate's skills and understanding in the following areas:

1. Ability to improve student achievement;

2. Leadership; and

3. Advanced knowledge of curriculum, instruction, and

assessment; and

(b) An agreement from a school district pledging support that includes opportunities for the candidate to participate in a clinical experience. The agreement shall include:

1. A description of how the district will provide opportunities for the candidate:

a. To observe school and district leadership; and

b. To participate in school and district leadership activities;

2. Confirmation that the candidate shall be permitted to utilize aggregated school and district information and data; and

3. The signature of the district superintendent or the district superintendent's designee.

(2) Candidates who have not obtained their Rank II may be admitted to the program of preparation for Advanced Educational Leadership-School Principal if the educator preparation provider determines that the candidate has met all other requirements for admission.

(3) In addition to the requirements established in 16 KAR 5:010, Section 22, the educator preparation provider shall prepare and submit to the Education Professional Standards Board for each principal preparation program for which the provider is seeking approval program review documents which meet the submission requirements and include [the following] documented information:

(a) Signed collaborative agreements with school districts that include the following:

1. Joint screening of principal candidates by both district and university;

2. Joint identification of potential program leaders and mentors;
 3. District and university co-design and co-delivery of courses;
 and

4. The manner in which the principal preparation program is based on the identified leadership needs of each district;

(b) The protocol for screening applicants that ensures the identification and admission of candidates into the program;

(c) A matrix that illustrates the alignment between the standards identified in Section 2 of this administrative regulation, and the program's curriculum and clinical experiences;

(d) A syllabus for each of the program's required courses identified in the documentation required by paragraph (c) of this subsection;

(e) The program's plan to collaborate with each district in providing clinical experiences that:

1. Enhance courses throughout the entire program;

 Ensure that the candidate has a continuum of school-based experiences that range from observing, to participating, to leading; and

3. Expose the candidate to diverse student populations and school environments;

(f) The program's plan to use rigorous formative and summative evaluations of each candidate's:

1. Knowledge and skills to advocate, nurture, and sustain a school culture that promotes and supports high levels of learning for all students; and

2. Knowledge and skills to manage a school for efficiency, accountability, and safety; and

(g) The program's plan to require all candidates to conduct a capstone project and defend it to a panel of program faculty and practicing school administrators at the end of Level I preparation.

(4) A statement of eligibility for internship for the provisional certificate for Advanced Educational Leader- School Principal shall be issued for a five (5) year period to an applicant who:

(a) Has successfully completed an approved program of preparation;

(b) Has three (3) years of full-time teaching experience; and

(c) Has successfully completed the appropriate assessment requirements in Section 3 of this administrative regulation, or qualifies for a one (1) year period for completion of assessments under KRS 161.027(6).

(5) Application for a Statement of Eligibility shall be made on Form CA-1.

(6) A request for renewal of the Statement of Eligibility pursuant to KRS 161.027(7) shall be made on Form CA-2,

incorporated by reference in 16 KAR 4:060.

(7) The professional certificate for Advanced Educational Leader- School Principal shall be issued upon successful completion of the principal internship as provided in KRS 161.027 and 16 KAR 7:020.

(8) The provisional or professional certificate for Advanced Educational Leader-School Principal shall be valid for the position of school principal or school assistant principal for all grade levels.

Section 10. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Professional Standards for Educational Leaders", 2015

(b) "Form CA-1, <u>Application for Kentucky Certification or</u> Change in Salary Rank", 10/18;

(c) "Form CA-2, Application for Certificate Renewal or Duplicate", 10/18;

(d) "Form CA-28, Request for Two-Year Certificate for Director of Special Education," 8/15; and

(e) "Forms CA-40, Request for a One-Year Certificate for Director of Pupil Personnel", 8/15. [10/18, Education Professional Standards Board;

(c) Form CA-2, 10/18, Education Professional Standards Board:

(d) Form CA-28, 08/15, Education Professional Standards Board; and

(e) Form CA-40, 08/15, Education Professional Standards Board.]

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Education Professional Standards Board, 300 Sower Boulevard, 5th Floor, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

CONTACT PERSON: Todd G. Allen, Interim General Counsel, Kentucky Department of Education, 300 Sower Boulevard, 5th Floor, Frankfort, Kentucky, 40601, phone 502-564-4474, fax 502-564-9321; email regcomments@education.ky.gov.

EDUCATION AND WORKFORCE DEVELOPMENT CABINET Education Professional Standards Board (As Amended at ARRS, October 13, 2020)

16 KAR 9:010. Professional certificate for exceptional work experience[, limited to secondary education].

RELATES TO: KRS 161.028, 161.030, 161.048

STATUTORY AUTHORITY: KRS 161.028, 161.030, 161.048

NECESSITY, FUNCTION, AND CONFORMITY: KRS 161.048 establishes the eligibility requirements for a candidate seeking to participate in an alternative teacher preparation program. This administrative regulation establishes the requirements for issuance and renewal of a professional certificate [for secondary education] based on exceptional work experience.

Section 1. Definitions. (1) "Exceptional work experience" means a person with recognized superiority as compared with others in rank, status, and attainment or superior knowledge and skill in comparison with the generally accepted standards in the area in which certification is sought.

(2) "Population based certificate" means a certificate for teaching elementary, exceptional children, or interdisciplinary early childhood education.[

(2) "Secondary education" means the area in which certification is sought in a subject taught in grades 9 - 12 in a Kentucky school.]

Section 2. Verification of exceptional qualifications of an applicant for certification, in a field of endeavor taught or service practiced in a public school of Kentucky, shall include:

(1) Sufficient documentation that demonstrates to the local school district and the Education Professional Standards Board that an applicant is one who has exceptional work experience **[as defined in Section 1 of this administrative regulation]** and has

talents and abilities commensurate with the [new] teacher standards, established in 16 KAR 1:010;

(2) Documentation [of achievement that] may include advanced degrees earned, distinguished employment, evidence of related study or experience, publications, professional <u>awards</u>, achievement, or recognition attained for contributions to an applicant's field of endeavor; and <u>recommendations</u> [(3) <u>Recommendations</u>] from professional associations, former employers, professional colleagues, or any other individual or group whose evaluations shall support exceptional work in the field.

(3) Exceptional work experience shall not apply to population based certificates.

Section 3. Certification Requirements. An eligible candidate <u>for</u> <u>certification other than a population based certificate</u> who meets the requirements of <u>KRS 161.048(2)</u> [KRS 161.048(1)] <u>and 16</u> <u>KAR 2:010</u>, <u>Section 3(1)</u>, [and character and fitness review established in KRS 161.040] shall be issued [the provisional] <u>a</u> certificate[, limited to secondary education and valid for one (1) year]. [Upon successful completion of the Kentucky Teacher Internship Program as established in KRS 161.030(5) to (8), the professional certificate, limited to secondary education, shall be issued and shall be valid for an additional four (4) years.

Section 4. Renewal Requirements. Each five (5) year renewal of the professional certificate identified in Section 3 of this administrative regulation shall meet the renewal requirements established in 16 KAR 4:060-]

CONTACT PERSON: Todd G. Allen, Interim General Counsel, Kentucky Department of Education, 300 Sower Boulevard, 5th Floor, Frankfort, Kentucky, 40601, phone 502-564-4474, fax 502-564-9321; email regcomments@education.ky.gov.

BOARDS AND COMMISSIONS Board of Pharmacy (As Amended at ARRS, October 13, 2020)

201 KAR 2:311. Compounding drugs for veterinary use.

RELATES TO: KRS 315.191(1)(a), <u>321.441[</u>-] STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) <u>authorizes[requires]</u> the board to promulgate administrative regulations <u>necessary</u> to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, and pharmacies. This administrative regulation <u>establishes requirements for[addresses]</u> compounding for veterinary use.

Section 1. <u>The pharmacist shall receive a written, verbal,</u> <u>facsimile, or electronic request for a compounded drug from a</u> <u>practitioner, indicating the formulation, strength, and quantity</u> <u>ordered.</u> [A pharmacist, pharmacist intern, or pharmacy technician may prepare a compounded drug to be dispensed for a veterinarian's administration with beyond use dates as assigned in accordance.]

Section 2. A compounded drug <u>containing</u> [that contains] a controlled substance shall only be compounded for patient specific dispensation [directly] from <u>the</u> pharmacy to the ultimate user.

Section 3. (1) A pharmacist, pharmacist intern, or pharmacy technician may prepare a non-controlled compounded drug to be dispensed for veterinary use or administration that is either [{]institutional or ambulatory,[]] and which does not designate a specific patient for the purpose of direct administration to patients for:

(a) Emergency treatment;

(b) [,] Situations when a time delay would negatively affect a patient outcome; [,] or

(c) Diagnostic purposes.

(2) The compounded drug shall have a beyond use date.

(3) The veterinary institution or ambulatory unit shall maintain only an emergency stock supply.

(4) A veterinarian or licensed veterinary technician, [[]as defined in KRS 321.441, may [] shall be able to] administer a compounded drug for veterinary use. [The pharmacist shall receive a written, verbal, facsimile, or electronic request for a compounded drug from a practitioner, indicating the formulation, strength, and quantity ordered.]

Section 4. Label Requirements. <u>Except as provided for in</u> <u>Section 5,</u> a label shall be generated for the compounded drug and shall include:

(1) The name of the requesting veterinarian[practitioner];

(2) The designated name and strength of the compounded drug;

(3) The quantity dispensed;

(4) If for a specific patient and the patient is a food producing animal, the withdrawal time;

(5) A lot or batch number of the compounded drug;

(6[(5)]) The beyond use date for the compounded drug;

(7[(6)]) The date the compounded drug is dispensed;

(8[(7)]) The pharmacy's name, address, and telephone number;

(9[(8)]) Any special storage requirements;

(<u>10[(9)]</u>) A notation stating "For [Office or Institutional administration for] veterinary use"; <u>and</u>

(<u>11[(10)]</u>) Any auxiliary label required for the compounded drug.

<u>Section 5. (1) A non-controlled substance</u> [(11) The] compounded drug shall be [administered or] dispensed by a[the] veterinarian [or veterinarian technician] for emergency take home use when in his or her professional judgment, failure to provide the drug would result in potential harm to the patient.

(2) *If[When]* dispensed from the veterinary institution or ambulatory unit, a compounded drug prescription for a veterinary patient shall be for up to a 14-day supply in accordance with the veterinarian prescription and dispensation labeling requirements as *established[found]* in 201 KAR 16:600. [for up to a 14 day supply in accordance with veterinarian labeling requirements.]

Section <u>6[</u>5]. The prescription for the compounded drug shall be kept pursuant to 201 KAR 2:170.

CONTACT PERSON: Larry Hadley, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Larry.Hadley@ky.gov.

BOARDS AND COMMISSIONS Kentucky Board of Medical Licensure\ (As Amended at ARRS, October 13, 2020)

201 KAR 9:016. Restrictions on use of amphetamine and amphetamine-like anorectic controlled substances.

RELATES TO: KRS 311.550, 311.595(9), 311.597<u>, 311.842</u>, <u>311.850(1)(s)</u>

STATUTORY AUTHORITY: KRS 311.565(1), 311.842(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) authorizes the board to promulgate administrative regulations to regulate the conduct of licensees. KRS 311.595(9) and 311.597 authorize disciplinary action against <u>physicians</u> [licensees] for specified offenses. <u>KRS 311.842(1) requires</u> [authorizes] the board to promulgate administrative regulations establishing prescribing and administering standards for physician assistants. This administrative regulation establishes the amphetamine-like anorectic controlled substances.

Section 1. Definitions. (1) "Board" is defined *by[in]* KRS 311.550(1).

(2) "Body mass index" means the weight of the patient in kilograms divided by the height in meters, squared.

(3) "Licensee" means a person licensed to practice medicine or osteopathy or to practice as a physician assistant in the Commonwealth of Kentucky and authorized to prescribe, dispense, or administer controlled substances unless otherwise exempted by law.

(4) "Schedule II amphetamine or amphetamine-like controlled substance" means:

(a) Amphetamine, its salts, optical isomers, and salts of optical isomers; or

(b) Methylphenidate.

(5)[(4)] "Schedule III or IV amphetamine-like controlled substance" means a drug classified as a stimulant pursuant to <u>902</u> KAR 55:015, Section 3 or 4[-

(a) 902 KAR 55:025, Section 2; or

(b) 902 KAR 55:030 Section 1].[

(5) "Licensee" means a person licensed to practice medicine or osteopathy or to practice as a physician assistant in the Commonwealth of Kentucky and authorized to prescribe, dispense or administer controlled substances unless otherwise exempted by law.]

Section 2. Prior to prescribing, ordering, dispensing, administering, selling, supplying, or giving **an[a]** [Schedule II, III or IV] amphetamine or amphetamine-like controlled substance, a <u>licensee</u> [physician] shall take into account the:

(1) Drug's potential for abuse;

(2) Possibility that a drug may lead to dependence;

(3) Possibility a patient will obtain the drug for a nontherapeutic use;

(4) Possibility a patient will distribute it to others; and

(5) Potential illicit market for the drug.

Section 3. Schedule II Amphetamine or Amphetamine-like Controlled Substances. (1) The patient's record shall denote the diagnosis that justifies treatment with a Schedule II amphetamine or amphetamine-like controlled substance.

(2) A Schedule II amphetamine or amphetamine-like controlled substance shall be used to treat only:

(a) Narcolepsy;

(b) Attention deficit/hyperactive disorder;

(c) Resistant depressive disorder in combination with other antidepressant medications, or if alternative antidepressants and other therapeutic modalities are contraindicated;

(d) Drug-induced brain dysfunction;

(e) A diagnosis for which the clinical use of the Schedule II amphetamine or amphetamine-like controlled substance is investigational and the investigative protocol has been submitted, reviewed, and approved by the board prior to the clinical use of the drug; or

(f) An adult patient with a moderate to severe binge-eating disorder, if diagnosed according to criteria set forth in the Diagnostic and Statistical Manual of Mental Disorders at the time of diagnosis.

(3) A Schedule II amphetamine or amphetamine-like controlled substance shall not be utilized to treat obesity.

Section 4. Treatment of Obesity with a Schedule III or IV Amphetamine-like Controlled Substance. (1) Prior to prescribing, administering, dispensing, ordering, selling, supplying, or giving a Schedule III or IV amphetamine-like controlled substance to treat obesity in a patient sixteen (16) years of age or older, the <u>licensee</u> [physician] shall:

(a) Establish a licensee [physician]/patient relationship;

(b) Determine that the patient is obese or overweight with medical risk factors and is a proper candidate for weight reduction treatment;

(c) Determine and record the extent of prior anorectics or other controlled substances used by the patient. The prescribing <u>licensee</u> [physician] shall obtain and review a KASPER report for

the twelve (12) month period immediately preceding the patient encounter, before prescribing or dispensing controlled substances to the patient;

(d) Determine that the patient has either:

1. A body mass index of twenty-seven (27) or more, unless the body mass index is twenty-five (25) to twenty-seven (27) and the patient has a co-morbidity such as a cardiovascular disease, diabetes mellitus, dyslipidemia, hypertension, or sleep apnea;

2. Body fat greater than or equal to thirty (30) percent in females or greater than or equal to twenty-five (25) percent in males;

3. Current body weight greater than or equal to 120 percent of a well-documented, long-standing, healthy weight that the patient maintained after age eighteen (18);

4. A waist-hip ratio or waist circumference at a level indicating that the individual is known to be at increased cardiovascular or co-morbidity risk because of abdominal visceral fat; or

5. Presence of a co-morbid condition or conditions aggravated by the patient's excessive adiposity; and

(e) Provide the patient with carefully prescribed diet, together with counseling on exercise, behavior modification, and other appropriate supportive and collateral therapies.

(2) During treatment for obesity, a licensee [physician] shall:

(a) Maintain a <u>licensee</u> [physician]/patient relationship throughout the treatment process;

(b) Maintain an adequate patient record in accordance with subsection (4) of this section; and

(c) Justify in the patient record the use of any Schedule III or IV amphetamine-like controlled substance beyond three (3) months. Before the <u>licensee</u> [physician] continues the use of a substance beyond three (3) months, the <u>licensee</u> [physician] shall obtain and review a current KASPER report.

(3) A <u>licensee</u> [physician] shall terminate the use of Schedule III or IV amphetamine-like controlled substances if:

(a) The patient does not demonstrate weight loss and does not attempt to comply with exercise and dietary changes;

(b) The body mass index of the patient without a co-morbid condition is less than twenty-seven (27) and the percentage of body fat is normal at less than thirty (30) percent in females or less than twenty-five (25) percent in males;

(c) The body mass index of the patient with a co-morbid condition is less than twenty-five (25) and the percentage of body fat is normal at less than thirty (30) percent in females or less than twenty-five (25) percent in males;

(d) The patient has regained the weight lost, using sympathomimetics as part of a complete program and reuse of the medication does not produce loss of the weight gain to help maintain a minimum of five (5) percent weight loss; or

(e) The patient has obtained a Schedule III or IV amphetaminelike controlled substance from another <u>provider</u> [physician] without the <u>licensee's</u> [prescriber's] knowledge and consent.

(4) The board shall consider the following factors in reviewing the adequacy of a patient record:

(a) Medical history, including:

1. Illnesses, with particular emphasis on cardiovascular diseases;

2. Surgery;

3. Lifestyle;

4. Medications, including controlled substances;

5. Eating habits;

6. Exercise;

7. Weight gain or loss;

8. Prior efforts at weight control or reduction;

9. Prior treatment compliance;

10. Menstruation or pregnancy; and

11. Psychiatric history with particular reference to depression, paranoia, psychosis, or chemical dependency;

(b) Social history;

(c) Family history;

(d) Complete physical examination;

(e) Evaluation of laboratory tests including:

1. CBC;

2. Fasting blood sugar;

3. Thyroid panel or TSH;

4. Lipid profile;

5. Serum potassium;

6. Liver function test; and

7. Renal function test;

(f) An informed consent signed by the patient that cites the limitations and risk of anorectic treatment including potential dependency or psychiatric illness;

(g)1. A signed agreement that the patient has voluntarily agreed to:

a. Have one (1) prescribing <u>licensee</u> [physician] for controlled substances;

b. Use one (1) pharmacy to fill prescriptions for controlled substances;

c. Not have early refills on the prescriptions for controlled substances; and

d. Provide full disclosure of other medications taken; or

2. Documentation that:

a. The <u>licensee</u> [physician] requested the patient sign an agreement meeting the requirements of subparagraph 1 of this paragraph;

b. The patient declined to sign the agreement; and

c. Indicates the <u>licensee's</u> [physician's] clinical reasons for prescribing, or continuing to prescribe, a Schedule III or IV amphetamine-like controlled substance to the patient, in light of the patient's refusal to sign the agreement; and

(h) A record of each office visit, including:

1. The patient's weight;

2. The patient's blood pressure;

3. The patient's pulse;

4. The presence or absence of medication side effects or complications;

5. The doses of medications prescribed;

6. The patient's body mass index; and

7. Evaluation of the patient's compliance with the total treatment regimen.

Section 5. Waiver. For a legitimate medical purpose, a <u>licensee</u> [physician] may apply in writing for a written waiver of any requirement in this administrative regulation. The board may issue a waiver with terms and conditions it deems appropriate.

Section 6. Failure to comply with the requirements of this administrative regulation shall constitute dishonorable, unethical, or unprofessional conduct by a <u>licensee</u> [physician] which is apt to deceive, defraud, or harm the public under:

(1) KRS 311.595(9) and 311.597; or (2) KRS 311.850(1)(s).

CONTACT PERSON: Leanne K. Diakov, General Counsel, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, phone (502) 429-7943, fax (502) 429-7118, email Leanne.Diakov@ky.gov.

BOARDS AND COMMISSIONS Kentucky Board of Medical Licensure (As Amended at ARRS, October 13, 2020)

201 KAR 9:200. National Practitioner Data Bank Reports.

RELATES TO: KRS 218A.205, 311.565, 311.571, 311.595, 311.842, 311.850

STATUTORY AUTHORITY: KRS 218A.205(3)(g),(h),((f),((3)(g)2,,] 311.565(1)(a), (k), <u>311.842(1)</u>

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(b) authorizes the board to promulgate administrative regulations establishing moral, physical, intellectual, educational, scientific, technical, and professional qualifications of applicants for licenses and permits that may be issued by the board. <u>KRS</u> 311.842(1) **requires[authorizes]** the board to promulgate administrative regulations relating to the licensing and regulation of physician assistants. KRS 311.595 establishes the legal grounds for denial for an application for licensing <u>physicians</u>. <u>KRS 311.850</u> <u>establishes the legal grounds for denial for an application for</u> <u>licensing physician assistants</u>. KRS 218A.205(3)(<u>g</u>) [(f)] requires the board to promulgate an administrative regulation that establishes a procedure for continuous submission of all disciplinary and other reportable information to the National Practitioner Data Bank. KRS 218A.205(3)(<u>h</u>) [(g)2.] requires the board to promulgate an administrative regulation establishing a procedure to submit a query on each applicant for licensure to the National Practitioner Data Bank to retrieve any relevant data on the applicant. This administrative regulation establishes the requirements of obtaining information from and reporting information to the National Practitioner Data Bank.

Section 1. (1)(a) The board shall submit a query to the National Practitioner Data Bank on each applicant for initial licensing within the Commonwealth of Kentucky, to retrieve any relevant data on the applicant.

(b) The board shall not grant an initial license [to practice medicine or osteopathy] within the Commonwealth unless and until it has received and reviewed the National Practitioner Data Bank report for that applicant.

(2) The board shall promptly report each order issued by its panels, whether a final order or an agreed order, relating to a specific licensee to the National Practitioner Data Bank.

CONTACT PERSON: Leanne K. Diakov, General Counsel, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, phone (502) 429-7943, fax (502) 429-7118, email Leanne.Diakov@ky.gov.

BOARDS AND COMMISSIONS Kentucky Board of Medical Licensure (As Amended at ARRS, October 13, 2020)

201 KAR 9:210. Criminal background checks required for all new applicants.

RELATES TO: KRS 218A.205, 311.565, 311.571, 311.595, 311.850

STATUTORY AUTHORITY: KRS 218A.205<u>(8)[(3)(g)]</u>, 311.565(1)(b), (k), (t)<u>, 311.842(1)</u>

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(b) authorizes the board to promulgate administrative regulations establishing moral, physical, intellectual, educational scientific, technical, and professional qualifications of applicants for licenses and permits that may be issued by the board. KRS 311.842(1) requires[authorizes] the board to promulgate administrative regulations relating to the licensing and regulation of physician assistants. KRS 311.595 establishes the legal grounds for denial for an application for licensing physicians. KRS 311.850 establishes the legal grounds for denial for an application for licensing physician assistants. KRS 311.565(1)(t) authorizes the board to require a criminal background investigation of all persons applying for licensure at the time of initial application by means of a fingerprint check by the Department of Kentucky State Police and Federal Bureau of Investigation. KRS 218A.205(8)[(3)(g)] requires the board to promulgate an administrative regulation establishing a process for obtaining a national and state fingerprint-supported criminal record check for initial applicants of any license that may authorized to prescribe controlled substances. be This administrative regulation establishes the requirement for criminal background checks for all new applicants.

Section 1. (1) The board shall obtain a fingerprint-supported criminal record check conducted by the Department of Kentucky State Police and Federal Bureau of Investigation, on each applicant for initial licensing to practice medicine or osteopathy or to practice as a physician assistant within the Commonwealth of Kentucky.

(2) The board shall not grant an initial license to practice medicine or osteopathy or to practice as a physician assistant

within the Commonwealth until it has received and reviewed the criminal background investigations by both the Department of Kentucky State Police and the Federal Bureau of Investigation for that applicant.

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BOARDS AND COMMISSIONS Kentucky Board of Medical Licensure (As Amended at ARRS, October 13, 2020)

201 KAR 9:260. Professional standards for prescribing. [and] dispensing, and administering controlled substances.

RELATES TO: KRS 218A.172, 218A.205, 311.530-311.620, 311.990, 311.840-311.862

STATUTORY AUTHORITY: KRS 218A.205(3)(a), (b), 311.565(1)(a), 311.842(1)(b)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) authorizes the board to promulgate administrative regulations to regulate the conduct of its licensees. KRS 218A.205(3)(a) and (b) require the board, in consultation with the Kentucky Office of Drug Control Policy, to establish mandatory prescribing and dispensing standards related to controlled substances, and in accordance with the Centers for Disease Control and Prevention (CDC) guidelines, to establish a prohibition on a practitioner issuing a prescription for a Schedule II controlled substance for more than a three (3) day supply if intended to treat pain as an acute medical condition, unless an exception applies. KRS 311.842(1)(b) requires that the board promulgate administrative regulations establishing professional standards for prescribing and administering controlled substances by physician assistants. This administrative regulation establishes the professional standards for prescribing and dispensing controlled substances for any licensee authorized to prescribe, dispense, or administer controlled substances.

Section 1. Applicability. (1) <u>Any licensee [A physician]</u> who is authorized to prescribe, [or] dispense, <u>or administer</u> a controlled substance shall comply with the standards of acceptable and prevailing medical practice for prescribing, [and] dispensing, <u>or</u> <u>administering</u> a controlled substance established in this administrative regulation.

(2) <u>A physician assistant shall only prescribe or administer a</u> controlled substance to the extent delegated by the supervising physician in the applications required under KRS **311.854**[**341.854**] and 311.858. This administrative regulation, including any exemptions stated herein, shall not alter the prescribing limits established in KRS **311.858** or the requirements for delegation from a supervising physician established in KRS **311.854**.

(a) Any change in the supervising physician application, including changes in practice address, scope of practice, or scope of delegated prescriptive authority, required under KRS 311.854 and 311.858 shall be reported in writing to the board within ten (10) days of the change.

(b) If the physician assistant's supervising physician changes or the supervising physician **becomes[become]** restricted or suspended from the practice of medicine or osteopathy, the physician assistant shall cease prescribing or administering controlled substances until the restriction or suspension is terminated or a new supervising physician is approved.

(c) Prescribing or administering controlled substances without the applications required under KRS 311.854 and 311.858 shall constitute a violation of this administrative regulation and shall be grounds for an emergency order of restriction or suspension.

(3) The professional standards established in this administrative regulation shall not apply to [a physician] prescribing, [er] dispensing, or administering a controlled substance:

(a) To a patient as part of the patient's hospice or end-of-life treatment;

(b) To a patient admitted to a licensed hospital as an inpatient, outpatient, or observation patient, during and as part of a normal and expected part of the patient's course of care at that hospital;

(c) To a patient for the treatment of pain associated with cancer or with the treatment of cancer;

(d) To a patient who is a registered resident of a long-termcare facility as defined in KRS 216.510;

(e) During the effective period of any period of disaster or mass casualties <u>that</u> [which] has a direct impact upon the physician's practice;

(f) In a single dose to relieve the anxiety, pain, or discomfort experienced by that patient submitting to a diagnostic test or procedure;

(g) That has been classified as a Schedule V controlled substance;

(h) That is a Schedule II controlled substance as part of a narcotic treatment program licensed by the Cabinet for Health and Family Services; [or]

(i) Within seven (7) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing:

a. Is done as a substitute for the initial prescribing or

dispensing: b. Cancels any refills for the initial prescription; and

c. Requires the patient to dispose of any remaining unconsumed medication;

(j) Within ninety (90) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing is done by another physician in the same practice or in an existing coverage arrangement, if done for the same patient for the same medical condition;

(k) To a research subject enrolled in a research protocol approved by an institutional review board that has an active federalwide assurance number from the United States Department for Health and Human Services, Office for Human Research Protections if the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health; or

(I) 1. <u>To a patient</u> [That is a Schedule II controlled substance prescribed or administered] immediately prior to, during, or within the fourteen (14) days following:

a. A major surgery, being any operative or invasive procedure or a delivery; or

b. A significant trauma, being any acute blunt, blast, or penetrating bodily injury that has a risk of death, physical disability, or impairment; and

2. The usage does not extend beyond fourteen (14) days.

Section 2. Professional Standards for Documentation of Patient Assessment, Education, Treatment Agreement and Informed Consent, Action Plans, Outcomes, and Monitoring. (1) Each <u>licensee</u> [physician] prescribing, [er] dispensing, or administering a controlled substance shall obtain and document all relevant information in a patient's medical record in a legible manner and in sufficient detail to enable the board to determine whether the <u>licensee</u> [physician] is conforming to professional standards for prescribing, [er] dispensing, or administering controlled substances and other relevant professional standards. <u>Relevant information shall include as appropriate:</u>

(a) Medical history and physical or mental health examination;

(b) Diagnostic, therapeutic, and laboratory results;

(c) Evaluations and consultations;

(d) Treatment objectives;

(e) Discussion of risk, benefits, and limitations of treatments;

(f) Treatments;

(g) Medications, including date, type, dosage, and quantity prescribed or dispensed;

(h) Instructions and agreements; and

(i) Periodic reviews of the patient's file.

(2) If a <u>licensee [physician</u>] is unable to conform to professional standards for prescribing. [er] dispensing, or administering controlled substances due to circumstances beyond the <u>licensee's</u>

[physician's] control, or the <u>licensee</u> [physician] makes a professional determination that it is not appropriate to comply with a specific standard, based upon the individual facts applicable to a specific patient's diagnosis and treatment, the <u>licensee</u> [physician] shall document those circumstances in the patient's record and only prescribe, [er] dispense, or administer a controlled substance to the patient if the patient record appropriately justifies the prescribing. [er] dispensing, or administering of a controlled substance under the circumstances.

Section 3. Professional Standards for the Prescribing, [er] Dispensing, or Administering of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. Prior to the initial prescribing, [er] dispensing, or administering of any controlled substance for pain or other symptoms associated with the same primary medical complaint: $[_{T}]$

(1) The first <u>licensee</u> [physician] prescribing. [or] dispensing, or <u>administering</u> a controlled substance shall:

(a) [(1)] Obtain an appropriate medical history relevant to the medical complaint, including a history of present illness, and:

<u>1.</u> [(a)] If the complaint does not relate to a psychiatric condition, conduct a physical examination of the patient relevant to the medical complaint and related symptoms and document the information in the patient's medical record; or

2. [(b)] If the complaint relates to a psychiatric condition, perform, or have performed by a psychiatrist or other designated mental health provider, an evaluation appropriate to the presenting complaint and document the relevant findings;

(b) [(2)] Obtain and review a KASPER report for that patient for the twelve (12) month period immediately preceding the patient encounter, and appropriately utilize that information in the evaluation and treatment of the patient;

(c) [(3)] After examining the benefits and risks of prescribing. [er] dispensing, or administering a controlled substance to the patient, including nontreatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe. [er] dispense, or administer the controlled substance in the minimum amount necessary to treat the medical complaint [specified];[

(4) Only prescribe or dispense Schedule II controlled substances in accordance with the standards established in Section 9 of this administrative regulation;]

(d) [(5)] Not prescribe. [or] dispense. or administer a longacting or controlled-release opioid [(e.g. OxyContin, fentanyl patches, or methadone)] for acute pain that is not directly related to and close in time to a specific surgical procedure;

(e) [(6)] Discuss the risk and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence and explain to the patient that a controlled substance used to treat an acute medical complaint is for time-limited use, and that the patient should discontinue the use of the controlled substance when the condition requiring the controlled substance use has resolved; and

(f) [(7)] Explain to the patient how to safely use and properly dispose of any unused controlled substance and educate the patient in accordance with Section 8 of this administrative regulation: and

(2) [(8)] If the controlled substance is a Schedule II, a physician shall also:

(a) Make a written plan stating the objectives of the treatment and further diagnostic examinations required;

(b) Obtain written consent for the treatment; and

(c) Not prescribe or dispense more than a three (3) day supply of a Schedule II controlled substance, unless the physician:

1. Determines that more than a three (3) day supply is medically necessary; and

2. Documents the acute medical condition and lack of alternative medical treatment options to justify the amount of the controlled substance prescribed or dispensed.

Section 4. Professional Standards for Commencing Long Term

Use of Prescribing, [er] Dispensing, or Administering of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. (1) Before a <u>licensee</u> [physician] commences to prescribe, [er] dispense, or <u>administer</u> any controlled substance to a patient sixteen (16) years or older for pain or other symptoms associated with the same primary medical complaint for a total period of longer than three (3) months, the <u>licensee</u> [physician] shall comply with the mandatory professional standards established in subsection (2) of this section. These standards may be accomplished by different licensed practitioners in a single group practice at the direction of or on behalf of the <u>licensee</u> [prescribing physician] if:

(a) Each practitioner involved has lawful access to the patient's medical record;

(b) There is compliance with all applicable standards; and

(c) Each practitioner performing an action to meet the required standards is acting within the practitioner's legal scope of practice.

(2)(a) The <u>licensee</u> [physician] shall obtain the following information from the patient and record all relevant information in the patient's medical record:

1. History of present illness;

2. Past medical history;

3. History of substance use and any prior treatment for that use by the patient, and history of substance abuse by first degree relatives of the patient;

4. Past family history of relevant illnesses and treatment; and

5. Psychosocial history.

(b) The <u>licensee</u> [physician] shall conduct an appropriate physical examination of the patient sufficient to support the medical indications for prescribing. [er] dispensing, or administering a controlled substance on a long-term basis.

(c) The <u>licensee</u> [physician] shall perform appropriate baseline assessments to establish beginning values to assist in establishing and periodically evaluating the functional goals of any treatment plan.

(d) If a specific or specialized evaluation is necessary for the formulation of a working diagnosis or treatment plan, the <u>licensee</u> [physician] shall only continue the use of a controlled substance after determining that continued use of the controlled substance is safe and medically appropriate in the absence of that information.

(e) If the <u>licensee</u> [physician] determines that the patient has previously received medical treatment for the presenting medical complaint or related symptoms and that review of the prior treatment records is necessary to justify long-term prescribing, <u>dispensing</u>, or <u>administering</u> of a controlled substance, the <u>licensee</u> [physician] shall obtain those prior medical records and incorporate the information therein into the evaluation and treatment of the patient.

(f)1. Based upon consideration of all information available, the <u>licensee</u> [physician] shall promptly formulate and document a working diagnosis of the source of the patient's medical complaint and related symptoms without simply describing or listing the related symptoms.

2. If the <u>licensee [physician]</u> is unable, despite best efforts, to formulate a working diagnosis, the <u>licensee [physician]</u> shall consider the usefulness of additional information, such as a specialized evaluation or assessment, referral to an appropriate specialist, and the usefulness of further observation and evaluation, before attempting again to formulate a working diagnosis.

3. If the <u>licensee</u> [physician] is unable to formulate a working diagnosis, despite the use of an appropriate specialized evaluation or assessment, the <u>licensee</u> [physician] shall only prescribe, <u>dispense, or administer</u> long term use of a controlled substance after establishing that its use at a specific level is medically indicated and appropriate.

(g)1. To the extent that functional improvement is medically expected based upon the patient's condition, the <u>licensee</u> [physician] shall formulate an appropriate treatment plan.

2. The treatment plan shall include specific and verifiable goals of treatment, with a schedule for periodic evaluations.

(h)1. The <u>licensee</u> [physician] shall utilize appropriate screening tools to screen each patient to determine if the patient:

a. Is presently suffering from another medical condition which may impact the prescribing. [er] dispensing, or administering of a controlled substance; or

b. Presents a significant risk for illegal diversion of a controlled substance.

2. If, after screening, the <u>licensee [physician]</u> determines that there is a reasonable likelihood that the patient suffers from substance abuse or dependence, or a psychiatric or psychological condition, the <u>licensee [physician]</u> shall take the necessary actions to facilitate a referral to an appropriate treatment program or provider. The <u>licensee [physician]</u> shall appropriately incorporate the information from the treatment program or provider into the evaluation and treatment of the patient.

3. If, after screening, the <u>licensee [physician]</u> determines that there is a risk that the patient may illegally divert a controlled substance, but determines to continue long term prescribing of the controlled substance, the <u>licensee</u> [physician] shall use a prescribing agreement that meets professional standards. The prescribing agreement and informed consent document may be combined into one (1) document.

4. The <u>licensee</u> [physician] shall obtain and document a baseline drug screen.

5. If, after screening, the physician determines that the controlled substance prescribed <u>or dispensed</u> to the patient will be used or is likely to be used other than medicinally or other than for an accepted therapeutic purpose, the <u>licensee</u> [physician] shall not prescribe <u>or dispense</u> any controlled substance to that patient.

(i) After explaining the risks and benefits of long-term use of a controlled substance, the <u>licensee</u> [physician] shall obtain the written informed consent of the patient in a manner that meets professional standards and educate the patient in accordance with Section 8 of this administrative regulation.

(j) The <u>licensee</u> [physician] shall initially attempt, to the extent possible, or establish and document a previous attempt by another physician, of a trial of noncontrolled modalities and lower doses of a controlled substance in increasing order to treat the pain and related symptoms associated with the primary medical complaint, before continuing with long term prescribing, <u>dispensing</u>, or <u>administering</u> of a controlled substance at a given level.

Section 5. Professional Standards for Continuing Long Term Prescribing, [er] Dispensing, or Administering of Controlled Substances for the Treatment of Pain and Related Symptoms Associated with a Primary Medical Complaint. (1) If a licensee [physician] continues to prescribe, [er] dispense, or administer a controlled substance beyond three (3) months to a patient sixteen (16) years or older for pain and related symptoms associated with the primary medical complaint, the licensee [physician] shall comply with the professional standards established in subsection (2) of this section [and, if a Schedule II controlled substance, Section 9 of this administrative regulation]. These standards may be accomplished by different licensed practitioners in a single group practice at the direction of or on behalf of the licensee [prescribing physician] as established in Section 4(1) of this administrative regulation.

(2)(a)[4.] The <u>licensee</u> [physician] shall ensure that the patient is seen at least once a month initially for evaluation and review of progress. The <u>licensee</u> [physician] may determine that the patient is to be evaluated less frequently, on a schedule determined by the <u>licensee's</u> [physician's] professional judgment after the <u>licensee</u> [physician] has determined:

<u>1.</u> [a.] The controlled substance prescribed, [er] dispensed, or <u>administered</u> has been titrated to the level appropriate and necessary to treat the medical complaint and related symptoms;

<u>2.</u> [b-] The controlled substance prescribed, [or] dispensed, or <u>administered</u> is not causing unacceptable side effects; and

<u>3.</u> [c.] There is sufficient monitoring in place to minimize the likelihood that the patient will use the controlled substance in an improper or inappropriate manner or divert it for an improper or inappropriate use.

(b) At appropriate intervals, the <u>licensee</u> [physician] shall:

1. Ensure that a current history is obtained from the patient;

2. Ensure that a focused physical examination is considered, and performed, if appropriate; and

3. Perform appropriate measurable examinations as indicated in the treatment plan.

(c) At appropriate intervals, the <u>licensee</u> [physician] shall evaluate the working diagnosis and treatment plan based upon the information gained to determine whether there has been functional improvement or any change in baseline measures. The <u>licensee</u> [physician] shall modify the diagnosis, treatment plan, or controlled substance therapy, as appropriate.

(d) If the <u>licensee</u> [physician] determines that the patient presents a significant risk of diversion or improper use of a controlled substance, the <u>licensee</u> [physician] shall discontinue the use of the controlled substance or justify its continued use in the patient record.

(e) If the medical complaint and related symptoms continue with no significant improvement in function despite treatment with a controlled substance, and if improvement is medically expected, the <u>licensee</u> [physician] shall obtain appropriate consultative assistance to determine whether there are undiagnosed conditions to be addressed in order to resolve the medical complaint.

(f) For a patient exhibiting symptoms suggestive of a mood, anxiety, or psychotic disorder, the <u>licensee</u> [physician] shall obtain a psychiatric or psychological consultation for intervention if appropriate.

(g) If a patient reports experiencing episodes of breakthrough pain, the licensee [physician] shall:

1. Attempt to identify the trigger or triggers for each episode;

2. Determine whether the breakthrough pain may be adequately treated through noncontrolled treatment; and

3. If the <u>licensee</u> [physician] determines that the nonmedication treatments do not adequately address the triggers, and after considering the risks and benefits, determines to add an asneeded controlled substance to the regimen, take appropriate steps to minimize the improper or illegal use of the additional controlled substance.

(h) At least once a year, the <u>licensee [physician]</u> shall perform or shall ensure that the patient's primary treating physician performs a preventive health screening and physical examination appropriate to the patient's gender, age, and medical condition.

(i)1. At least once every three (3) months, the <u>licensee</u> [physician] shall obtain and review a current KASPER report, for the twelve (12) month period immediately preceding the request, and appropriately use that information in the evaluation and treatment of the patient.

2. If the <u>licensee</u> [physician] obtains or receives specific information that the patient is not taking the controlled substance as directed, is diverting a controlled substance, or is engaged in any improper or illegal use of a controlled substance, the <u>licensee</u> [physician] shall immediately obtain and review a KASPER report and appropriately use the information in the evaluation and treatment of the patient.

3. If a KASPER report discloses that the patient is obtaining a controlled substance from another practitioner without the <u>licensee's</u> [physician's] knowledge and approval, in a manner that raises suspicion of illegal diversion, the <u>licensee</u> [physician] shall promptly notify the other practitioner of the relevant information from the KASPER review.

4. The <u>licensee</u> [physician] shall obtain consultative assistance from a specialist if appropriate.

(j) If appropriate, the <u>licensee</u> [physician] shall conduct random pill counts and appropriately use that information in the evaluation and treatment of the patient.

(k)1. During the course of long-term prescribing, [er] dispensing, or administering of a controlled substance, the licensee [physician] shall utilize drug screens, appropriate to the controlled substance and the patient's condition, in a random and unannounced manner at appropriate times. If the drug screen or other information available to the licensee [physician] indicates that the patient is noncompliant, the licensee [physician] shall:

a. Do a controlled taper, consistent with subparagraph 3 of this paragraph;

b. Stop prescribing, [or] dispensing, or administering the controlled substance immediately; or

c. Refer the patient to an addiction specialist, mental health

professional, pain management specialist, or drug treatment program, depending upon the circumstances.

2. The <u>licensee</u> [physician] shall discontinue controlled substance treatment or refer the patient to addiction management if:

a. There has been no improvement in function and response to the medical complaint and related symptoms, if improvement is medically expected;

b. Controlled substance therapy has produced significant adverse effects, including instances such as an overdose or events leading to hospitalization or disability;

c. The patient exhibits inappropriate drug-seeking behavior or diversion; or

d. The patient is taking a high-risk regimen, such as dosages \geq fifty (50) MME/day or opioids with benzodiazepines, without evidence of benefit.

3. The licensee [physician] shall:

a. Taper controlled substances in a manner slow enough to minimize symptoms and signs of opioid withdrawal; and

b. Collaborate with other specialists as needed to optimize nonopioid pain management and psychosocial support for anxiety related to the taper.

4. A <u>licensee</u> [physician] shall stop prescribing. [or] dispensing. or administering any controlled substance diverted by or from the patient or taken less frequently than once a day.

Section 6. Professional Standards for the Prescribing, [and] Dispensing, or Administering of Controlled Substances in an Emergency Department. In addition to complying with the standards for the initial prescribing, [er] dispensing, or administering of a controlled substance as established in Sections 3 and 7 of this administrative regulation, a licensee [physician] prescribing, [er] dispensing, or administering a controlled substance for a specific medical complaint and related symptoms to a patient in an emergency department shall not routinely:

(1) Administer an intravenous controlled substance for the relief of acute exacerbations of chronic pain, unless intravenous administration is the only medically appropriate means of delivery;

(2) Provide a replacement prescription for a controlled substance that was lost, destroyed, or stolen;

(3) Provide a replacement dose of methadone, suboxone, or subutex for a patient in a treatment program;

(4) Prescribe a long-acting or controlled-release controlled substance, such as OxyContin, fentanyl patches, or methadone or a replacement dose of that medication;

(5) Administer Meperidine to the patient; or

(6) Prescribe. [or] dispense, or administer more than the minimum amount medically necessary to treat the patient's medical condition until the patient can be seen by the primary treating physician or another <u>practitioner</u> [physician], with no refills. If the controlled substance prescription exceeds seven (7) days in length or exceeds three (3) days if a Schedule II controlled substance, the patient record shall justify the amount of the controlled substance prescribed.

Section 7. Professional Standards for the Prescribing. [and] Dispensing, or Administering of Controlled Substances for the Treatment of Other Conditions. (1) Before initially prescribing, [er] dispensing, or administering a controlled substance to a patient for a condition other than pain, the licensee [physician] shall comply with the standards as established in Section 3 of this administrative regulation.[:

(a) Obtain an appropriate medical history relevant to the medical complaint, including a history of present illness, and:

1. If the complaint does not relate to a psychiatric condition, conduct a physical examination of the patient relevant to the medical complaint and related symptoms and document the information in the patient's medical record; or

2. If the complaint relates to a psychiatric condition, perform, or have performed by a psychiatrist or other designated mental health provider, an evaluation appropriate to the presenting complaint and document the relevant findings;

(b) Obtain and review a KASPER report for that patient, for the twelve (12) month period immediately preceding the patient

encounter, and appropriately utilize that information in the evaluation and treatment of the patient;

(c) After examining the benefits and risks of prescribing or dispensing a controlled substance to the patient, including nontreatment or other treatment, make a deliberate decision that it is medically appropriate to prescribe or dispense the controlled substance in the amount specified;

(d) Avoid providing more controlled substances than necessary by prescribing or dispensing only the amount of a controlled substance needed to treat the specific medical complaint;

(e) Explain to the patient that a controlled substance used to treat an acute medical complaint is for time-limited use, and that the patient should discontinue the use of a controlled substance when the condition requiring the controlled substance use has resolved; and

(f) Explain to the patient how to safely use and properly dispose of any unused controlled substance and educate the patient in accordance with Section 8 of this administrative regulation.]

(2) If the <u>licensee</u> [physician] continues to prescribe, [er] dispense, or administer a controlled substance to a patient for the same medical complaint and related symptoms, the <u>licensee</u> [physician] shall fully conform to the standards of acceptable and prevailing practice for treatment of that medical complaint and for the use of the controlled substance.

(3) If a <u>licensee</u> [physician] receives a request from an established patient to prescribe. [or] dispense, or administer a limited amount of a controlled substance to assist the patient in responding to the anxiety or depression resulting from a nonrecurring single episode or event, the <u>licensee</u> [physician] shall:

(a) Obtain and review a KASPER report for that patient for the twelve (12) month period immediately preceding the patient request and appropriately utilize the information obtained in the evaluation and treatment of the patient;

(b) Make a deliberate decision that it is medically appropriate to prescribe. [er] dispense, or administer the controlled substance in the amount specified, with or without requiring a personal encounter with the patient to obtain a more detailed history or to conduct a physical examination; and

(c) If the decision is made that it is medically appropriate to <u>use a</u> [prescribe or dispense the] controlled substance, prescribe. [or] dispense, or administer the minimum amount of the controlled substance to appropriately treat the situational anxiety or depression.

Section 8. Responsibility to Educate Patients Regarding the Dangers of Controlled Substance Use. (1) A <u>licensee [physician]</u> prescribing. [or] dispensing, or administering a controlled substance shall:

(a) Take appropriate steps to educate a patient receiving a controlled substance; and

(b) Discuss with each patient the effect the patient's medical condition and medication use may have on the patient's ability to safely operate a vehicle in any mode of transportation.

(2) Educational materials relating to these subjects may be found on the board's Web site, www.kbml.ky.gov.

Section 9. [Additional Standards for Prescribing or Dispensing Schedule II Controlled Substances. (1) In addition to the other standards established in this administrative regulation, prior to the initial prescribing or dispensing of a Schedule II controlled substance to a human patient, a physician shall:

(a) Obtain a medical history and conduct a physical or mental health examination of the patient, as appropriate to the patient's medical complaint, and document the information in the patient's medical record;

(b) Query KASPER for all available data on the patient for the twelve (12) month period immediately preceding the patient encounter and appropriately utilize that data in the evaluation and treatment of the patient;

(c) Make a written plan stating the objectives of the treatment and further diagnostic examinations required;

(d) Discuss the risks and benefits of the use of controlled substances with the patient, the patient's parent if the patient is an

unemancipated minor child, or the patient's legal guardian or health care surrogate, including the risk of tolerance and drug dependence; and

(e) Obtain written consent for the treatment.

(2) In addition to the other standards established in this administrative regulation, for purposes of treating pain as or related to an acute medical condition, a physician shall not prescribe or dispense more than a three (3) day supply of a Schedule II controlled substance, unless the physician determines that more than a three (3) day supply is medically necessary and the physician documents the acute medical condition and lack of alternative medical treatment options to justify the amount of the controlled substance prescribed or dispensed.

(3)(a) In addition to the other standards established in this administrative regulation, a physician prescribing or dispensing additional amounts of a Schedule II controlled substance for the same medical complaint and related symptoms shall:

1. Review, at reasonable intervals based on the patient's individual circumstances and course of treatment, the plan of care;

 $\ensuremath{\text{2. Provide to the patient any new information about the treatment; and}$

3. Modify or terminate the treatment as appropriate.

(b) If the course of treatment extends beyond three (3) months, the physician shall:

1. Query KASPER no less than once every three (3) months for all available data on the patient for the twelve (12) month period immediately preceding the query; and

2. Review that data before issuing any new prescription or refills for the patient for any Schedule II controlled substance.

(4) To the extent not already required by the standards established in this administrative regulation, for each patient for whom a physician prescribes or dispenses a Schedule II controlled substance, the physician shall keep accurate, readily accessible, and complete medical records which include, as appropriate:

(a) Medical history and physical or mental health examination;

(b) Diagnostic, therapeutic, and laboratory results;

(c) Evaluations and consultations;

(d) Treatment objectives;

(e) Discussion of risk, benefits, and limitations of treatments; (f) Treatments:

(g) Medications, including date, type, dosage, and quantity

prescribed or dispensed;

(h) Instructions and agreements, and

(i) Periodic reviews of the patient's file.

(5) The additional standards for prescribing or dispensing a Schedule II controlled substance established in this section shall not apply to:

(a)1. A physician prescribing or administering that controlled substance immediately prior to, during, or within the fourteen (14) days following:

a. A major surgery, being any operative or invasive procedure or a delivery; or

b. A significant trauma, being any acute blunt, blast, or penetrating bodily injury that has a risk of death, physical disability, or impairment; and

2.If the prescribing or administering is medically related to the operative or invasive procedure or delivery with medication usage that does not extend beyond the fourteen (14) days; or

(b) A physician prescribing or dispensing that controlled substance:

1. For administration in a hospital or long-term-care facility if the hospital or long-term-care facility with an institutional account, or a physician in those hospitals or facilities if no institutional account exists, queries KASPER for all available data on the patient or resident for the twelve (12) month period immediately preceding the query, within twelve (12) hours of the patient's or resident's admission, and places a copy of the query in the patient's or resident's medical records for use during the duration of the patient's stay at the facility;

2. As part of a narcotic treatment program licensed by the Cabinet for Health and Family Services;

3. As part of the patient's hospice or end-of-life treatment;

4. For the treatment of pain associated with cancer or with the

treatment of cancer;

5. In a single dose to relieve the anxiety, pain, or discomfort experienced by a patient submitting to a diagnostic test or procedure;

6. Within seven (7) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing:

a. Is done as a substitute for the initial prescribing or dispensing:

b. Cancels any refills for the initial prescription; and

c. Requires the patient to dispose of any remaining unconsumed medication;

7. Within ninety (90) days of an initial prescribing or dispensing under subsection (1) of this section if the prescribing or dispensing is done by another physician in the same practice or in an existing coverage arrangement, if done for the same patient for the same medical condition; or

8. To a research subject enrolled in a research protocol approved by an institutional review board that has an active federalwide assurance number from the United States Department for Health and Human Services, Office for Human Research Protections if the research involves single, double, or triple blind drug administration or is additionally covered by a certificate of confidentiality from the National Institutes of Health.

Section 10.] Violations. (1) Any violation of the professional standards established in this administrative regulation shall constitute a violation of KRS 311.595(12) and (9) or KRS 311.850(1)(p) and (s), which may result in the imposition of disciplinary sanctions by the board, pursuant to KRS 311.595 or KRS 311.850.

(2) Each violation of the professional standards established in this administrative regulation shall be established by expert testimony by one (1) or more physicians retained by the board, following a review of the licensee's patient records and other available information including KASPER reports.

CONTACT PERSON: Leanne K. Diakov, General Counsel, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, phone (502) 429-7943, fax (502) 429-7118, email Leanne.Diakov@ky.gov.

BOARDS AND COMMISSIONS Kentucky Board of Medical Licensure (As Amended at ARRS, October 13, 2020)

201 KAR 9:360. Continuing education requirements for physician assistants.

RELATES TO: KRS 13B.125(3), 214.610, 214.620, 218A.205, 311.565(1)(b), 311.601, 311.842(1), 311.844, 311.850(1)(p), (s), 311.852, 620.020

STATUTORY AUTHORITY: KRS 218A.205(3)(i), 311.565(1)(a), (b), 311.601(1), (2), 311.842(1) NECESSITY, FUNCTION, AND CONFORMITY: KRS

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.601(1) authorizes the board to promulgate an administrative regulation that establishes requirements to ensure the continuing professional competency of licensees. KRS 311.842(1) authorizes the board to promulgate administrative regulations relating to the licensing and regulation of physician assistants. This administrative regulation establishes continuing medical education requirements for physician assistant licensees in Kentucky, including requirements for courses relating to the use of KASPER, pain management, and addiction disorders required for licensees who prescribe or dispense controlled substances in the Commonwealth of Kentucky.

Section 1. Continuing Medical Education. (1) At the time a licensee seeks to renew his or her license, the licensee shall certify that he or she has met the continuing education requirements for the two (2) year continuing education cycle using the Continuing Education Certification Form provided by the board and submitting it by the renewal deadline.

(2) The board may randomly require licensees submitting

certification of continuing education to demonstrate satisfactory completion of the continuing education hours stated in the certification by providing verification documentation. If requested, the licensee shall provide verification within ten (10) days of receiving the request from the board.

Section 2. Required Hours of Continuing Education. (1) For each two (2) year renewal period and continuing education cycle, a licensee shall complete a minimum of 100 hours of continuing education approved by the following:

(a) The American Medical Association;

(b) The American Osteopathic Association;

(c) The American Academy of Family Physicians;

(d) The American Academy of Physician Assistants; or

(e) Another entity approved by the board.

(2) If the licensee is authorized to prescribe or administer controlled substances, for each two (2) year continuing education cycle, the licensee shall complete, as part of the required 100 continuing education hours, a minimum of seven and one-half (7.5) hours of board-approved continuing education relating to:

(a) Controlled substance diversion;

(b) Pain management;

(c) Addiction disorders;

(d) The use of KASPER: or

(e) Any combination of [the] two (2) or more of these subjects.

(3) If the licensee is authorized to prescribe or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, the licensee shall complete, as part of the required 100 continuing education hours, a minimum of twelve (12) hours of board-approved continuing education relating to addiction medicine for each two (2) year continuing education cycle.

(4) A licensee shall not be granted authorization for prescriptive authority of controlled substances or Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone until he or she submits to the board proof of completion of the minimum hours of continuing education in subsections (2) and (3) of this section within the prior two (2) years.

(5)(a) To qualify as board-approved continuing education <u>under</u> subsections (2) and (3) of this section, the educational program shall have been approved in advance for the specified number of continuing education hours by the board.

(b) The board may approve an educational program that:

1. Consists of a live presentation;

2. Is presented by a live or recorded webinar; or

3. Is presented through an online module.

(c) The board shall maintain a current listing of approved continuing education programs on its official Web site, www.kbml.ky.gov.

Section 3. Continuing education related to pediatric abusive head trauma. Each licensee shall complete at least one and a half (1.5) hours of continuing education regarding the recognition and prevention of pediatric abusive head trauma in a course approved by the board pursuant to KRS 620.020, within the first two (2) years of initial licensure or prior to the expiration of first renewal cycle after the promulgation of this <u>administrative</u> regulation. These hours shall be counted toward the 100 continuing education hours required in Section 2 of this administrative regulation.

Section 4. Continuing education related to human immunodeficiency virus and acquired immunodeficiency syndrome. Each licensee shall complete at least one (1) hour of continuing education regarding the human immunodeficiency virus and acquired immunodeficiency syndrome within the first two (2) years of initial licensure or prior to the expiration of first renewal cycle after the promulgation of this administrative regulation. These hours shall be counted toward the 100 continuing education hours required in Section 2 of this administrative regulation.

Section 5. Sanctions. (1) Failure to complete the required number of continuing education hours for the required period or to submit the required written verification within the time specified within this administrative regulation shall constitute a violation of KRS 311.850(1)(p) and (s), which shall constitute an immediate danger to the public health, safety, or welfare, for the purposes of KRS 311.852 and 13B.125.

(2) If the board determines that a licensee has failed to complete the required continuing education hours within the time specified or has failed to provide the written verification of completion within the time specified, the appropriate inquiry panel or its chair shall promptly issue an emergency order suspending the licensee from practice or restricting that licensee from prescribing or administering controlled substances within the Commonwealth of Kentucky until the licensee has completed the required continuing education hours for that period and has provided written verification of completion to the board.

(3) An emergency order issued pursuant to subsection (2) of this section shall remain valid and in effect until the board has received written verification that the licensee has successfully completed the required continuing education hours for the time period specified. Upon receipt of the written verification, the panel or its chair shall immediately issue an order terminating the emergency order issued pursuant to this section.

(4) If a licensee who is affected by an emergency order issued pursuant to this section requests an emergency hearing pursuant to KRS 13B.125(3), the hearing officer conducting the emergency hearing shall affirm the emergency order if presented with written notification on board letterhead stating that the board has not received the required written verification that the licensee completed the required continuing education hours for the continuing medical education cycle by the deadline date for the cycle.

Section 6. Extensions of Time. (1) To request an extension of time, the licensee shall submit:

(a) A completed Request for Extension to Complete Required CE Hours; and

(b) The fee established in 201 KAR 9:041, Section 1(17).

(2) The board may grant an extension of time to a licensee who for sufficient cause has not yet received continuing education certification, following the submission of the items required by subsection (1) of this section. For the purposes of this subsection, sufficient cause shall include situations such as the following:

(a) An illness;

(b) Any event meeting the Family Medical Leave Act (FMLA) of 1993, 29 U.S.C. 2601 et seq., Pub.L. 103-3 criteria, and the federal regulations implementing the act, 29 C.F.R. Part 825;

(c) Financial exigencies; or

(d) Practice circumstances making it prohibitive to attend the courses.

(3)(a) A licensee who obtains an extension of time shall be granted an extension of six (6) months to come into compliance.

(b) If a licensee has not completed the continuing education requirements within the six (6) month extension established by this subsection, his or her license shall:

1. Be immediately suspended; and

2. Remain suspended until the licensee has submitted verifiable evidence that he or she has completed the continuing education requirements.

Section 7. A waiver of the requirements established by this administrative regulation shall not be granted.

Section 8. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Continuing Education Certification Form", 072020; and

(b) "Request for Extension to Complete Required CE Hours", 072020.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, Monday through Friday, 8 a.m. to 4:30 p.m.

CONTACT PERSON: Leanne K. Diakov, General Counsel, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, phone (502) 429-7943, fax (502) 429-7118, email Leanne.Diakov@ky.gov.

BOARDS AND COMMISSIONS Board of Chiropractic Examiners (As Amended at ARRS, October 13, 2020)

201 KAR 21:041. Licensing; standards, fees.

RELATES TO: KRS 312.085, 312.095, 312.145, 312.175 STATUTORY AUTHORITY: KRS 312.019, 312.085, 312.095, 312.175

NECESSITY, FUNCTION, AND CONFORMITY: KRS 312.019(9) authorizes the Kentucky Board of Chiropractic Examiners to promulgate administrative regulations consistent with KRS Chapter 312, regulating the practice of chiropractic. This administrative regulation establishes the procedures relating to application for licensure, license renewal, and fees.

Section 1. Initial Application. An applicant for initial licensure shall submit to the board:

(1) A completed New Licensee Application; and

(2) A nonrefundable application fee of \$350.

Section 2. Licenses. Each license by the board shall:

(1) Set forth the:

(a) Name of the issuing board;

(b) Name of the licensee;

(c) Number of license; and

(d) Date of the license issuance;

(2) Be signed by a minimum of three (3) members of the board; and

(3) Have the seal of the board affixed.

Section 3. License Renewal. (1)(a) Each licensee of the board shall annually renew the license on or before the first day of March. (b)1. A licensee seeking active status shall:

a. Submit a completed Application for Annual License Renewal: and

b. Pay a renewal fee of \$250.

2. A licensee seeking inactive status shall:

a. Submit a completed Annual Inactive License Renewal Application; and

b. Pay a renewal fee of seventy-five (75) dollars.

(2) The amount of the restoration fee established by KRS 312.175(2) and (4) shall be \$250 per year, or any part of a year.

(3) Continuing education requirements.

(a) Each active licensee shall complete at least twelve (12) hours of board-approved continuing education, with: <u>1</u> [:

1. a minimum of six (6) hours obtained within Kentucky;] <u>A</u> minimum of six (6) hours of the required twelve (12) hours [must be] obtained at a live event, which is an event at which both the licensee and presenter are present in-person;[.]

2. No more than eight (8) hours completed in a day; and

3. Proof of completion submitted with the Application for Annual License Renewal upon request by the Board.[,]

(b) A new licensee shall complete a two (2) hour jurisprudence course, provided by the board, [prior to the first license renewal] within one (1) year of the date of **the licensee's[their]** initial license approval. The course shall account for two (2) of the twelve (12) hours of continuing education required by paragraph (a) of this subsection.

(c) <u>A new licensee **shall[must]** complete **the licensee's[their]** required **twelve** (12) hours of continuing education by the first relicensing period following the completion of **his or her[their]** first calendar year in practice.</u>

(d) An inactive licensee may renew the inactive license without meeting the continuing education requirements required by this subsection.

Section 4. Activation of an Inactive License.

(1) To activate an inactive license, a licensee shall submit:

(a) A completed Application for Activation or Reinstatement of Kentucky License;

(b) The renewal fee required by Section 3(1)(b) of this administrative regulation;

(c) Proof that the licensee has met the continuing education requirements established by Section 3(3) of this administrative regulation; and

(d) License verification from each state or jurisdiction from which the licensee has held a license.

(2) If the licensee was inactive for more than four (4) years, proof of successfully passing the Special Purposes Examination for Chiropractic given by the National Board of Chiropractic Examiners within the past six (6) months shall be submitted to the board.

Section 5. Denial or Refusal of License. The board may deny or refuse to renew a license if an applicant or licensee:

(1) Has a conviction for a felony or violation of any law involving moral turpitude; or

(2) Violates any of the provisions of KRS Chapter 312 or 201 KAR Chapter 21.

Section 6. Change of Address. Each licensee shall notify the board within ten (10) days of each change of mailing address or place of business.

Section 7. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "New Licensee Application", 2016;

(b) "Application for Annual License Renewal", <u>September</u> 2020[November 2009];

(c) "Annual Inactive License Renewal Application", 2013; and

(d) "Application for Activation or Reinstatement of Kentucky License", 2013.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Chiropractic Examiners, [209 South Green Street, Glasgow, Kentucky 42142,] 500 Mero Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

CONTACT PERSON: David C. Trimble, Board Attorney, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 782-8823, fax +1 (502) 564-3969, email DavidC.Trimble@ky.gov.

BOARDS AND COMMISSIONS Board of Chiropractic Examiners (As Amended at ARRS, October 13, 2020)

201 KAR 21:042. Standards, application and approval of continuing education

RELATES TO: KRS 312.085, 312.095, 312.145, 312.175

STATUTORY AUTHORITY: KRS 312.019, 312.085, 312.095, 312.175

NECESSITY, FUNCTION, AND CONFORMITY: KRS 312.019(9) authorizes the Kentucky Board of Chiropractic Examiners to promulgate administrative regulations consistent with KRS Chapter 312, regulating the practice of chiropractic. This administrative regulation establishes <u>standards for continuing</u> <u>education and</u> the procedures relating to <u>the</u> [standards₇] application[₇] and approval <u>off(fer]</u> continuing education.

Section 1. Standards for Continuing Education. (1) Continuing education shall be either:

(a) A post graduate course of study at or sponsored by a chiropractic college accredited by the Council on Chiropractic Education or its successors; or

(b) A continuing education program approved by the board, or a committee designated by the board to act between sessions of the board.

(2) The continuing education program shall be:

(a) Sponsored by a national or state chartered organization of chiropractors; and

(b) Open to all doctors of chiropractic in Kentucky who desire to attend.

(3) The instructors and speakers shall be in the field of chiropractic, chiropractic education, or allied sciences.

(4)[(a)](4)]The programs to be presented shall contain subjects of clinical benefit to licensees and on a postgraduate level of education.

Section 2. <u>Requirements for Online Continuing Education. (1)</u> Any entity submitting an online course for approval *shall[must]* be <u>Pre-Approved Continuing Education (PACE) Commission</u> certified and submit the program through the PACE pre-check program using the PACE Pre-Check Expedited Course <u>Submission for Kentucky form.</u> Any entity not certified through PACE shall[can] submit an application for approval for a program directly to the board through December 31, 2020 by completing the Kentucky Board of Chiropractic Examiners Continuing <u>Education Application.</u>

(2) Any entity submitting an online course for approval must be PACE certified and submit the program through the PACE precheck program.

(2) The program shall:

(a) Have a mechanism to ensure that users view each page of the program:

(b)[(3) The program shall] Ensure the user has earned all of the time required for the program;

(c)[(4) The program shall] Have a mechanism in place for the user to be able to contact the provider regarding questions about the continuing education programs;

(d)](5) The program shall] Include a mechanism to evaluate the user's knowledge of the subject matter contained in the program;

(e)[(6) The program shall] Provide a printed verification or allow the user to print verification only upon completion of the program; and

(f)[(7) The program shall] Ensure that the course time cannot be earned away from the program and that[shall ensure] automatic lock out occurs if the keyboard becomes unattended.[;]

(3)[(8)] Programs shall be **completed and** earned one (1) at a time. The **user of a** program shall not earn credit for multiple windows or programs completed simultaneously.

Section 3. Application for Approval. (1) The sponsoring party of a proposed educational program for license renewal shall apply for approval of the program prior to its presentation <u>by submitting</u> either the PACE Pre-Check Expedited Course Submission for Kentucky form if PACE certified, or if not certified through PACE by submitting the Kentucky Board of Chiropractic Examiners Continuing Education Application, and by providing to the board:

(a) The name of the course;

(b) The name of the sponsoring organization;

(c) The objective of the program;

(d) The number of classroom hours over which the educational program will be presented and the dates presented;

(e) The names of the instructors and speakers and the name and address of the institution with which they are associated, if applicable;

(f) The instructors' or speakers' educational background and other relevant qualifications;

(g) The name and address of the person authorized to certify attendance; and

(h) <u>An</u> [A non-refundable] educational program review fee <u>as</u> <u>established in subparagraph 1. through 3. of this paragraph.</u> [of][twenty-five (25) dollars for programs with one (1) date and one (1) location or \$100 for programs with multiple dates and locations.]

1.[(i)] Live Events Only - A live event is an event at which both the presenter and attendee are present in person. A minimum fee of twenty-five (25) dollars for a live one- time event of sixteen (16) hours or less. Any event over sixteen (16) hours will be two (2) dollars[\$2.00] per requested credit hour with a maximum fee of \$100. For events with multiple dates and locations there will be an additional twenty-five (25) dollar fee.

2.[(#)] Online Events Only - A minimum fee of twenty-five (25) dollars for a live one- time event or recorded event of sixteen (16) hours or less. Any event over sixteen (16) hours will be two (2)

dollars[\$2.00] per requested credit hour with a maximum fee of \$100. The online event shall[will] remain approved for one (1) calendar year.

3.[(iiii)] Live Event That Will Also Be Recorded To Be Used As Online CE – A minimum **fee of** fifty (50) dollars for an event of sixteen (16) hours or less. Any event over sixteen (16) hours will be two (2) dollars per requested credit hour with a maximum fee of \$100. The online event **shall[will]** remain approved for one (1) calendar year.

(2) The educational program may be monitored by an officer of the board, the field coordinator of the board, or a person designated by the president of the board.

(3)(a) A proposed program [shall be submitted to] <u>shall[must]</u> be received by the board for approval at least sixty (60) days prior to the date of the presentation.

(b) The board, or a designee of the board to act between meetings of the board, shall give written notification of the board's approval or disapproval of the program to the sponsoring party not more than thirty (30) days after receiving the proposed educational program.

(c) <u>An online course **shall[will]** remain approved for one (1)</u> calendar year from a date of the event **provider's[providers]** choosing **iffso-long-as]** that date is no earlier than sixty (60) days from the date the board received the submission for approval. [Within thirty (30) days of completion of the program, the sponsoring party shall submit to the board an individual, written certification of the:

1. Name and license number of each licensee in attendance at the program;

2. Sessions attended by each licensee; and

3. Number of hours of each session attended.]

Section 4. Incorporation[Incorporated] by Reference. (1) The following material is[forms are] incorporated by reference:

(a) "PACE Pre-Check Expedited Course Submission for Kentucky form[application]", (2020); and

(b) "Kentucky Board of Chiropractic Examiners Continuing Education Application[for approval to provide CE program]". September [[2020[]].

(2) These materials may be *inspected, copied, or obtained, subject to applicable copyright law,[reviewed]* at the Kentucky Board of Chiropractic Examiners, 500 Mero Street, Frankfort, Kentucky 40601, from 8:00 a.m. to 4:00 p.m.

CONTACT PERSON: David C. Trimble, Board Attorney, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 782-8823, fax +1 (502) 564-3969, email DavidC.Trimble@ky.gov.

BOARDS AND COMMISSIONS Board of Chiropractic Examiners (As Amended at ARRS, October 13, 2020)

201 KAR 21:095. Licensure, registration, and standards of persons performing peer review.

RELATES TO: KRS 312.175, 312.200(3)

STATUTORY AUTHORITY: KRS 312.019(9)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 312.019(9) authorizes the board to promulgate administrative regulations <u>consistent with KRS Chapter 312 governing the practice of chiropractic</u>. KRS 312.200(3) requires that persons performing peer review of chiropractic claims be licensed by the board, complete annually a board approved utilization review course, and annually register with the board and pay a registration fee. This administrative regulation establishes the requirements for the licensure, review course, registration, and registration fee for persons to perform peer review services.

Section 1. Requirements for Licensure and Registration. A person performing chiropractic peer review shall:

(1) Hold a current active license to practice chiropractic within the Commonwealth of Kentucky;

(2) (a) For the first year that a person seeks to register to perform peer review, have previously successfully completed a course consisting of a minimum of 100 hours of utilization review and independent medical examination from a chiropractic college or university accredited by the Council on Chiropractic Education; and

(b) [For each year thereafter that a person seeks to register to perform peer review, have completed six (6) hours of utilization review offered by a chiropractic college or university accredited by the Council on Chiropractic Education, which shall be obtained within the Commonwealth of Kentucky;] For each year thereafter that a person seeks to register to perform peer review, have completed six (6) hours of continuing education in topics specifically related to utilization review and approved by the **board/KBCE1** to meet this requirement which shall be obtained at a live, in-person event **[**, which shall be obtained] within the Commonwealth of Kentucky; and

(3) Register annually with the board, by June 1 of each year, by:

(a) Presenting evidence of satisfactory compliance with the requirements established in this section and of having met the education requirements of KRS 312.175;

(b) Completing the Registration Form for Persons Performing Peer Review of Kentucky Chiropractic Claims; and

(c) Paying a registration fee of fifty (50) dollars.

Section 2. In performing peer review activities, a licensee shall: (1) Render the actual review service and documented report;

(2) Personally retain a copy of all records associated with each peer review case for a minimum of seven (7) years;

(3) Employ minimum standards associated with the practice of chiropractic and comply with the code of ethical conduct established in 201 KAR 21:015;

(4) Provide a report that includes the rationale for the determination in order that the licensee provider is given adequate information to appeal;

(5) Sign all reports, unless the review is performed under the Kentucky Chiropractic Board of Examiners Peer Review Committee, in which case, the board's administrator or designee shall sign the determination;

(6) Review in accordance with accepted standards as defined in 201 KAR 21:001;

(7) Review thoroughly and rely on all documents provided to the reviewer;

(8) List in the resulting report all documents provided to the reviewer and list all documents reviewed; and

(9) Personally conduct the review and prepare the report.

Section 3. Complaint Procedure Related to Peer Reviewers. A complaint against a peer reviewer alleging a violation of this administrative regulation or any other provision of KRS Chapter 312 or 201 KAR Chapter 21 shall be filed and processed according to the procedure established in 201 KAR 21:051.

Section 4. Incorporation by Reference.

(1) "Registration Form for Persons Performing Peer Review of Kentucky Chiropractic Claims" 2013, is incorporated by reference.

(2) <u>This material may be inspected, copied, or obtained,</u> <u>subject to applicable copyright law, at the Kentucky Board of</u> <u>Chiropractic Examiners, 500 Mero Street, Frankfort, Kentucky</u> <u>40601, from 8:00 a.m. to 4:00 p.m.</u> [This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Chiropractic Examiners, 209 South Green Street, Glasgow, Kentucky 42141, Monday through Friday, 8:00 a.m. to 4:30 p.m.] [These materials may be reviewed at the Kentucky Board of Chiropractic Examiners, 500 Mero Street, Frankfort, Kentucky 40601, from 8:00 a.m. to 4:00 p.m.]</u>

CONTACT PERSON: David C. Trimble, Board Attorney, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 782-8823, fax +1 (502) 564-3969, email DavidC.Trimble@ky.gov.

JUSTICE AND PUBLIC SAFETY CABINET Department of Corrections (As Amended at ARRS, October 13, 2020)

501 KAR 6:120. Blackburn Correctional Complex.

RELATES TO: KRS Chapters 196, 197, 439

STATUTORY AUTHORITY: KRS 196.035, 197.020, 439.470, 439.590, 439.640

NECESSITY, FUNCTION, AND CONFORMITY: KRS 196.035, 197.020, 439.470, 439.590, and 439.640 authorize the Justice and Public Safety Cabinet and Department of Corrections to promulgate administrative regulations necessary and suitable for the proper administration of the department or any division therein. These policies and procedures are incorporated by reference in order to comply with the accreditation standards by the American Correctional Association. This administrative regulation establishes the policies and procedures for the Blackburn Correctional Complex.

Section 1. Incorporation by Reference.

(1) "Blackburn Correctional Complex Policies and Procedures," <u>October 13[September 1], [May 14,]</u> 2020[March 14, 2008], are incorporated by reference. Blackburn Correctional Complex Policies and Procedures include:

[BCC 01-11-01	Roles of Consultants, Contract Employees,
	Volunteers and Employees of Other
	Agencies
DOO 01 10 01	
BCC 01-13-01	Relationships with Public, Media, and
	Other Agencies
BCC 01-13-02	Public Information and News Media Access
BCC 01-19-01	Inmate Access to BCC Staff]
BCC 02-01-01	Inmate Canteen (Amended
	<u>10/13/20[5/14/20])</u>
BCC 02-01-02	Inmate Canteen Committee (Added
	5/14/20)
BCC 02-07-01	Inmate [Personal] Accounts (Amended
200 02 01 01	<u>10/13/20[5/14/20])</u>
[BCC 05-01-01	
[800 03 01 01	Posoarch
BCC 06-02-02	Offender Records (Amended
DCC 00-02-02	
	0/14/20[10/14/02])
[BCC 08-02-01	Natural Disaster Plan (Tornado)
BCC 08-04-01	Fire Safety Plan, Drills and Related Duties]
BCC 08-06-01	Storage, Control and Accountability of
	Flammable, Toxic, Caustic and Other
	Hazardous Materials (Amended
	<u>5/14/20[10/14/02])</u>
BCC 08-08-01	Lockdown in Place (Added 5/14/20)
BCC 09-02-03	Daily Controlled[Regulation of] Inmate
	Movement (Amended 5/14/20)
BCC 09-03-02	Population Counts and Count
	Documentation (Added 10/13/20[5/14/20])
[BCC 09-03-01	Inmate Identification]
BCC 09-14-01	Prohibiting Inmate Authority Over Other
BCC 09-23-01	Inmates (Amended 5/14/20)
BCC 09-23-01	Inmates (Amended 5/14/20) Restricted Areas (Added 5/14/20)
BCC 09-23-01 [BCC 09-19-01	Inmates (Amended 5/14/20) Restricted Areas (Added 5/14/20) Duties and Responsibilities of the
[BCC 09-19-01	Inmates (Amended 5/14/20) Restricted Areas (Added 5/14/20) Duties and Responsibilities of the Institutional Captain]
	Inmates <u>(Amended 5/14/20)</u> <u>Restricted Areas (Added 5/14/20)</u> <u>Duties and Responsibilities of the</u> <u>Institutional Captain</u>] Temporary [Segregation] Holding Area
[BCC 09-19-01 BCC 10-01-02	Inmates (Amended 5/14/20) Restricted Areas (Added 5/14/20) Duties and Responsibilities of the Institutional Captain] Temporary [Segregation] Holding Area (Amended 10/13/20[9/1/2020][5/14/20])
[BCC 09-19-01	Inmates (Amended 5/14/20) Restricted Areas (Added 5/14/20) Duties and Responsibilities of the Institutional Captain] Temporary [Segregation] Holding Area (Amended 10/13/20[9/1/2020][5/14/20]) Meal Planning and Procedure [Menu-and
[BCC 09-19-01 BCC 10-01-02	Inmates (Amended 5/14/20) Restricted Areas (Added 5/14/20) Duties and Responsibilities of the Institutional Captain] Temporary [Segregation] Holding Area (Amended 10/13/20[9/1/2020][5/14/20]) Meal Planning and Procedure [Menu and Restricted Diets] (Amended
[BCC 09-19-01 BCC 10-01-02 BCC 11-01-01	Inmates (Amended 5/14/20) Restricted Areas (Added 5/14/20) Duties and Responsibilities of the Institutional Captain] Temporary [Segregation] Holding Area (Amended 10/13/20[9/1/2020][5/14/20]) Meal Planning and Procedure [Menu and Restricted Diets] (Amended 10/13/20[5/14/20][12/10/02])
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CONTACT PERSON: Amy V. Barker, Assistant General Counsel, Justice & Public Safety Cabinet, 125 Holmes Street, Frankfort, Kentucky 40601, phone (502) 564-3279, fax (502) 564-6686, email Justice.RegsContact@ky.gov.

KENTUCKY COMMUNITY AND TECHNICAL COLLEGE SYSTEM Kentucky Fire Commission (As Amended at ARRS, October 13, 2020)

739 KAR 2:040. Survivor benefits for death of a firefighter.

RELATES TO: KRS 95A.210, KRS 61.315 STATUTORY AUTHORITY: KRS 61.315(3)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 61.315(3) authorizes the <u>Kentucky Fire Commission to</u> promulgate administrative regulations establishing criteria and procedures applicable to the administrative regulation of survivor benefits for death of a firefighter. This administrative regulation establishes these requirements. [payment of survivor benefits of \$80,000 the survivor of a paid or volunteer firefighter who is killed in the line of duty after July 1, 2002. This administrative regulation establishes the procedures and criteria that shall be utilized to determine the eligibility of the paid or volunteer firefighter's survivor benefits.]

Section 1. Definitions. (1) "Child or children" means a:

(a) Biological child or children, including a child or children born after the firefighter's death;

(b) Stepchild or stepchildren; and

(c) Legally adopted child or children.

(2) "Commission" means commission as defined by KRS 95A.210(1).

(3) "Death in the line of duty" means death that occurs as a direct result of an act or acts in the "performance of duty" as defined in subsection (6) of this section and includes death that results from a heart or circulatory malfunction that is treated within forty-eight (48) hours after participation in the performance of these duties or as the result of illness, cancer as established in KRS $61.315(\underline{11})[(\underline{10})]$, or other sickness or injury caused by the performance of these duties that result in death within twelve (12) months of the activities as established in this administrative regulation, if death is not caused by suicide or self-inflicted injury.

(4) "Firefighter" means firefighter as defined by KRS 61.315(1)(*b*).

(5) "Heart or circulatory malfunction" means myocardial infarction, angina pectoris, coronary thrombosis, cardiac arrest, or a cerebral vascular accident that **is[the symptoms are]** first medically treated within forty-eight (48) hours after participation in the performance of the duties of a paid firefighter as established in subsection (6) of this section.

(6) "Performance of duty" means a firefighter acting in the performance of his or her duties while engaged in the following activities if the activities are performed at the direction or with the knowledge of an officer of the fire department or if immediate action is required at the scene of an emergency not involving his department or other emergency organization:

(a) Firefighting;

(b) Fire drills or other related training;

(c) Rescue or emergency activities;

(d) Repairing or doing other work about or in the fire or emergency apparatus or building and grounds of the fire department;

(e) Traveling to or from a call for service;

(f) Riding in or upon the fire or emergency apparatus that is owned or used by the fire department;

(g) Performing other activities of the fire department as authorized by the jurisdiction that the department serves; or

(h) Attending meetings related to the fire service and travel to and from the meetings, as long as he or she is representing his or her local, state, or national fire related organization.

Section 2. Requirements for Eligibility. (1)(a) If death occurs after twelve (12) months and is related to the causes established in KRS $61.315(\underline{11})[(\underline{10})](b)$, the commission shall review the conditions to determine if the death constituted death in the performance of duty.

(b) Survivors. Benefits shall be paid to the surviving spouse,

surviving child or children or both; or the surviving parents, as set forth in KRS 61.315(2).

(2) Heart or circulatory malfunction limitations. (a) Eligible survivors shall receive benefits through KRS 61.325 if the firefighter:

1. Becomes an active member of a fire department;

2. Has not been medically diagnosed as having had, or has not been prescribed any medication for, the following conditions within 5 years prior to the date of membership:

a. Myocardial infarcation;

b. Angina pectoris;

c. Coronary thrombosis;

d. Cardiac arrest; or

e. Cerebral vascular incident; and

3. Dies in the line of duty. [If an individual becomes an active member of a fire department and has not within five (5) years prior to the date of membership been medically diagnosed as having had or has received any medication for myocardial infarction, angina pectoris, coronary thrombosis, cardiac arrest or a cerebral vascular accident, his or her eligible survivors shall receive the benefits if the firefighter dies in the line of duty.]

(b)Eligible survivors shall receive the benefits granted through KRS 61.315 [(a)] if the firefighter dies in the line of duty and:

<u>1. The firefighter</u> has been medically diagnosed as having had, or <u>having been prescribed[receiving]</u>medication for, an illness <u>listed[established]</u> in <u>paragraph (a) of</u> this subsection within five (5) years prior to becoming an active member of a fire department; <u>and</u>

2. The commission has been presented with a medical statement from the firefighter's doctor that the firefighter has recovered or been medically rehabilitated sufficiently to meet the physical demands of firefighting.

(c) 1. Survivors shall not be eligible to receive benefits from this program until the medical statement required by paragraph

(b) of this subsection is supplied to the commission in the following circumstances. The firefighter:

<u>a. Has been medically diagnosed as having had, or having been prescribed medication for, an illness listed in paragraph (a) of this subsection;</u>

b. Returns to active fire service; and

c. Dies as a result of a heart or circulatory malfunction.[

(b)1. If a firefighter of a fire department is medically diagnosed as having had or is prescribed medication for myocardial infarction, angina pectoris, coronary thrombosis, cardiac arrest or a cerebral vascular accident and returns to active fire service, his or her survivors shall not be eligible to receive benefits from this program in event of the firefighter's death caused by heart or circulatory malfunction until a medical statement from a physician establishes that the individual has recovered or has been medically rehabilitated sufficiently to meet the physical demands of firefighting is supplied the commission.]

2. Upon <u>the commission's</u> review and approval <u>of the</u> <u>medical statement</u>, pursuant to KRS Chapter 61 and this administrative regulation, [of the statement by the commission,] the firefighter's survivors shall become eligible to receive benefits from this program.

(d)[(c)] A deceased firefighter's survivors shall not be eligible for benefits under this administrative regulation if the deceased firefighter was mistakenly or fraudulently included on a fire department's roster, or did not actively serve as a firefighter for a minimum of five (5) years prior to diagnosis of the cause of death.

(3)(a) Autopsy. The commission shall reserve the right to request an autopsy *if [providing]* sufficient cause is shown for this request.

(b) If an autopsy is performed for any reason, a copy of the report signed by the individual who performs the autopsy and a notary public shall be submitted to the commission.

Section 3. Application. (1)(a) The fire department [Upon the

death in the line of duty of a firefighter, the fire department of which the firefighter was a member at the time of death] shall notify the commission's administrator [of the death] immediately upon the death in the line of duty of a firefighter who is a member of the department.

(b) Upon receipt of the notification, the administrator shall submit the Report of Firefighter's Death, Form KPF-4, to the notifying fire department in care of the chief; Claim for Survivor Benefits Form KPF-5, to the known survivors of the deceased firefighter; and the Requirements for Cancer Death Benefits form to both the notifying fire department in care of the chief and the known survivors of the deceased firefighter.

(2) Upon receipt of the forms required by subsection (1) of this section, the chief and survivors or their representative shall complete the forms and return them to the commission in care of the administrator.

(3) Upon the receipt of the completed forms established in subsection (1) of this section, a licensed physician [member of the commission] shall review all pertinent medical records and forms submitted on behalf of the deceased firefighter and make a medical determination <u>as to whether[of if]</u> the conditions surrounding the death qualify the family members for benefits pursuant to this administrative regulation.

(a) Upon the <u>licensed physician's</u> [medical director's] determination that the requirements of KRS 61.315 and this administrative regulation have been met, a committee of the commission appointed by the chair of the commission shall review the forms and forward the forms with the <u>committee's</u> [commission's] recommendations to the full commission for determination of eligibility.

(b) If there are questions about the forms, the committee and the administrator may seek clarification of the questions on behalf of the commission.

Section 4. Certification of Payment of Benefits. Upon certification of survivorship rights to the Firefighter's Death Benefit, the sum of \$80,000 shall be paid in check by the state treasurer from the general expenditure fund of the state treasury, as required by KRS 61.315(2) and the treasurer shall transmit the check to the commission's administrator for payment to the eligible survivor or survivors.

Section 5. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Report of Firefighter's Death" Form KPF-4, November 7, 2016;

(b) "Claim for Survivor Benefits" Form KPF-5, December 1, 2014; and

(c) "Requirements for Cancer Death Benefits", July 2016.

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CONTACT PERSON: Jonathan L. Gay, Counsel for the Kentucky Fire Commission, 118 James Court, Lexington, Kentucky 40505, phone (859) 225-4714, fax (859) 225-1493, email administrativeregulations@wgmfirm.com.

KENTUCKY COMMUNITY AND TECHNICAL COLLEGE SYSTEM Kentucky Fire Commission (As Amended at ARRS, October 13, 2020)

739 KAR 2:155. Alan "Chip" Terry Professional Development and Wellness Program.

RELATES TO: KRS 95A.292

STATUTORY AUTHORITY: KRS 95A.292(<u>4</u>) NECESSITY, FUNCTION, AND CONFORMITY: KRS 95A.292(4) requires the <u>Kentucky Fire</u> Commission to promulgate administrative regulations to implement the provisions of KRS 95A.292. This administrative regulation establishes (1) the qualifications and duties of persons used by the Commission to implement and administer the Alan "Chip" Terry Professional Development and Wellness Program; (2) the curriculum, programming, seminar type, and treatment modalities used in the program; (3) the extent to which a participating firefighter's relatives or friends may participate in seminars; (4) the standards by which professional and volunteer firefighters from other states may be accepted into the program by the executive director; and (5) a protocol for establishing reciprocity for interagency assistance with other state, federal, and tribal professional and volunteer firefighters in administering the program.

Section 1. Definitions. (1) "IAFF" means the International Association of Fire Fighters.

(2) "Program" means the Alan "Chip" Terry Professional Development and Wellness Program and the seminars conducted <u>under this program[thereunder]</u>.

Section 2. Instructor Qualifications. (1) Any instructor used by the commission to implement and administer the program shall:

(a) Be a professional, retired, or volunteer firefighter;

(b) Have a minimum of two (2) years' experience as a peer supporter;

(c) Have a minimum of one (1) year of teaching or training experience; and

(d) Submit proof of completion of the two-day IAFF Peer Support Training, or its equivalent, to the commission.

(2) Any instructor used by the commission to implement and administer the program shall have training in general stress, [;] group processes, [;] human communication skills, [;] direct intervention strategies, [;] post-traumatic stress disorder and depression, [;] suicide awareness and postvention, [;] addressing stigma, [;] understanding barriers to care, [;] and substance abuse.

Section 3. Curriculum, Programming, Seminar Type, and Treatment Modalities. (1) The curriculum, programming, and treatment modalities used in the program shall be the IAFF Behavioral Health Peer Support Training Student Manual.

(2) The seminar shall consist of a prerequisite online course and two (2) in-person, eight (8) hour day peer support seminars designed to train peer support personnel to provide peer support to other firefighters.

Section 4. Non-firefighter Participation. (1) A participating Kentucky firefighter may permit no more than two (2) non-firefighters to attend and participate in the program with the Kentucky firefighter.

(2) Out-of-state non-firefighters shall not attend or participate in the program.

Section 5. Out-of-state Firefighter Participation. (1) The executive director shall permit any out-of-state, federal, or tribal professional or volunteer firefighter to participate in the program if the out-of-state, federal, or tribal professional or volunteer firefighter submits to the commission:

(a) A driver's license identifying the professional or volunteer firefighter;

(b) Proof of current status as a professional or volunteer firefighter;

(c) A completed Alan "Chip" Wellness Program Out-of-State Participant Application; and

(d) A letter from the chief of the fire department for which the firefighter works or volunteers setting forth the professional or volunteer firefighter's need to participate in the program.

(2)[(i)] The letter <u>required by subsection (1)(d) of this</u> <u>section</u> shall not include any medical or confidential information regarding the professional or volunteer firefighter without the professional or volunteer firefighter's written consent.

(3)(2)) Notwithstanding section (1) of this section, an out-ofstate professional or volunteer firefighter shall not be accepted into the program if the out-of-state professional or volunteer firefighter's participation in the program would prevent a Kentucky professional or volunteer firefighter from participating in the program, <u>in</u> <u>accordance with KRS 95A.292(3)</u>.

Section 6. Out-of-state Reciprocity for Interagency Assistance in Administering the Program.

(1) Any out-of-state instructor used by the commission to implement and administer the program shall:

(a) Satisfy the requirements of Section 2 of this administrative regulation;

(b) Submit a driver's license identifying the out-of-state instructor to the commission;

(c) Submit proof of status as a professional, retired, or volunteer firefighter to the commission; and

(d) Submit a completed Alan "Chip" Wellness Program Out-of-State Instructor Application to the commission.

(2) An out-of-state instructor who satisfies the requirements of this section shall be permitted to administer seminars under the program in the Commonwealth of Kentucky in coordination with the commission.

Section 7. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "IAFF Behavioral Health Peer Support Training Student Manual", 9/2018;[-]

(b) "Alan "Chip" Wellness Program Out-of-State Participant Application", 6/20; and[-]

(c) "Alan "Chip" Wellness Program Out-of-State <u>Instructor</u> [Participant] Application", 6/20.

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PUBLIC PROTECTION CABINET Department of Insurance Financial Standards and Examination Division (As Amended at ARRS, October 13, 2020)

806 KAR 3:170. Annual audited financial reports.

RELATES TO: KRS <u>304.1-040</u>, 304.1-050, 304.2-065, 304.2-210-304.2-290, 304.3-120, 304.3-125, 304.3-240, 304.3-241, 304.17A-820, 304.32-210, 304.35-040, <u>304.36-140</u>, 304.37-010, 304.37-020, **[304.36-140,]**304.42-150, 304.45-030, 304.45-040, 304.48-110, 304.49-070(2), 304.49-080, 304.49-090, 304.50-060, 304.50-075, 18 U.S.C. Chapter 96, Pub. L. 107-204[1961, 1968]

STATUTORY AUTHORITY: KRS 304.2-110, 304.3-240, 304.49-140

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110 authorizes the Commissioner of the Department of Insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code as established[defined] in KRS 304.1-010. KRS 304.3-240 authorizes the commissioner to promulgate administrative regulations concerning the publication of financial statements. KRS 304.49-170[304-49-140] authorizes the commissioner to promulgate administrative regulations relating to captive insurance companies that are necessary to enable the commissioner to carry out the provisions of KRS 304.49-010 through [304.39-010 to] 304.49-230. This administrative regulation establishes requirements concerning the annual filing of audited financial reports by insurers.

Section 1. Definitions. (1)(a) "Accountant" <u>means:</u> (a)[and "independent certified public accountant" mean] An independent certified public accountant or accounting firm in good standing with the American Institute of Certified Public Accountants and in all states in which <u>the accountant is[they are]</u> licensed to practice:

(b) For Canadian and British insurers, **["accountant" means]** a Canadian-chartered or British-chartered accountant.

(2) "Affiliate" or "affiliated" is defined by KRS 304.37-010(4).

(3) "Audit committee" means a committee, or equivalent body, established by the board of directors of an entity for the purpose of overseeing the accounting and financial reporting processes of an insurer or group of insurers, the internal audit function of an insurer of group of insurers, if applicable, and external audits of financial statements of the insurer or group of insurers.

(4) "Audited financial report" means <u>a report consisting of</u> those items <u>established[specified]</u> in Section 4 of this administrative regulation.

(5) "Commissioner" is defined *by[in]* KRS 304.1-050(1).

(6) "<u>Control[Controlling person]</u>" is defined <u>by[in]</u> KRS 304.37-010(3)[(8)].

(7) "Department" is defined in KRS 304.1-050(2).

(8) "Group of insurers" means those licensed insurers included in the reporting requirements of KRS 304.37-020, or a set of insurers as identified by management, for the purpose of assessing the effectiveness of internal control over financial reporting.

(9) "Insurer" is defined by KRS 304.1-040.

(10) <u>"Internal audit function" means a person who[that]</u> provides independent objective and reasonable assurance designed to add value and improve an organization's operations and accomplish its objectives by bringing a systematic, disciplined approach to evaluate and improve the effectiveness of risk management, control, and governance processes."

(11) "Internal control over financial reporting" means a process affected by an entity's board of directors, management, and other personnel designed to provide reasonable assurance regarding the reliability of the financial statements and includes those policies and procedures that:

(a) Pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of assets;

(b) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements and that receipts and expenditures are being made only in accordance with authorizations of management and directors; and

(c) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of assets that could have a material effect on the financial statements.

(12) [(11)] "SEC" means the United States Securities and Exchange Commission.

(13) [(12)] "Section 404" means Section 404 of the Sarbanes-Oxley Act of 2002, *Pub. L. 107-204*, and the SEC's rules and regulations promulgated under Section 404.

(<u>14</u>) [(13)] "Section 404 Report" means management's report on "internal control over financial reporting" as defined by the SEC <u>at 17 C.F.R. 240.13a-15(f)</u> and the related attestation report of the [independent certified public]accountant.

(15) [(14)] "SOX compliant entity" means an entity that either is required to be compliant with, or voluntarily is compliant with, all of the following provisions of the Sarbanes-Oxley Act of 2002, <u>Pub.</u> L. 107-204:

(a) The preapproval requirements of Section 202[201];

(b) The audit committee independence requirements of Section 301; and

(c) The internal control over financial reporting requirements of Section 404.

(16) [(15)] "Work papers" mean the records kept by the [independent certified public]accountant of the procedures followed, the tests performed, the information obtained, and the conclusions reached pertinent to the <u>accountant's[independent</u> certified public accountants] audit of the financial statements of an insurer. Work papers <u>can[may]</u> include audit planning documentation, work programs, analyses, memoranda, letters of confirmation and representation, abstracts of insurer documents, and schedules or commentaries prepared or obtained by the *[independent certified public]* accountant in the course of the accountant's[independent certified public accountants] audit of the financial statements of an insurer and <u>that[which]</u> support the accountant's[independent certified public accountants] opinion of the financial statements of an insurer.

Section 2. Purpose and Scope. (1) This administrative regulation shall be to improve the department's surveillance of the financial condition of insurers by requiring:

(a) An annual audit of financial statements reporting the financial position and the results of operations of insurers by **[independent certified public]** accountants;

(b) Communication of internal control related matters noted in an audit; and

(c) Management's report of internal control over financial reporting.

(2) <u>Except as established in paragraph (a) of this</u> <u>subsection</u>, every insurer shall be subject to this administrative regulation.[Insurers having direct premiums written in this state of less than one (1) million dollars in any calendar year and less than 1,000 policyholders or certificate holders of direct written policies nationwide at the end of the calendar year shall be exempt from this administrative regulation.]

(a) Unless the commissioner makes a specific finding that compliance is necessary for the department to carry out its statutory responsibilities, <u>an insurer[insurers]</u> shall be exempt during years in which the following conditions exist. The insurer has, at the end of the calendar year:

1. Direct premiums written in this state of less than 1,000,000; and

2. Less than 1,000 policyholders or certificate holders of direct written policies nationwide.

(b) <u>An insurer with[Insurers that have]</u> assumed premiums of \$1,000,000 or more pursuant to contracts or treaties of reinsurance shall not be exempt from this administrative regulation.

(3) <u>A</u> foreign or alien <u>insurer[insurers]</u> filing the audited financial report in another state, pursuant to the other state's requirement for filing an audited financial report, which has been found by the commissioner to be substantially similar to the requirements of this administrative regulation, shall be exempt from this administrative regulation if:

(a) The following documents, which are filed with the other state, are filed with the commissioner in accordance with Sections 4, <u>10[11]</u> and <u>11[12]</u> of this administrative regulation:

1. A copy of the audited financial report;

2. Communication of internal control related matters noted in an audit; and

3. The accountant's letter of qualifications.[;] Canadian insurers may submit accountants' reports as filed with the Office of Superintendent of Financial Institutions, Canada; and

(b) A copy of any notification of adverse financial condition report filed with the other state is filed with the commissioner within the time **<u>established[specified]</u>** in Section 9 of this administrative regulation.

(4) <u>A</u> foreign or alien <u>insurer[insurers]</u> required to file management's report of internal control over financial reporting in another state shall be exempt from filing the report in this state if:

(a) The other state has substantially similar reporting requirements; and

(b) The report is filed with the commissioner of the other state within the **other state's required** time[**specified**].

(5) This administrative regulation shall not prohibit, preclude, or in any way limit the commissioner from ordering, conducting, or performing examinations of insurers under KRS 304.2-210 through **304.2-290 through 304.2-300[304.2-290]**, 304.17A-820, 304.32-210, 304.35-040, 304.36-140, 304.42-150, 304.48-110, 304.49-080, or 304.50-075.

Section 3. General Requirements Related to Filing and Extensions for Filing of Annual Audited Financial Reports and Audit Committee Appointment. (1) All insurers shall have an annual audit

by an *[independent certified public]* accountant and shall file an audited financial report with the commissioner on or before June 1 for the year ended December 31 immediately preceding. The commissioner may, <u>based on whether or not the company is</u> <u>determined to be in a "hazardous condition" pursuant to KRS</u> <u>304.2-065</u>, require an insurer to file an audited financial report earlier than June 1 with ninety (90) days advance notice to the insurer.

(2) Extensions of the June 1 filing date may be granted by the commissioner for thirty (30) day periods upon showing by the insurer and its *[independent certified public]* accountant the reasons for requesting the extension and determination by the commissioner of good cause for an extension. The request for extension shall be submitted in writing not less than ten (10) days prior to the due date and contain sufficient detail to permit the commissioner to make an informed decision as to the requested extension.

(3) If an extension is granted in accordance with subsection (2) of this section, a similar extension of thirty (30) days shall be granted to the filing of management's report of internal control over financial reporting.

(4) Every insurer required to file an annual audited financial report pursuant to this administrative regulation shall designate a group of individuals as constituting its audit committee. The audit committee of an entity that controls an insurer may be deemed to be the insurer's audit committee for purposes of this administrative regulation at the election of the controlling person.

Section 4. Contents of Annual Audited Financial Report. (1) The annual audited financial report shall report the financial condition of the insurer as of the end of the most recent calendar year and the results of its operations, cash flows, and changes in capital and surplus for the year then ended in conformity with statutory accounting practices <u>established[prescribed]</u>, or otherwise permitted, by the insurance supervisory authority of the insurer's state of domicile.

(2) The annual audited financial report shall include the [following]:

(a) Report of the independent certified public accountant;

(b) Balance sheet for reporting admitted assets, liabilities,

capital, and surplus;

(c) Statement of operations;

(d) Statement of cash flows;

(e) Statement of changes in capital and surplus;

(f) Notes to financial statements as required by KRS 304.3-240 in accordance with KRS 304.3-241. These notes shall also include:

1. A reconciliation of differences, if any, between the audited statutory financial statements and the annual statement filed pursuant to KRS 304.3-240 with a written description of the nature of these differences; and

2. A summary of ownership and relationships of the insurer and all affiliated companies; and

(g) The financial statements included in the audited financial report shall be:

1. Prepared in a form and using language and groupings substantially the same as the relevant sections of the annual statement of the insurer filed with the commissioner; and

2. Comparative, presenting the amounts as of December 31 of the current year and the amounts as of the immediately preceding December 31. **[However,]**In the first year in which an insurer is required to file an audited financial report, the comparative data may be omitted. The annual statement forms and instructions <u>shall</u> <u>be[are]</u> those <u>established[prescribed]</u> by the National Association of Insurance Commissioners as required by KRS 304.3-240.

Section 5. Designation of **[Independent Certified Public]**Accountant. (1) Each insurer required by this administrative regulation to file an annual audited financial report shall, within sixty (60) days after becoming subject to this requirement, register with the commissioner in writing the name and address of the **[independent certified public]**accountant or accounting firm retained to conduct the annual audit <u>required by[set forth in]</u> this administrative regulation. [Insurers not retaining an independent certified public accountant on the effective date of this administrative regulation shall register the name and address of their retained certified public accountant not less than six (6) months before the date when the first audited financial report is to be filed.]

(2) The insurer shall obtain a letter from the accountant [,] and file a copy with the commissioner, stating that the accountant is aware of the provisions of the insurance laws of the insurer's state of domicile that relate to accounting and financial matters and affirming that the accountant <u>shall[will]</u> express the accountant's opinion on the financial statements in terms of their conformity to the statutory accounting practices <u>established[prescribed]</u> or otherwise permitted by the insurance regulatory authority in that state, <u>stating[specifying]</u> any exceptions as the accountant <u>believes[may believe]</u> appropriate.

(3) If an accountant who was the accountant for the immediately preceding filed audited financial report is dismissed or resigns the insurer shall:

(a) Within five (5) business days notify the commissioner of this event;

(b) <u>Submit to</u>[Furnish] the commissioner, [with] a separate letter within ten (10) business days of the [above] notification <u>established in paragraph (a) of this subsection, if</u> stating [whether] in the twenty-four (24) months preceding the accountant's resignation, there were any disagreements with the former accountant <u>that</u>[which], if not resolved to the satisfaction of the former accountant, would cause the accountant to make reference to the subject matter of the disagreement in connection with the opinion. These shall include disagreements:

1. Concerning accounting principles, financial statement disclosure, or auditing scope or procedure;

2. That have been resolved to the former accountant's satisfaction and those not so resolved; and

3. That occur at the decision-making level, that is, between personnel of the insurer responsible for presentation of its financial statements and personnel for the accounting firm responsible for rendering its report;

(c) Request the former accountant to <u>submit[furnish]</u> a letter addressed to the insurer stating whether <u>or not</u> the accountant agrees with the statements contained in the insurer's letter, and, if not, stating the reasons for which the accountant does not agree; and

(d) <u>Submit[Furnish]</u> the responsive letter from the former accountant to the commissioner together with its own.

Section 6. Qualifications of **[Independent Certified Public]**Accountant. (1) The commissioner shall not recognize any person or firm as a qualified **[independent certified public]**accountant if the person or firm:

(a) Is not in good standing with the American Institute of Certified Public Accountants and in all states in which the accountant is licensed to practice, or, for a Canadian or British insurer, that is not a chartered accountant; or

(b) Has either directly or indirectly entered into an agreement of indemnity or release from liability with respect to the audit of the insurer.

(2) Except as otherwise <u>established[provided]</u> in this administrative regulation, an *[independent certified public]* accountant shall be recognized as qualified if the *[independent certified public]* accountant conforms to the standards of the accounting profession, as contained in the statutes, administrative regulations, and codes of ethics and rules of professional conduct administered by the State Board of Accountancy of Kentucky in accordance with KRS Chapter 325 and 201 KAR Chapter 1.

(3) The lead or coordinating audit partner having primary responsibility for the audit shall not act in that capacity for more than five (5) consecutive years. <u>After five (5) consecutive years</u>, the person shall be disqualified from acting in that or a similar capacity for the same insurer or its insurance subsidiaries or affiliates for a period of five (5) years.

(a) An insurer may make application to the commissioner for

relief from this rotation requirement on the basis of <u>undue</u> <u>hardship[unusual circumstances]</u>. Application shall be made at least thirty (30) days before the end of the calendar year. The commissioner <u>shall[may]</u> consider the following factors in determining if the relief should be granted:

1. Number of partners, expertise of the partners, or the number of insurance clients in the currently registered firm;

2. Premium volume of the insurer; or

3. Number of jurisdictions in which the insurer transacts business.

(b) The insurer shall file with its annual statement filing the approval for relief from paragraph (a)1 of this subsection with the states that it is licensed in or doing business in and with the National Association of Insurance Commissioners. If the nondomestic state accepts electronic filing with the National Association of Insurance Commissioners, the insurer shall file the approval in an electronic format acceptable to the National Association of Insurance Commissioners via the Web site, https://www2.naic.org/servlet/Index.

(c) The commissioner shall not recognize as a qualified *[independent certified public]* accountant, nor accept any annual audited financial report, prepared in whole or in part by any natural person who:

1. Has been convicted of fraud, bribery, or a conviction of the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. *Chapter 96*[1961, 1968];

2. Has been found to have violated the insurance laws of this state with respect to any previous reports submitted under this administrative regulation; or

3. Has demonstrated a pattern or practice of failing to detect or disclose material information in previous reports filed under this administrative regulation.

(4) If an insurer disagrees with a determination made by the commissioner pursuant to subsection (3) of this section, it may request a hearing in accordance with KRS 304.2-310.

(5)(a) The commissioner shall not recognize as a qualified **[independent certified public]** accountant, nor accept an annual audited financial report prepared in whole or in part by an accountant who provides to an insurer, contemporaneously with the audit, the following nonaudit services:

1. Bookkeeping or other services related to the accounting records or financial statements of the insurer;

2. Financial information systems design and implementation;

3. Appraisal or valuation services, fairness opinions, or contribution-in-kind reports;

4. Actuarially-oriented advisory services involving the determination of amounts recorded in the financial statements. The accountant may assist an insurer in understanding the methods, assumptions, and inputs used in the determination of amounts recorded in the financial statement only if it is reasonable to conclude that the services provided will not be subject to audit procedures during an audit of the insurer's financial statements. An accountant's actuary may also issue an actuarial opinion or certification on an insurer's reserves if [the following conditions have been met]:

a. Neither the accountant nor the accountant's actuary has performed any management functions or made any management decisions;

b. The insurer has competent personnel or engages a third party actuary to estimate the reserves for which management takes responsibility; and

c. The accountant's actuary tests the reasonableness of the reserves after the insurer's management has determined the amount of the reserves;

5. Internal audit outsourcing services;

6. Management functions or human resources;

7. Broker or dealer, investment adviser, or investment banking services; or

8. Legal services or expert services unrelated to the audit.

(b) A qualified independent public accountant shall not:

1. Function in the role of management;

2. Audit his or her own work; and

3. Serve in an advocacy role for the insurer.

(6)(a) <u>An insurer[Insurers]</u> having direct written and assumed premium of less than \$100,000,000 in any calendar year may request an exemption from subsection (5)(a) of this section.

(b) To request an exemption, the insurer shall file with the commissioner a written statement discussing the reasons why the insurer should be exempt from these provisions.

(c) If <u>requested and if</u> the commissioner finds, upon review of this statement, that compliance with this administrative regulation would constitute an organizational hardship upon the insurer, an exemption <u>shall[may]</u> be granted.

(7) A qualified **[independent certified public]** accountant who performs the audit may engage in other nonaudit services, including tax services, that are not **established[described]** in subsection **(**5)(a) of this section or that do not conflict with subsection **(**5)(b) of this section, only if the activity is approved in advance by the audit committee in accordance with subsection (8) of this section.

(8)(a) All auditing services and nonaudit services provided to an insurer by the qualified *[independent certified public]*accountant of the insurer shall be preapproved by the audit committee.

(b) The preapproval requirement shall be waived with respect to nonaudit services if:

1. The insurer is a SOX compliant entity or a direct or indirect wholly-owned subsidiary of a SOX compliant entity; or

2.a. The aggregate amount of all non-audit services provided to the insurer constitutes not more than five (5) percent of the total amount of fees paid by the insurer to its qualified *[independent certified public]* accountant during the fiscal year in which the nonaudit services are provided;

b. The services were not recognized by the insurer at the time of the engagement to be nonaudit services; and

c. The services are **[promptly]** brought to the attention of the audit committee and approved prior to the completion of the audit by the audit committee or by one (1) or more members of the audit committee who are the members of the board of directors to whom authority to grant approvals has been delegated by the audit committee.

(9) The audit committee may delegate to one (1) or more designated members of the audit committee the authority to grant the preapprovals required by subsection (8) of this section. The decisions of any member to whom this authority is delegated shall be presented to the full audit committee at each of its scheduled meetings.

(10)(a)1. The commissioner shall not recognize an *[independent certified public]* accountant as qualified for a particular insurer if the following were employed by the *[independent certified public]* accountant and participated in the audit of that insurer during the one (1) year period preceding the date that the most current statutory opinion is due:

a. A member of the board;

b. President;

c. Chief executive officer;

d. Controller;

e. Chief financial officer;

f. Chief accounting officer; or

g. Any person serving in an equivalent position for that insurer.2. This subsection shall only apply to partners and senior managers involved in the audit.

3. An insurer may make application to the commissioner for relief from the **[above]**requirements **established in this subsection** on the basis of **undue hardship[unusual circumstances]**.

(b) The insurer shall file, with its annual statement filing, the approval for relief from *paragraph (a)[subsection (10)(a)]* of this *subsection[section]* with the states that it is licensed in or doing business in and the National Association of Insurance Commissioners. If the nondomestic state accepts electronic filing with the National Association of Insurance Commissioners, the insurer shall file the approval in an electronic format acceptable to the National Association of Insurance Commissioners via the Web site, https://www2.naic.org/servlet/Index.

Section 7. Consolidated or Combined Audits. An insurer may make written application to the commissioner for approval to file audited consolidated or combined financial statements in lieu of separate annual audited financial reports if the insurer is part of a group of insurers **<u>that</u>[which]** utilizes a pooling or 100 percent reinsurance agreement that affects the solvency and integrity of the insurer's reserves and the insurer cedes all of its direct and assumed business to the pool. In these cases, a columnar consolidating or combining worksheet shall be filed with the report, as **established** *in* **subsections** (1) **through** (5) of **this section.[follows:]**

(1) Amounts shown on the consolidated or combined audited financial report shall be shown on the worksheet.[;]

(2) Amounts for each insurer subject to this section shall be stated separately.[;]

(3) Noninsurance operations may be shown on the worksheet or a combined or individual basis_[;]

(4) Explanations of consolidating and eliminating entries shall be included_*[; and]*

(5) A reconciliation shall be included of any differences between the amounts shown in the individual insurer columns of the worksheet and comparable amounts shown in the annual statements of the insurers.

Section 8. Scope of Examination and Report of *[Independent Certified Public]*Accountant. (1) Financial statements *submitted[furnished]* pursuant to Section 4 of this administrative regulation shall be examined by the *[independent certified public]*accountant.

(2) The examination of the insurer's financial statements shall be conducted in accordance with generally accepted auditing standards.

(3) In accordance with SAS No. 109, ["]Understanding the Entity and Its Environment and Assessing the Risks of Material Misstatement["] and SAS No. 110, ["]Performing Audit Procedures in Response to Assessed Risks and Evaluating the Audit Evidence Obtained[", or their replacements], the [independent certified public]accountant shall obtain an understanding of internal control sufficient to plan the audit.

(4) To the extent required by SAS 109 and SAS 110, for those insurers required to file a management's report of internal control over financial reporting pursuant to Section 2 of this administrative regulation, the *[independent certified public]* accountant shall consider the most recently available report in planning and performing the audit of the statutory financial statements.

(5) Consideration shall also be given to other procedures illustrated in the Financial Condition Examiner's Handbook of the National Association of Insurance Commissioners <u>that[which]</u> the *[independent certified public]* accountant deems necessary.

Section 9. Notification of Adverse Financial Condition. (1)(a) The insurer required to <u>submit[furnish]</u> the annual audited financial report shall require the *[independent certified public]* accountant to report, in writing, within five (5) business days to the board of directors or its audit committee any determination by the *[independent certified public]* accountant that the insurer has materially misstated its financial condition as reported to the commissioner as of the balance sheet date currently under examination or that the insurer does not meet the minimum capital and surplus requirements of KRS 304.3-120 and 304.3-125 as of that date.

(b) An insurer <u>that[which]</u> has received a report pursuant to this subsection shall forward a copy of the report to the commissioner within five (5) business days of receipt of the report and shall provide the *[independent certified public]* accountant making the report with evidence of this report being <u>submitted[furnished]</u> to the commissioner.

(c) If the **[independent certified public]** accountant fails to receive this evidence within the required five (5) business day period, the **[independent certified public]** accountant shall **submit[furnish]** to the commissioner a copy of its report within the next five (5) business days.

(2) An *[independent certified public]* accountant shall not be

liable in any manner to any person for any statement made in connection with subsection (1) of this section if the statement is made in good faith in compliance with subsection (1) of this section.

(3) If the accountant, subsequent to the date of the audited financial report filed pursuant to this administrative regulation, becomes aware of facts <u>that[which]</u> might have affected his report, the commissioner <u>shall note[netes]</u> the obligation of the accountant to take the action <u>established[prescribed]</u> in Volume 1, Section AU 561 of the Professional Standards of the American Institute of Certified Public Accountants.

Section 10. Communication of Internal Control Related Matters Noted in an Audit.

(1)(a) In addition to the annual audited financial statements, each insurer shall <u>submit to[furnish]</u> the commissioner [with] a written communication as to any unremediated material weakness in its internal control over financial reporting noted during the audit.

(b) The communication shall be prepared by the accountant within sixty (60) days after the filing of the annual audited financial report **[**,**]** and shall contain a description of any unremediated material weaknesses as of December 31 immediately preceding in the insurer's internal control over financial reporting noted by the accountant during the course of <u>the accountant's[their]</u> audit of the financial statements.

(c) If **[no]**unremediated material weaknesses were <u>not</u> noted, the communication shall state that none were found.

(2) <u>If the action is not included in the accountant's</u> <u>communication</u>, an insurer shall provide a description of remedial actions taken or proposed to correct unremediated material weaknesses[, if the action is not described in the accountant's communication].

Section 11. Accountant's Letter of Qualifications. The accountant shall <u>submit to[furnish]</u> the insurer in connection with, and for inclusion in, the filing of the annual audited financial report, a letter stating:

(1) That the accountant is independent with respect to the insurer and conforms to the standards of the accountant's profession as contained in statutes, administrative regulations, and rules of professional conduct of the State Board of Accountancy of Kentucky set forth in KRS Chapter 325 and 201 KAR Chapter 1;

(2) The background and experience in general, and the experience in audits of insurers of the staff assigned to the engagement and whether <u>or not</u> each is an *[independent certified public]* accountant. This administrative regulation shall not prohibit the accountant from utilizing staff as the accountant deems appropriate if use is consistent with the standards <u>established[prescribed]</u> by generally accepted auditing standards;

(3) That the accountant understands the annual audited financial report, that the accountant's opinion on it <u>shall[will]</u> be filed in compliance with this administrative regulation, and that the commissioner will be relying on this information in monitoring the financial position of insurers;

(4) That the accountant consents to the requirements of Section 12 of this administrative regulation and that the accountant consents and agrees to make <u>the work papers</u> available for review by the commissioner, <u>the commissioner's[his]</u> designee, or <u>the commissioner's[his]</u> appointed agent[, the work papers];

(5) **[A representation]** That the accountant is properly licensed by an appropriate state licensing authority and is a member in good standing of the American Institute of Certified Public Accountants; and

(6) **[A representation]**That the accountant is in compliance with the requirements of Section 6 of this administrative regulation.

Section 12. Availability and Maintenance of *[Independent Certified Public]*Accountant Work Papers. (1) Every insurer required to file an audited financial report pursuant to this administrative regulation shall require the accountant to make available for review by department examiners all work papers prepared in the conduct of the accountant's audit and any

communications related to the audit between the accountant and the insurer, at the offices of the insurer, at the department, or any other reasonable place designated by the commissioner. The insurer shall require that the accountant retain the audit work papers and communications until the department has filed a report on examination covering the period of the audit, but no longer than seven (7) years from the date of the audit report.

(2) In the conduct of the periodic review by department examiners <u>established[described]</u> in subsection (1) of this section, it shall be agreed that photocopies of pertinent audit work papers may be made and retained by the department. Reviews by the department examiners shall be considered investigations, and all working papers and communications obtained during the course of shall be afforded the same confidentiality as other examination work papers generated by the department.

Section 13. Requirements for Audit Committees. This section shall not apply to foreign or alien insurers licensed in this state or an insurer that is a SOX compliant entity or a direct or indirect wholly-owned subsidiary of a SOX compliant entity.

(1) The audit committee shall be directly responsible for the appointment, compensation, and oversight of the work of any accountant, including resolution of disagreements between management and the accountant regarding financial reporting, for the purpose of preparing or issuing the audited financial report or related work pursuant to this administrative regulation. Each accountant shall report directly to the audit committee.

(2)(a) The audit committee of an insurer or group of insurers shall be responsible for **supervising[overseeing]** the insurer's internal audit function and granting the person performing the function suitable authority and resources to fulfill the responsibilities if required by Section 14 of this administrative regulation.

(b) If an audit committee is not designated by the insurer, the insurer's entire board of directors shall constitute the audit committee.

(3) Each member of the audit committee shall be a member of the board of directors of the insurer or a member of the board of directors of an entity elected pursuant to subsection (6) [(5)] of this section and section 3(4) of this administrative regulation.

(4)[(3)](a) <u>Except as established in paragraph (b) of this</u> <u>subsection</u>, a member of the audit committee shall not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee;

1. Accept any consulting advisory or other compensatory fee from the entity; or

2. Be an affiliated person of the entity or any subsidiary.

(b) [Notwithstanding paragraph (a) of this subsection,] If the law requires board participation by otherwise nonindependent members, that law shall prevail and the members may participate in the audit committee and be designated as independent for audit committee purposes, unless <u>the member is[they are]</u> an officer or employee of the insurer or one (<u>1</u>) of its affiliates.

(5) [(4)] If a member of the audit committee ceases to be independent for reasons outside the member's reasonable control, that person, with notice by the responsible entity to the state, may remain an audit committee member of the responsible entity until the earlier of:

(a) The next annual meeting of the responsible entity; or

(b) One (1) year from the occurrence of the event that caused the member to be no longer independent.

(6) [(5)](a) At the election of the controlling person, the audit committee of any entity that controls a group of insurers may be deemed to be the audit committee for one (1) or more of these controlled insurers solely for the purposes of this administration regulation.

(b) To exercise the election of the controlling person to designate the audit committee for purposes of this administrative regulation, the ultimate controlling person shall provide written notice to the commissioners of the affected insurers.

(c) [(b)] Notification shall be made timely prior to the issuance of the statutory audit report and shall include a description of the basis for the election.

(d) [(c)] The election can be changed through notice to the commissioner by the insurer which shall include a description of the basis for the change.

(e) [(d)] The election shall remain in effect for perpetuity, until rescinded.

(7)[(6)](a) The audit committee shall require the accountant that performs for an insurer any audit required by this administrative regulation to timely report to the audit committee in accordance with the requirements of SAS 114, ["]The Auditor's Communication With Those Charged With Governance["], or its replacement, including:

1. All significant accounting policies and material permitted practices;

2. All material alternative treatments of financial information within statutory accounting principles that have been discussed with management officials of the insurer, ramifications of the use of the alternative disclosures and treatments, and the treatment preferred by the accountant; and

3. Other material written communications between the accountant and the management of the insurer, including any management letter or schedule of unadjusted differences.

(b)<u>1</u>. If an insurer is a member of an insurance holding company system, the reports required by paragraph (a) of this subsection may be provided to the audit committee on an aggregate basis for insurers in the holding company system.

<u>2.[, provided that]</u> Any substantial differences among insurers in the system <u>shall be[are]</u> identified to the audit committee.

(8)[(7)](a) <u>Except as established in paragraph (b) of this</u> <u>subsection</u>, the proportion of independent audit committee members shall meet or exceed the following criteria:

1. For prior calendar year direct written and assumed premiums between \$0 and \$300,000,000, no minimum requirements;

2. For prior calendar year direct written and assumed premiums over \$300,000,000 to \$500,000,000, fifty (50) percent or more of members shall be independent; and

3. For prior calendar year direct written and assumed premiums over \$500,000,000; seventy-five (75) percent of members shall be independent.

(b) **[Notwithstanding subsection (7)(a) of this section,]**The commissioner may require the audit committee's board to enact improvements to the independence of the audit committee membership if the insurer:

1. Is in a risk-based capital action level in accordance with 806 KAR 3:190; or

2. Meets one <u>(1)</u> or more of the standards of an insurer deemed to be in <u>"hazardous financial condition"</u>, as established in KRS 304.2-065, or otherwise exhibits qualities of a <u>"troubled insurer"</u>, as <u>established[set forth]</u> in KRS <u>304.3-625[304.2-065]</u>.

(c) An insurer with less than \$500,000,000 in prior year direct written and assumed premiums may structure its audit committee with at least a supermajority of independent audit committee members.

(d) For purposes of subsection (7)(a) of this section, prior calendar year direct written and assumed premiums shall be the combined total of direct premiums and assumed premiums from nonaffiliates for the reporting entities.

(9) [{8}](a) An insurer with direct written and assumed premium, excluding premiums reinsured with the Federal Crop Insurance Corporation and <u>National Flood Insurance[Federal</u> Floed] Program, less than \$500,000,000 may make application to the commissioner for a waiver from the requirements of this section based upon hardship.

(b) The insurer shall file, with its annual statement filing, the approval for relief from this section with the states that it is licensed in or doing business in and the National Association of Insurance Commissioners.

(c) If the nondomestic state accepts electronic filing with the National Association of Insurance Commissioners, the insurer shall file the approval in an electronic format acceptable to the National Association of Insurance Commissioners, via the Web site, https://www2.naic.org/servlet/Index.

Section 14. Internal Audit Function Requirements.

(1) An insurer shall be[is] exempt from the requirements [requirement] of this section if the insurer.

(a) [The insurer]Has annual direct written and unaffiliated assumed premium, including international direct and assumed premium but excluding premiums reinsured with the Federal Crop Insurance Corporation and National Flood Insurance[Federal Flood] Program, less than \$500,000,000[\$5,000,000,000]; or

(b) [The insurer] is a member of a group of insurers that has annual direct written and unaffiliated assumed premium including international direct and assumed premium, but excluding premiums reinsured with the Federal Crop Insurance Corporation and **National Flood Insurance**[Federal_Flood] Program, less than \$1,000,000,000.

(2) The insurer or group of insurers shall establish an internal audit function providing independent, objective, and reasonable assurance to the audit committee and insurer management regarding the insurer's governance, risk management, and internal controls. This assurance shall be provided by:

(a) Performing general and specific audits, reviews, and tests; and

(b) Employing other techniques deemed necessary to protect assets, evaluate control effectiveness and efficiency, and evaluate compliance with policies and *KAR Title 806[regulations]*.

(3) In order to ensure that internal auditors remain objective, the internal audit function **shall[must]** be organizationally independent.

(a) [Specifically,] The internal audit function shall:

1. [Shall]Not defer ultimate judgment on audit matters to others; and

2. **[Shall]**Appoint an individual to **head[health]** the internal audit function who shall have direct and unrestricted access to the board of directors.

(b) Organization independence shall not preclude dualreporting relationships.

(4) The head of the internal audit function shall report to the audit committee regularly, but no less than annually, on:

(a) The periodic audit plan;

(b) Factors that **could[may]** adversely impact the internal audit function's independence or effectiveness;

(c) Material findings from completed audits; and

(d) The appropriateness of corrective actions implemented by management as a result of audit findings.

(5) If an insurer is a member of an insurance holding company system or included in a group of insurers, the insurer may satisfy the internal audit function requirements **established**[set forth] in this section at:

(a) The ultimate controlling parent level;

(b) An intermediate holding company level; or

(c) The individual legal entity level.

<u>Section 15.</u> Conduct of Insurer in Connection with the Preparation of Required Reports and Documents. (1) A director or officer of an insurer shall not, directly or indirectly:

(a) Make or cause to be made a materially false or misleading statement to an accountant in connection with any audit, review, or communication required under this administrative regulation; or

(b) Omit to state, or cause another person to omit to state, any material fact necessary in order to make statements made, in light of the circumstances under which the statements were made, not misleading to an accountant in connection with any audit, review, or communication required under this administrative regulation.

(2) An officer or director of an insurer, or any other person acting under the direction of the officer or director, shall not, directly or indirectly, take any action to coerce, manipulate, mislead, or fraudulently influence any accountant engaged in the performance of an audit pursuant to this administrative regulation if that person knew or should have known that the action, if successful, could result in rendering the insurer's financial statements materially misleading.

(3) An officer or director of an insurer, or any other person acting under the direction of the officer or director, shall not, directly or indirectly, take any of the following actions to coerce, manipulate, mislead, or fraudulently influence an accountant with respect to the professional engagement period:

(a) To issue or reissue a report on an insurer's financial statements that is not warranted in the circumstances due to material violations of statutory accounting principles as required by KRS 304.3-241, generally accepted auditing standards, or other professional or regulatory standards;

(b) Not to perform audit, review, or other procedures required by generally accepted auditing standards or other professional standards;

(c) Not to withdraw an issued report; or

 $(\ensuremath{\mathsf{d}})$ Not to communicate matters to an insurer's audit committee.

Section <u>16</u> [45]. Management's Report of Internal Control over Financial Reporting. (1)(a) <u>Except as established in subsection</u> (2) of this section, every insurer required to file an audited financial report pursuant to this administrative regulation that has annual direct written and assumed premiums, excluding premiums reinsured with the Federal Crop Insurance Corporation and <u>National Flood Insurance[Federal Flood]</u> Program, of \$500,000,000 or more shall prepare a report of the insurer's or group of insurers' internal control over financial reporting.

(b) The report shall be filed with the commissioner along with the communication of internal control related matters noted in an audit.

(c) Management's report of internal control over financial reporting shall be as of December 31 immediately preceding.

(2) [Notwithstanding the premium threshold in subsection (1)(a) of this section,] The commissioner may require an insurer to file management's report of internal control over financial reporting if the insurer:

(a) Is in any risk-based capital level event in accordance with 806 KAR 3:190; or

(b) Meets one (1) or more of the standards of an insurer deemed to be in <u>"hazardous financial condition"</u> in accordance with KRS 304.2-065.

(3) An insurer or a group of insurers meeting the following requirements may file its or its parent's Section 404 Report and an addendum in satisfaction of the requirements of this section if those internal controls of the insurer or group of insurers having a material impact on the preparation of the insurer's or group of insurer's audited statutory financial statements were included in the scope of the Section 404 Report:

(a) Directly subject to Section 404;

(b) Part of a holding company system whose parent is directly subject to Section 404;

(c) Not directly subject to Section 404, but is a SOX compliant entity; and

(d) A member of a holding company system whose parent is not directly subject to Section 404 but is a SOX compliant entity.

(4) Management's report of internal control over financial reporting shall include:

(a) A statement that management <u>shall be[is]</u> responsible for establishing and maintaining adequate internal control over financial reporting;

(b) A statement that management has established internal control over financial reporting and an assertion, to the best of management's knowledge and belief, after diligent inquiry, as to whether <u>or not</u> its internal control over financial reporting is effective to provide reasonable assurance regarding the reliability of financial statements in accordance with statutory accounting principles;

(c) A statement that briefly describes the approach or processes by which management evaluated the effectiveness of internal control over financial reporting;

(d) A statement that briefly describes the scope of work that is included and whether <u>or not</u> any internal controls were excluded;

(e) Disclosure of any unremediated material weaknesses in the internal control over financial reporting identified by management as of December 31 immediately preceding. Management shall not conclude that the internal control over financial reporting is effective to provide reasonable assurance regarding the reliability

of financial statements in accordance with statutory accounting principles if there is one (1) or more unremediated material weaknesses in its internal control over financial reporting;

(f) A statement regarding the inherent limitations of internal control systems; and

(g) Signatures of the chief executive officer and the chief financial officer.

(5) Management shall document and make available upon financial condition examination the basis upon which its assertions, required in subsection (4) of this section, are made. Management may base its assertions, in part, upon its review, monitoring, and testing of internal controls undertaken in the normal course of its activities.

(a) Management shall have discretion as to the nature of the internal control framework used, and the nature and extent of the documentation, in order to make its assertion in a cost effective manner and may include assembly of or reference to existing documentation.

(b) The following shall have one (1) year following the year the threshold is exceeded to comply with the independence requirements in Section 6 of this administrative regulation, but not earlier than January 1, 2010. An insurer or group of insurers that, pursuant to Section 13 of this administrative regulation:

1. Is not required to have independent audit committee members or is required to have only a majority of independent audit committee members because the total written and assumed premiums is below the threshold; and

2. Subsequently becomes subject to one (1) of the independence requirements due to changes in premium.

Section 17 [16]. Exemptions and Effective Dates. (1) Upon written application of any insurer, the commissioner may grant an exemption from compliance with any or[and] all provisions[provision] of this administrative regulation if the commissioner finds, upon review of the application, that compliance with this administrative regulation would constitute a financial or organizational hardship upon the insurer. An exemption may be granted any time and from time to time for a specified period or periods. Upon denial of an insurer's written request for an exemption from this administrative regulation, the insurer may request a hearing on its application for an exemption. The hearing process shall be pursuant to KRS 304.2-310.

(2) <u>The requirements of this administrative regulation shall</u> be in effect for audits of calendar years beginning January 1, <u>2010[Domestic insurers retaining a certified public accountant</u> on the effective date of this administrative regulation who qualify as independent shall comply with this administrative regulation for the year ending December 31, 2010, and each year thereafter unless the commissioner permits otherwise.

(3) Domestic insurers not retaining a certified public accountant on the effective date of this administrative regulation who qualify as independent shall meet the following schedule for compliance unless the commissioner permits otherwise:

(a) As of December 31, 2010, file with the commissioner an audited financial report.

(b) For the year ending December 31, 2010, and each year thereafter, these insurers shall file with the commissioner all reports and communication required by this administrative regulation.

(4) Foreign insurers shall comply with this administrative regulation for the year beginning January 1, 2010, and each year thereafter.

(5)(a) The requirements of Section 13 of this administrative regulation shall be effective January 1, 2010.

(b) An insurer or group of insurers that, pursuant to Section 13 of this administrative regulation, is not required to have independent audit committee members or only a majority of independent audit committee members because the total written and assumed premiums is below the threshold and subsequently becomes subject to one (1) of the independence requirements due to changes in premium shall have one (1) year following the year the threshold is exceeded, but not earlier than January 1, 2010, to comply with the independence requirements in Section 6 of this administrative regulation.

(c) An insurer that becomes subject to one of the independence requirements as a result of a business combination shall have one (1) calendar year following the date of acquisition or combination to comply with the independence requirements in Section 13 of this administrative regulation.

(6)(a) The requirements of Section <u>16</u>] [15][of this administrative regulation shall be effective beginning with the reporting period ending December <u>31</u>, 2010 and each year thereafter.

(b) An insurer or group of insurers that is not required to file an annual audit report because the total written premium is below the threshold and subsequently becomes subject to the reporting requirements shall have two (2) years following the year the threshold is exceeded, but not earlier than December 31, 2010, to file an annual audit report.

(c) An insurer acquired in a business combination shall have two (2) calendar years following the date of acquisition or combination to comply with the reporting requirements in Section 4 of this administrative regulation].

Section <u>18</u> [47]. Canadian and British Companies. (1) In the case of Canadian and British insurers, the annual audited financial reports shall be *[defined as]* the annual statement of total business in the manner filed by these insurers with their supervisory authority duly audited by an independent chartered accountant.

(2) For Canadian and British insurers, the letter required by Section 5 of this administrative regulation shall state that the accountant is aware of the requirements relating to the annual audited financial report filed with the commissioner pursuant to Section 3 of this administrative regulation and shall affirm that the opinion expressed is in conformity with the requirements of Section 3 of this administrative regulation.

Section <u>19</u> [18]. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Financial Condition Examiner's Handbook", <u>2020</u> [2008], National Association of Insurance Commissioners;

(b) AU Section 561, "Subsequent Discovery of Facts Existing at the Date of the Auditor's Report", 1996 Professional Standards of the American Institute of Certified Public Accountants;

(c) SAS 114, "The Auditors Communication with Those Charged with Governance", 2007, American Institute of Certified Public Accountants;

(d) SAS 109, "Understanding the Entity and Its Environment and Assessing the Risks of material Misstatement", 2007 American Institute of Certified Public Accountants; and

(e) SAS 110, "Performing Audit Procedures in Response to Assessed Risks and Evaluating the Audit Evidence", 2007 American Institute of Certified Public Accountants.

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PUBLIC PROTECTION CABINET Department of Insurance Financial Standards and Examination Division (As Amended at ARRS, October 13, 2020)

806 KAR 6:010. Valuation standards; audits.

RELATES TO: KRS 304.2-290, 304.6-130-304.6-180 STATUTORY AUTHORITY: KRS 304.2-110

NECESSITY, FUNCTION, AND CONFORMITY: JEO 2004-731, signed July 9, 2004, created the Department [Office] [of Insurance.]KRS 304.2-110(1) authorizes the commissioner [executive director] of insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any the provision of Kentucky Insurance Code as established[defined] in KRS 304.1-010. KRS 304.6-130 through[te] 304.6-180 requires the commissioner [executive director] to annually value the liability item of the NAIC Annual Statement form as itemized in Exhibit 5 of that statement. This administrative regulation establishes[provides] the framework for acceptable valuation standards and establishes[that are acceptable, and provides] mortality tables for the determination of adequate reserves.

Section 1. Definitions. (1) "1958 Commissioners Extended Term Table of Mortality" means the mortality table <u>that[which]</u>:

(a) Is based on underwriting requirements that do not include evidence of medical insurability; and

(b) Incorporates mortality rates adequate to take into account the increase in mortality rate to which the class of persons whose lives are insured with credit life insurance are subject.

(2) "1958 Commissioners Standard Ordinary Table of Mortality" means the mortality table <u>that is[which]</u>:

(a) **[#s]**Based on underwriting requirements that include evidence of medical insurability; and

(b) **[Is]**A recognized table of mortality that will produce substantially the same result as the "1958 Commissioners Extended Term Table of Mortality" if thirty (30) percent is added, the additional thirty (30) percent being the amount necessary to result in mortality rates adequate to take into account the increase in mortality to which the class or persons whose lives are insured by credit life insurance are subject.

(3) "2001 Commissioners Standard Ordinary Male Composite Ultimate Mortality Table" means a mortality table <u>that[which]</u>:

(a) Consists of rates for male lives in the ultimate form with smokers and nonsmokers combined;

(b) Was developed by the American Academy of Actuaries CSO Task Force from the Valuation Basic Mortality Table developed by the Society of Actuaries Individual Life Insurance Valuation Mortality Task Force and adopted by the NAIC in December 2002; and

(c) Includes both the age-nearest-birthday and age-lastbirthday bases of the mortality tables.

(4) "Credit Life Insurance" is defined in KRS 304.19-020(1).

(5) <u>"Life actuary" means a person who computes premium</u> <u>rates, dividends, and risks according to probabilities based on</u> statistical records for life insurance and annuities.

(6) "Single Premium Credit Life Insurance" means credit life insurance for which a charge often is passed on to the debtor for the term of the coverage of the term of the debt and that is often included in the total sum of the obligation.

Section 2. Valuation. In conjunction with the valuation required by KRS 304.6-130, each domestic life insurer shall, in the form of an affidavit by its actuary or consulting actuary, <u>submit to[furnish]</u> the life actuary[, in the manner, form, and order as he may **prescribe**], totals and summaries in connection with valuation as the life actuary may deem necessary. In addition, each domestic life insurer shall supply and <u>submit[furnish]</u> to the life actuary, in corresponding order, with the necessary documentation, lists, tabulations and working papers for policy contract obligations to be valued, which shall be in readily accessible and auditable form at the home office of the insurer.

Section 3. Certificate of Valuation. The <u>commissioner</u> [executive director] <u>shall[may]</u> accept for purposes of issuing a certificate of valuation, the ["]Request for Certification of Reserves["] by a domestic life insurance company, which <u>shall</u> <u>be[is]</u> certified by an actuary[deemed satisfactory for the purpose by the <u>commissioner</u>[executive director]. [However,]The <u>commissioner</u> [executive director] shall annually cause the records of domestic life insurance companies to be audited, using appropriate methods to assure [himself]that life insurance companies are properly valuing their reserve liabilities as established by KRS Chapter 304[provided by statute].

Section 4. Components of life insurance policies, annuities, and pure endowment contracts shall include contracts and[,] any riders or additional benefits related to the contract.

Section 5. Credit Life Insurance. (1) Pursuant to the authority established[contained] in KRS 304.6-140(2)(a), the reserves for all policies of single premium group credit life insurance and all single premium individual credit life insurance issued to be effective prior to January 1, 2006 shall be computed on the basis of:

(a) 100 percent of the 1958 Commissioners Extended Term Table of Mortality;

(b) 130 percent of the 1958 Commissioners Standard Ordinary Table of Mortality; or

(c) In accordance with subsection (2) of this section.

(2) Pursuant to *[the authority contained in]*KRS 304.6-140(2)(a) the minimum standard for reserves for all policies of group credit life insurance and individual credit life insurance issued to be effective prior to January 1, 2006, may be determined as established in paragraphs (a) through (d) of this subsection.[according to the following:]

(a) The interest rates used in determining the minimum standard for valuation shall be the calendar year statutory valuation interest rates as established[defined] in KRS 304.6-145.[;]

(b) The method used in determining the minimum standard for valuation shall be the commissioners reserve valuation method as established[defined] in KRS 304.6-150.[;]

(c) The minimum mortality standard for both male and female insureds shall be the 2001 Commissioners Standard Ordinary Male Composite Ultimate Mortality Table.[; and]

(d) Where the credit life insurance policy or certificate insures two (2) lives, the minimum mortality standard shall be twice the mortality in the 2001 Commissioners Standard Ordinary Male Composite Ultimate Mortality Table based on the age of the older insured.

(3) Pursuant to the authority contained in KRS 304.6-140(2)(a) the minimum standard for reserves for all policies of group credit life insurance and individual credit life insurance issued to be effective on or after January 1, 2006, shall be determined according to the following:

(a) The interest rates used in determining the minimum standard for valuation shall be the calendar year statutory valuation interest rates as defined in KRS 304.6-145;

(b) The method used in determining the minimum standard for valuation shall be the commissioners reserve valuation method as defined in KRS 304.6-150:

(c) The minimum mortality standard for both male and female insureds shall be the 2001 Commissioners Standard Ordinary Male Composite Ultimate Mortality Table; and

(d) If [Where] the credit life insurance policy or certificate insures two (2) lives, the minimum mortality standard shall be twice the mortality in the 2001 Commissioners Standard Ordinary Male Composite Ultimate Mortality Table based on the age of the older insured.

(4) Department [Office] of Insurance examiners, in examining company affairs, shall deem reserves maintained in accordance with this administrative regulation to be in compliance with the Kentucky Insurance Code, KRS Chapter 304, for all years under examination.

Section 6. ["]Special ["] Policies. (1) "Coupon," "pure endowment," "founders," "charter," "special ____ and similar type policies, shall use all of the policy benefits afforded in the computation of the mean reserve formula.

(a) Mean reserve factors shall be printed for use in the computation of policy reserves.

(b) The timing:[,] frequency of contingency, [(]if any[)]:[,] and the method of pure endowment payment shall be clearly shown in the formula used to compute the mean reserve.

(c) Mean reserve computation shall not deviate from the

formula and factor developed.

(2) Discriminatory and arbitrary action by the life insurance company to pay some benefits prior to contract date shall not create an asset or create a reduction of aggregate reserve liability unless an enforceable negotiable instrument is evidenced.

(3) A separate file of the ["]special ["] type policies established[mentioned] in subsection (1) of this section, shall be initiated by the Life Actuary of the Department [Office] of Insurance and shall be maintained by that[his] department [Office] in addition to policies filed with the Policy Analyst in the Life Division. For each domestic life insurance company, a folder for each ["]special["] type policy in force shall include a specimen policy, actuarial formula used to arrive at the mean reserve, and a factor table of the various factors by age at issue distributed for the in-force durations considered.

(4) For domestic life insurance companies with less than \$500,000,000 of individual life in force and who do not use a standardized program package with unit programming, the following benefit breakdown shall be necessary.

(a) In force volume used in the mean reserve valuation run shall be segregated to allow for auditing of the various benefits.

(b) These benefits shall be enumerated as provided for in the filed specimen policy and shall include basic policy, return of premium, unmatured endowments, and termination benefit.

(5) Domestic life insurers excluded by subsection (4) of this section shall have reporting procedures and requirements compatible with the program package without sacrificing any audit trail of factors and their application. The requirements may vary from company to company based on the procedure but shall be in a pattern consistent with that approved for that company, based on the annual audit in accordance with KRS 304.6-130 through 304.6-180, and shall closely follow the requirements for other domestic life insurance companies.

Section 7. Cost of Noncompliance. (1) If material is not established in available as this administrative regulation[outlined above], the additional burden of cost for additional time required by the staff of the department [Office] of Insurance, or its actuary, shall be borne by the life insurance company as established[provided] for in KRS 304.2-290. A special examination may be ordered by the commissioner [executive director], providing for a written report to the commissioner,[him or her] together with a time and expense billing to the company [so]examined.

(2) If a detail audit of reserves reveals that an error was made in the filed annual statement and in the certificate issued by the department [Office], the commissioner [executive director] shall[may] order the withdrawal of certification and reissuance of certificates and copies, and require a refiled NAIC annual statement on a significant error, or require[prescribe] corrective internal procedures in the company prior to the next filed NAIC statement for when the resultant error is not significant.

Section 8. Incorporation by Reference. (1) The following material is incorporated by reference:

"1958 Commissioners Extended Term Table (a) of

Mortality [(1958)]". 1958; (b) "1958 Commissioners Standard Ordinary Table of Mortality[(1958)]", 1958; and

(c) "2001 Commissioner Standard Ordinary Male Composite Ultimate Mortality Table [(2001).]", 2001.

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PUBLIC PROTECTION CABINET Department of Insurance Financial Standards (As Amended at ARRS, October 13, 2020)

806 KAR 6:080. Reserve standards for individual health insurance policies.

RELATES TO: KRS 304.6-070

STATUTORY AUTHORITY: KRS 304.2-110(1), 304.6-070

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110(1) authorizes[provides that] the <u>Commissioner</u> [Executive Director] of Insurance <u>to promulgate[may make]</u> reasonable administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code. KRS 304.6-070 <u>authorizes[provides that]</u> the <u>Commissioner</u> [Executive Director] of Insurance <u>to promulgate[shall_issue]</u> administrative regulations establishing minimum standards for reserves for individual health insurance policies. <u>This</u> <u>administrative regulation establishes the minimum standards</u> for reserves for individual health insurance policies.

Section 1. Active Life Reserves. (1) General.

(a) Active life reserves <u>shall be</u> [are] required for all in-force policies and <u>shall be</u> [are] in addition to any reserves required in connection with claims. For policy Types A, B, and C, <u>established[described]</u> in subsection (2) of this section, the minimum reserve <u>shall be</u> [is] determined as <u>established[specified]</u> in subsection (3) of this section [herein].

(b) **1.** Minimum standards[These] shall be[It is emphasized, however, that these are] [minimum standards_Jin accordance with [and_that] KRS 304.6-070.[] [requires_that] Higher, adequate reserves shall be established by the insurer in any case in which[where] experience indicates that these minimum standards do not place a sound value on the liabilities under the policy.

<u>2.</u> For policy Type D, the minimum reserve <u>shall</u> [should] be the gross pro rata unearned premium [(premium reserve)].

(2) Types of individual health insurance policies.

(a) Type A *[-]* policies <u>shall include policies that[which]</u> are guaranteed renewable for life or to a specified age, [such as sixty (60) or sixty-five (65),] at guaranteed premium rates.

(b) Type B **[-]** policies <u>shall include policies that[which]</u> are guaranteed renewable for life or to a specified age, [such as sixty (60) or sixty-five (65),] but under which the insurer reserves the right to change the scale of premiums.

(c) Type C [-] policies <u>shall include policies</u> in which the insurer has reserved the right to cancel or refuse for one (1) or more reasons, but has agreed implicitly or explicitly that, prior to a specified time or age, it will not cancel or decline renewal solely because of deterioration of health after issue [; however,] Policies shall not be considered of this type if the insurer has reserved the right to refuse renewal provided the right is to be exercised at the same time for all policies in the same category, if premiums are graded so as to be substantially proportionate to the costs of insurance at the various attained ages. [Policies which comply with KRS 304.17-275, on which premiums are based on issue age shall be][are of][this type.]

(d) Type D [-] <u>policies shall include</u> all other individual policies <u>not already established in paragraphs (a) through (c)</u> <u>of this subsection</u>.

(e) <u>A franchise policy shall not be classified</u> [The above does not classify "franchise"] as a type of policy. <u>Contract provisions</u> within a franchise policy in which[where] the right to refuse [Such policies are frequently written under an agreement limiting the insurer's right to cancel or refuse renewal. Usually the right is reserved to refuse] renewal of all policies in the group or other categories including [such as] those ceasing to be members of the association, shall be classified as [, and this would place such policies in] Type D [in accordance with the last clause under paragraph (c) of this subsection]. [However,] f premiums are based on the level premium principle in which any reflection of age is on the basis of age at issue, or if the renewal undertaking for the individual meets the requirements for Type A, B, or C, the franchise policy <u>shall be</u> [should be so] classified for reserve purposes <u>according to the type to which it belongs</u>.

(f) A policy <u>that has</u> [may have] guarantees qualifying it as Type A, B, or C until a specified age or duration after which the guarantees, or lack of guarantees[, may qualify it as Type A, B, C, or D. In such case, the policy in each period] <u>shall</u> [should] be considered for reserve purposes according to the type to which it then belongs.

(g) <u>If</u> [Where] all of the benefits of a policy, as <u>established[provided]</u> by rider or otherwise, are not of the same Type [(A, B, C, or D)], each benefit <u>shall</u> [should] be considered for reserve purposes according to the type to which it belongs.

(3) Reserve standards for policies of Type A, B, or C.

(a) Interest. The maximum interest rate for reserves <u>shall</u> [should] be the greater of <u>the maximum rate allowed by KRS</u> <u>304.6-120 through 304.6-180 and KAR Title 806 in the valuation</u> <u>of</u>.

1. [The maximum rate permitted by law in the valuation of]Currently issued life insurance:[,,] or

2. [The maximum rate permitted by law in the valuation of]Life insurance issued on the same date as the health insurance.

(b) Mortality. The mortality assumptions used for reserves <u>shall</u> [should] be according to a table <u>allowed[permitted]</u> by <u>KRS</u> 304.6-120 through 304.6-180 and KAR Title 806[Haw] in the valuation of life insurance issued on the same date as the health insurance.

(c) Morbidity or other contingency. Minimum standards with respect to morbidity <u>shall be</u> [are those] stated in <u>["]Reserve</u> <u>Standards for Individual Health Insurance["] incorporated by</u> <u>reference in [Appendix A of]</u> this administrative regulation[, which is subject to revision from time to time with respect to dates of issue of contracts].

(d) Negative reserves. Negative reserves on any benefit may be offset against positive reserves for other benefits in the same policy, but the mean reserve on any policy <u>shall not</u> [should never] be taken as less than one-half (1/2) the valuation net premium.

(e) Preliminary term. The minimum reserve shall be on the basis of two (2) years preliminary term.

(f) Reserve method. Mean reserves diminished by appropriate credit for valuation net deferred premiums. <u>The</u> [In no event, however, should the] aggregate reserve for all policies valued on the mean reserve basis, diminished by any credit for deferred premiums, <u>shall not</u> be less than the gross pro rata unearned premiums under **[such]**policies.

(g) Alternative valuation procedures and assumptions. If [Previded] the reserve on all policies to which the method or basis is applied is not less in the aggregate than the amount determined according to the applicable standards <u>established in paragraphs</u> (a) through (f) of this subsection[specified above], an insurer may use any reasonable assumptions as to the interest rate, mortality rates, or the rates of morbidity or other contingency, and may introduce an assumption as to the voluntary termination of policies. [Also, subject to the preceding condition,]The insurer may employ methods other than the methods <u>established in</u> <u>paragraphs (a) through (f) of this subsection[stated above]</u> in determining a sound value of its liabilities under <u>its[such]</u> policies, including [but not limited to the following]:

1. The use of midterminal policy reserves in addition to either gross or net pro rata unearned premium reserves;

2. Optional use of either the level premium, the one (1) year preliminary term, or the two (2) year preliminary term method;

3. Prospective valuation on the basis of actual gross premiums with reasonable allowance for future expenses;

4. The use of approximations including [such as] those involving age groupings, groupings of several years of issue, and average amounts of indemnity;

5. The computation of the reserve for one (1) policy benefit as a percentage of, or by other relation to, the aggregate policy reserves, exclusive of the benefit or benefits so valued; and

6. The use of a composite annual claim cost for all or any combination of the benefits included in the policies valued. For statement purposes, the net reserve liability may be shown as the excess of the mean reserve over the amount of net unpaid and

deferred premiums, or, regardless of the underlying method of calculation, it may be divided between the gross pro rata unearned premium reserve and a balancing item for the ["]policy reverse.["]

(h) Gross unearned preliminary term premium. <u>If</u> [Where] a preliminary term method, either with a one (1) year or two (2) year preliminary term period, is employed, the gross pro rata unearned premium to be used in the comparison <u>established[set forth]</u> in paragraph (f) of this subsection shall bear the same relationship to the net premium for the preliminary term period on the basis of the mortality, morbidity, and interest assumptions used for subsequent valuation as the gross premium charged bears to the net valuation premium used in subsequent years.

Section 2. Claim Reserves, Present Value of Amounts not Yet Due on Claims [_][(also called "Disabled Life Reserves" in the case of insurance providing loss-of-time benefits for disability due to accident or sickness)].

(1) General. Reserves <u>shall be</u> [are] required for claims on all health insurance policies, <u>including[whether]</u> of Type A, C, or D, providing benefits for continuing loss, <u>including</u> [such as] loss of time or hospitalization.

(2) Claim reserve standards for total disability due to accident or sickness.

(a) Interest. The maximum interest rate for reserves <u>shall</u> [should] be the maximum rate <u>allowed[permitted]</u> by <u>KRS 304.6-120 through 304.6-180 and KAR Title 806[Jaw]</u> in the valuation of life insurance issued on the same date as the date the claim is incurred.

(b) Morbidity. Minimum standards with respect to morbidity shall be [are] those stated in ["]Reserve Standards for Individual Health Insurance[" incorporated by reference in][Appendix A of][this administrative regulation], except that for unreported claims and resisted claims and, at the option of the insurer, claims with a duration of disablement option of the insurer, claims with a duration of disablement of less than two (2) years, reserves may be based on the individual insurer's experience or other assumptions designed to place a sound value on the liabilities. Reserves based on that [such] experience or assumptions shall [should] be verified by the development of each year's claims over a sufficient period of years along the lines of Schedule O of the insurer's annual statement.

(c) For policies with an elimination period, the duration of disablement <u>shall</u> [should] be considered as dating from the time that benefits would have begun to accrue had there been no elimination period.

(d) A new disability connected directly or indirectly with a previous disability <u>that's[which]</u> had a duration of at least one (1) year and terminated within six (6) months of the new disability <u>shall</u> [should] be considered a continuation of the previous disability.

(3) Reserve standards for all other claim reserves.

(a) Interest. The maximum interest rate for reserves <u>shall</u> [should] be the maximum rate <u>allowed[permitted]</u> by <u>KRS 304.6-120 through 304.6-180 and KAR Title 806[law]</u> in the valuation of life insurance issued on the same date as the date the claim is incurred.

(b) Morbidity or other contingency. The reserve <u>shall</u> [should] be based on the individual insurer's experience or other assumptions designed to place a sound value on the liabilities. The results <u>shall</u> [should] be verified by the development of each year's claims over a sufficient period of years along the lines of Schedule O of the insurer's annual statement.

(4) Valuation procedures. The insurer may employ suitable approximations and estimates, including [but not limited to] groupings and averages, in computing claim reserves.

Section 3. [Severability. If any provision of this administrative regulation or the application thereof to any person or circumstance is for any reason held to be invalid, the remainder of the administrative regulation and the application of the] [such] [provision to other persons or circumstances shall not be affected] [thereby]].

Section 4. Effective Date. This administrative regulation

shall become effective upon completion of its review pursuant to KRS Chapter 13A.

<u>Section 5.1</u> Incorporation by Reference. (1) "Reserve Standards for Individual Health Insurance", [[]6/2020[]], is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department of Insurance, 500 Mero Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.[APPENDIX A RESERVE STANDARDS FOR INDIVIDUAL HEALTH INSURANCE

HEALTH INSURANCE			
Minimum morbidity standards for valuation of individual health			
insurance policies are as follows:			
1. Total disability due to accident or sickness.			
	Active life reserves:		
		Policies issued on or after January 1 1965:	
		The 1964 Commissioners Disability Table.	
	Claim ra		
	Claim reserves:		
		The minimum morbidity standard in effect for	
		active life reserves on currently issued policies	
		as of the claim is incurred.	
2. Hospital benefits surgical benefits, and maternity benefits (either			
specified or expense reimbursement).			
	Policies issued on or after January 1 1955 and before		
	January 1 1982:		
		The 1956 Intercompany Hospital surgical Tables.	
	Polices	ssued on or after January 1 1982:	
		The 1974 Medical Expense Tables (Table A).	
3. Accidental death benefits.			
	Polices issued on or after January 1 1965:		
		The 1959 Accidental Death Benefits Table.	
	All other benefits including major medical cancer expense, and		
other than total disability.			
	The insurer should adopt a standard which will produce		
	reserves that place a sound value on its liabilities under		
	such benefit. The use of morbidity tables reflecting the		
	insurer's own experience with suitable margins for		
	stochastic variation is encouraged.]		

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PUBLIC PROTECTION CABINET Department of Insurance Financial Standards and Examination Division (As Amended at ARRS, October 13, 2020)

806 KAR 6:100. Actuarial opinion and memorandum.

RELATES TO: KRS 304.3-240, 304.6-070, 304.6-150, 304.6-155, 304.6-171, 304.6-180

STATUTORY AUTHORITY: KRS 304.2-110<u>(1)</u>, 304.6-171[₇ EO 2009-535]

NECESSITY, FUNCTION, AND CONFORMITY: [EO 2009-535, signed June 12, 2009, created the Department of Insurance, headed by the Commissioner of Insurance.] KRS 304.2-110(1) authorizes[provides that] the Commissioner [Executive Director] of Insurance to promulgate[may make] reasonable administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code, as established[defined] in KRS 304.1-010. KRS 304.6-171 requires every life insurance company doing business in this state to annually submit the opinion of a qualified actuary as to whether or not the reserves and related actuarial items held in support of the established[specified] by policies and contracts the commissioner [executive director] are computed appropriately. KRS 304.6-171 requires the commissioner [executive director] to

establish[define], by administrative regulation, the <u>requirements</u> [specifics] of the actuarial opinion and to broaden the scope of the opinion if necessary. This administrative regulation <u>establishes</u> <u>provisions[is_necessary]</u> for the commissioner to determine whether <u>or not</u> reserves and related actuarial items are computed appropriately, are based on assumptions <u>that[which]</u> satisfy contractual provisions, are consistent with prior reported amounts, and comply with <u>KRS Chapter 304[the applicable laws of this</u> state].

Section 1. Definitions. (1) "Actuarial opinion" means the opinion of an appointed actuary regarding the adequacy of the reserves and related actuarial items based on an asset adequacy test in accordance with Section 4 of this administrative regulation and with presently accepted actuarial standards.

(2) "Actuarial Standards Board" means the board established by the American Academy of Actuaries to develop and promulgate standards of actuarial practice.

(3) "Annual statement" means the statement required by KRS 304.3-240.

(4) "Appointed actuary" is defined by KRS 304.6-131(2)[means a qualified actuary who is appointed or retained to prepare and provide the statement of actuarial opinion and supporting memorandum required by this administrative regulation; either directly or by the authority of the board of directors through an executive officer of the company other than the qualified actuary].

(5) "Asset adequacy analysis" means an analysis that meets the standards and other requirements of Section 4 of this administrative regulation.

(6) "Commissioner" is defined by KRS 304.1-050(1)[means the Commissioner of the Department of Insurance].

(7) "Company" <u>is defined by KRS 304.6-131(3)[means a life</u> insurance company; fraternal benefit society doing business in this state; or a life insurance company or fraternal benefit society which is authorized to reinsure life insurance, annuities, or accident and health insurance business].[

(8) "Noninvestment grade bond" means a bond that is designated as a class 3, 4, 5, or 6 by the National Association of Insurance Commissioners Securities Valuation Office.

(9) "Qualified actuary" means any individual who is qualified to sign a statement of actuarial opinion for a life and health insurance company annual statement and who meets the qualifications of Section 2 of this administrative regulation.]

Section 2. Actuarial Qualifications. In order to be considered a qualified actuary for the purposes of this administrative regulation, a person shall:

(1) Be a member in good standing of the American Academy of Actuaries;

(2) Be qualified to sign a statement of actuarial opinion for a life and health insurance company annual statement in accordance with the qualification standards for actuaries established by the American Academy of Actuaries for actuaries signing those statements;

(3) Be familiar with the valuation requirements applicable to life and health insurance companies;

(4) Not been found by the commissioner, or if so found has subsequently been reinstated as a qualified actuary, following appropriate notice and hearing to have:

(a) Violated any provision of, or any obligation imposed by, any law in the course of his or her dealings as a qualified actuary;

(b) Been found guilty of fraudulent or dishonest practices;

(c) Demonstrated incompetence, lack of cooperation, or untrustworthiness to act as a qualified actuary;

(d) Submitted to the commissioner during the past five (5) years, pursuant to this administrative regulation, an actuarial opinion or memorandum that the commissioner rejected because it did not comply with this administrative regulation or standards established by the Actuarial Standards Board; or

(e) Resigned or been removed as an actuary within the past five (5) years as a result of an act or omission indicated in any adverse report on examination or as a result of the failure to adhere to generally acceptable actuarial standards; and

(5) Not have failed to notify the commissioner of any action taken by any commissioner of any other state <u>if the[which]</u> action was based on a disqualification standard <u>established[outlined]</u> in subsection (4) of this section.

Section 3. General Requirements. (1) Every company doing business in this state shall annually submit the opinion of an appointed actuary <u>stating[setting forth]</u> an opinion relating to reserves and related actuarial items held in support of policies and contracts, in accordance with Section 4 of this administrative regulation. The actuarial opinion shall be:

(a) Included on or attached to Page 1 of the annual statement for each year [beginning with the year in which this administrative regulation becomes effective];

(b) Entitled "Statement of Actuarial Opinion"; and

(c) The statement of an appointed actuary <u>stating[setting</u> forth] an opinion relating to reserves and related actuarial items held in support of policies and contracts in accordance with Section 4 of this administrative regulation.

(2) The commissioner **<u>shall[may]</u>** accept the statement of actuarial opinion filed by a foreign or alien company with the insurance supervisory regulator of another state if the commissioner determines that the opinion meets the requirements applicable to a company domiciled in this state.

(3) The commissioner <u>shall[may]</u> grant an extension of the date for submission of the statement of actuarial opinion upon written request by the company.

(4) The company shall give the commissioner timely written notice:

(a) If an actuary is appointed or retained and the notice shall state:

1. The name of the appointed actuary;

2. The title of the appointed actuary;

3. If the actuary is a consulting actuary, the name of the firm;

4. The manner of appointment or retention by the company of each appointed actuary; and

5. That the person appointed or retained by the company meets the requirements of a qualified actuary pursuant to Section 2 of this administrative regulation;

(b) If the actuary ceases to be appointed or retained as an appointed actuary or to meet the requirements of a qualified actuary; or

(c) If that any person appointed or retained as an appointed actuary replaces a previously appointed actuary, which notice shall state the reason for replacement.

(5) The asset adequacy analysis required by Section 4 of this administrative regulation shall:

(a) Conform to the Standards of Practice as promulgated by the Actuarial Standards Board and <u>available at</u> <u>http://www.actuarialstandardsboard.org/standards-of-practice/</u> to this administrative regulation, which standards shall form the basis of the statement of actuarial opinion in accordance with this administrative regulation; and

(b) Be based on methods of analysis <u>that shall be[as are]</u> appropriate for those purposes based on standards established by the Actuarial Standards Board.

(6) Pursuant to KRS 304.6-171, the statement of actuarial opinion shall apply to all in force business on the statement date, whether directly issued or assumed, regardless of when or where issued.

(7) If the appointed actuary determines as the result of the asset adequacy analysis that a reserve in addition to the aggregate reserve held by the company and calculated in accordance with the methods <u>established[set_forth]</u> in KRS 304.6-171 is necessary, the company shall establish the additional reserve.

(8)(a) Additional reserves established under subsection (7) of this section and determined by an actuary to not be necessary in subsequent years may be released <u>as reserves on the company's financial statement</u>.

(b) Any amounts released shall be disclosed in the actuarial opinion for the applicable year.

(c) The release of reserves shall not result in the adoption of a lower standard of valuation.

Section 4. Statement of Actuarial Opinion Based on an Asset Adequacy Analysis. (1) The statement of actuarial opinion required

by this section shall contain an opening paragraph, which shall: (a) Identify the name and title of the appointed actuary;

(b) Identify the name of the consulting firm, if applicable;

(c) Identify the name of the company;

(d) Identify the qualifications of the appointed actuary;

(e) Identify the manner in which the actuary was appointed or retained to render the actuarial opinion; and

(f) Include language identical or substantially similar to the following:

1. For a company actuary: "I, (name of actuary), am (title) of (name of company) and a member of the American Academy of Actuaries. I was appointed by, or by the authority of, the Board of Directors of said insurer to render this opinion as stated in the letter to the commissioner dated (insert date). I meet the Academy qualification standards for rendering the opinion and am familiar with the valuation requirements applicable to life and health insurance companies."; or

2. For a consulting actuary: "I, (name and title of actuary), a member of the American Academy of Actuaries, am associated with the firm of (insert name of consulting firm). I have been appointed by, or by the authority of, the Board of Directors of (name of company) to render this opinion as stated in the letter to the commissioner dated (insert date). I meet the Academy qualification standards for rendering the opinion and am familiar with the valuation requirements applicable to life and health insurance companies."

(2) The statement of actuarial opinion shall contain a scope paragraph, which shall:

(a) Identify the subjects on which an opinion is to be expressed;

(b) Describe the scope of the work of the appointed actuary;

(c) Include a tabulation delineating the reserves and related actuarial items <u>that</u>[which] have been analyzed for asset adequacy and the method of analysis;

(d) Identify the reserves and related actuarial items covered by the opinion *that[which]* have not been *[so]* analyzed; and

(e) Include language identical or substantially similar to the following: "I have examined the actuarial assumptions and actuarial methods used in determining reserves and related actuarial items listed below, as shown in the annual statement of the company, as prepared for filing with state regulatory officials, as of December 31, (year). Tabulated below in the Table of Reserves and Liabilities are those reserves and related actuarial items **that[which]** have been subjected to asset adequacy analysis."

(3) If the appointed actuary has relied on other experts to develop portions of the analysis, the statement of actuarial opinion shall contain a reliance paragraph, which shall:

(a) Describe each <u>situation in which[area where]</u> the appointed actuary has deferred to another expert in developing data, procedures, or assumptions; and

(b) [If the appointed actuary has relied on other experts to develop certain portions of the analysis,]Include a statement identical or substantially similar to the following and be accompanied by a statement in accordance with subsection (10) of this section:

1. "I have relied on (name), (title) for (<u>for example[e.g.]</u>, anticipated cash flows from currently owned assets, including variations in cash flows according to economic scenarios) and, as certified in the attached statement,..."; or

2. "I have relied on personnel as cited in the supporting memorandum for certain critical aspects of the analysis in reference to the accompanying statement."

(4) If the appointed actuary has examined the underlying asset and liability records, the statement of actuarial opinion shall include a statement identical or substantially similar to the following: "My examination included **[such]**review of the actuarial assumptions and actuarial methods and of the underlying basic asset and liability records and **[such]**tests of the actuarial calculations as I considered necessary."; and

(5) If the appointed actuary has not examined the underlying records, but has relied upon listings and summaries of policies in force or asset records prepared by the company or a third party, the statement of actuarial opinion required shall include a statement identical or substantially similar to the following and be accompanied by a statement in accordance with subsection (10) of this section: "In forming my opinion on (specify types of reserves) I relied upon data prepared by (name and title of company officer certifying in-force records) as certified in the attached statement. I evaluated that data for reasonableness and consistency. I also reconciled that data to (exhibits and schedules to be listed as applicable) of the company's current annual statement. In other respects my examination included review of the actuarial assumptions and actuarial methods and tests of the actuarial calculations as I considered necessary."

(6) The statement of actuarial opinion required by this section shall contain an opinion paragraph, which shall:

(a) Express the opinion of the appointed actuary with respect to the adequacy of the supporting assets to mature the liabilities that reserves and related actuarial values concerning the identified statement items:

1. Are computed in accordance with presently accepted actuarial standards consistently applied and are fairly stated, in accordance with sound actuarial principles;

2. Are based on actuarial assumptions **<u>that[which]</u>** produce reserves at least as great as those called for in any contract provision as to reserve basis and method, and are in accordance with all other contract provisions;

3. Meet the requirements of <u>KRS Chapter 304, 201 KAR</u> <u>Chapter 1, and KAR Title 806[the insurance laws and</u> <u>administrative regulations]</u> of the state of domicile and are at least as great as the minimum aggregate amounts required by the state in which this statement is filed;

4. Are computed on the basis of assumptions consistent with those used in computing the corresponding items in the annual statement of the preceding year-end with any exception noted; and

5. Include provision for all actuarial reserves and related statement items *[which ought to be]*established;

(b) Express an opinion as to the adequate provision for the anticipated cash flow by including language identical or substantially similar to the following: "The reserves and related items, *[when]*considered in light of the assets held by the company with respect to *[such]*reserves and related actuarial items including, but not limited to, the investment earnings on *[such]*assets, and the considerations anticipated to be received and retained under *applicable[such]* policies and contracts, make adequate provision, according to presently accepted actuarial standards of practice, for the anticipated cash flows required by the contractual obligations and related expenses of the company.";

(c) State that the actuarial methods, considerations, and analyses used in forming the actuarial opinion conform to the appropriate Standards of Practice as promulgated by the Actuarial Standards Board, which standards form the basis of the statement of opinion;

(d) State whether or not there has been a material change from the applicable date of the annual statement to the date of the rendering of the actuarial opinion which should be considered in reviewing the opinion and include language identical or substantially similar to one (1) of the following:

1. "This opinion is updated annually as required by statute. To the best of my knowledge, there have been no material changes from the applicable date of the annual statement to the date of the rendering of this opinion which should be considered in reviewing this opinion."; or

2. "The following material change(s) <u>that</u>[which] occurred between the date of the statement for which this opinion is applicable and the date of this opinion should be considered in reviewing this opinion: (describe the change or changes.)";

(e) Include a statement regarding unanticipated events which is identical or substantially similar to the following: "The impact of unanticipated events subsequent to the date of this opinion is beyond the scope of this opinion. The analysis of asset adequacy portion of this opinion should be viewed recognizing that the company's future experience may not follow all the assumptions used in the analysis"; and

(f) Contain the signature, address, and telephone number of the appointed actuary.

(7) A change in actuarial assumptions shall not include the adoption for a new issue, a new claim, or other new liability of an actuarial assumption which differs from a corresponding assumption used for a prior new issue, new claim, or other new liability.

(8) If the appointed actuary is unable to form an opinion, the actuary shall refuse to issue a statement of actuarial opinion.

(9) If the opinion of the appointed actuary is adverse or qualified, the actuary shall issue an adverse or qualified actuarial opinion explicitly stating the reason for *the[such an]* opinion. This statement shall follow the scope paragraph and precede the opinion paragraph.

(10) If the appointed actuary relies on the certification of others on matters concerning the accuracy or completeness of any data underlying the actuarial opinion, or the appropriateness of any other information used by the appointed actuary in forming the actuarial opinion, the actuarial opinion shall:

(a) Indicate the persons the actuary is relying upon and a precise identification of the items subject to reliance; and

(b) Provide a certification from the persons on whom the appointed actuary relied that:

1. Precisely identifies the items on which the person is providing information;

2. Includes a statement as to the accuracy, completeness, or reasonableness, as applicable, of the items; and

Includes the following information for the person rendering the certification:

a. Signature and date signed;

b. Title;

c. Company;

d. Address; and

e. Telephone number.

(11) <u>Except as established in subsection (12) of this</u> <u>administrative regulation and</u> as an alternative to the requirements of <u>subsection[Section]</u> 4(6)(a)3. of this <u>section[administrative regulation]</u>, the commissioner may make one (1) or more of the following alternatives available to the opining actuary:

(a)1.a. A statement that the reserves meet the requirements of the insurance laws and administrative regulations of the insurer's state of domicile; and

b. A formal written list of the standards and conditions for filing an opinion based on the law of the insurer's state of domicile.

2. If an insurer uses this alternative, the standards and conditions in effect on July 1 of a calendar year shall apply to statements for that calendar year, and they shall remain in effect until they are revised or revoked.

3. If no formal written list of the standards and conditions is available, the commissioner shall not offer this alternative;[-]

(b)1.a. A statement that the reserves meet the requirements of the insurance laws and administrative regulations of the insurer's state of domicile:

b. Verification that the actuary's request to file an opinion based on the law of the insurer's state of domicile has been approved; and

c. A statement that any conditions required by the commissioner for approval of that request have been met.

2. If the commissioner offers this alternative, a formal written statement of the allowance shall be issued no later than March 31 of the year it is first effective.

3. Subsequent to that statement being issued, if an insurer wants to use this alternative, the insurer shall file a request with the commissioner, along with justification for its use, no later than April 30 of the year of the opinion to be filed. The request shall be deemed approved on October 1 of that year if the commissioner has not denied the request by that date: <u>and[.]</u>

(c)1.a. A statement that the reserves meet the requirements of the insurance laws and administrative regulations of the insurer's state of domicile; and

b. A statement that the actuary has submitted the required comparison as <u>established[specified]</u> by the insurer's state of domicile.

2. If the commissioner offers this alternative, a formal written list of products for which the required comparison shall be provided shall be published on the department's Web site, http://insurance.ky.gov.

3. If a company uses this alternative, the formal written list of products in effect on July 1 of a calendar year shall apply to statements for that calendar year, and it shall remain in effect until it is revised or revoked.

4. If a formal written list of products for which the required comparison shall be provided is not available, this alternative shall not be allowed.

5.a. If a company desires to use this alternative, the appointed actuary shall provide a comparison of the gross nationwide reserves held to the gross nationwide reserves that would be held under National Association of Insurance Commissioners' codification standards, as <u>established[set_forth]</u> in KRS 304.6-171.

b. Gross nationwide reserves shall equal the total reserves calculated for the total company in force business directly sold and assumed, indifferent to the state in which the risk resides, without reduction for reinsurance ceded.

c. The comparison shall include the following:

(i) Product type;

(ii) Death benefit or account value;

(iii) Reserves held;

(iv) Codification reserves; and

(v) Codification standard.

d. The comparison shall include all products identified by either the state of filing or any other states <u>that accept[subscribing to]</u> this alternative.

e. If there is no codification standard for the type of product or risk in force or if the codification standard does not directly address the type of product or risk in force, the appointed actuary shall provide detailed disclosure of the specific method and assumptions used in determining the reserves held.

f. The comparison provided by the company <u>shall</u> [is to] be kept confidential in accordance with KRS 304.6-171.

(12)(a) **[Notwithstanding the provisions of Section 4(11) of this administrative regulation,]**The commissioner may reject an opinion based on the laws and administrative regulations of the state of the insurer's domicile and require an opinion based on the laws of the Commonwealth of Kentucky.

(b) If an insurer is unable to provide the opinion within sixty (60) days of the request or other period of time determined by the commissioner after consultation with the insurer, the commissioner may contract an independent actuary at the company's expense to prepare and file the opinion.

Section 5. Description of Actuarial Memorandum Including an Asset Adequacy Analysis. (1) In accordance with KRS 304.6-171, the appointed actuary shall prepare a memorandum to the company <u>that</u>[which] shall describe the analysis done in support of the actuary's opinion regarding the reserves.

(2) The memorandum shall:

(a) Be made available to the commissioner, upon request, for examination;

(b) Be returned to the company after an examination by the commissioner; and

(c) Not be considered a record of the insurance department or subject to automatic filing with the commissioner.

(3) The commissioner may designate a qualified actuary to review the actuarial opinion and prepare a supporting memorandum, which reasonable and necessary expense of the independent review shall be paid by the company but shall be directed and controlled by the commissioner, if:

(a) The commissioner requests a memorandum and no memorandum exists;

(b) The commissioner finds that the analysis <u>stated[described]</u> in the memorandum fails to meet the standards of the Actuarial Standards Board; or

(c) The commissioner finds that the analysis **<u>stated[described]</u>** in the memorandum fails to meet the standards of this administrative regulation.

(4) In preparing the memorandum, the appointed actuary may rely on, and include as a part of the actuarial memorandum, memoranda prepared and signed by another actuary who is qualified in accordance with Section 2 of this administrative regulation with respect to the subjects covered in the memorandum.

(5) The reviewing actuary shall have the same status as an examiner for the purposes of obtaining data from the company and the work papers and documentation of the reviewing actuary shall be retained by the commissioner.

(6) Any information provided by the company to the reviewing actuary and included in the work papers shall be considered as material provided by the company to the commissioner and shall be kept confidential to the same extent as other material provided by the company to the commissioner pursuant to KRS 304.6-171.

(7) The reviewing actuary shall not be an employee of a consulting firm involved with the preparation of any prior memorandum or opinion for the insurer pursuant to this administrative regulation for any one (1) of the current year or the preceding three (3) years.

(8)(a) In accordance with KRS 304.6-171, the appointed actuary shall prepare a regulatory asset adequacy issues summary in accordance with subsection (12) of this section.

(b) The regulatory asset adequacy issues summary shall be submitted no later than March 15 of the year following the year for which a statement of actuarial opinion based on asset adequacy is required.

(c) The regulatory asset adequacy issues summary shall be kept confidential in accordance with KRS 304.6-171(5)(h).

(9) The memorandum shall demonstrate that the analysis has been done in accordance with the standards for asset adequacy referred to in Section 3(5) of this administrative regulation.

(10) The actuarial memorandum referred to in this section shall specify:

(a) For reserves, the documentation of the assumptions made shall be in a manner to allow an actuary reviewing the actuarial memorandum to form a conclusion as to the reasonableness of the assumptions and shall include.

1. Product descriptions including a market description, underwriting and any other aspect of a risk profile and the specific risks the appointed actuary deems significant;

2. Source of liability in force;

3. Reserve method and basis;

4. Investment reserves;

5. Reinsurance arrangements;

6. Identification of any explicit or implied guarantees made by the general account in support of benefits provided through a separate account or under a separate account policy or contract and the methods used by the appointed actuary to provide for the guarantees in the asset adequacy analysis; and

7. Documentation of assumptions to test reserves for the following:

a. Lapse rates, both base and excess;

b. Interest crediting rate strategy;

c. Mortality;

d. Policyholder dividend strategy;

e. Competitor or market interest rate;

- f. Annuitization rates;
- g. Commissions and expenses; and

h. Morbidity:[. The documentation of the assumptions shall be made in a manner to allow an actuary reviewing the actuarial memorandum to form a conclusion as to the reasonableness of the assumptions.]

(b) For assets, the documentation of the assumptions made shall be in a manner to allow an actuary reviewing the actuarial memorandum to form a conclusion as to the reasonableness of the assumptions and shall include:

1. Portfolio descriptions, including a risk profile disclosing the quality, distribution and types of assets;

- 2. Investment and disinvestment assumptions;
- Source of asset data;
- 4. Asset valuation bases; and
- 5. Documentation of assumptions made for:
- a. Default costs;
- b. Bond call function;
- c. Mortgage prepayment function;

d. Determining market value for assets sold due to disinvestment strategy; and

e. Determining yield on assets acquired through the investment strategy: [. The documentation of the assumptions shall be made in a manner to allow an actuary reviewing the actuarial memorandum to form a conclusion as to the reasonableness of the assumptions.]

- (c) Analysis basis:
- 1. Methodology;

2. Rationale for inclusion or exclusion of different blocks of business and how pertinent risks were analyzed;

3. Rationale for degree of rigor in analyzing different blocks of business, including the level of materiality that was used in determining how rigorously to analyze different blocks of business;

4. Criteria for determining asset adequacy, including the precise basis for determining if assets are adequate to cover reserves under moderately adverse conditions or other conditions as <u>established[specified]</u> in relevant actuarial standards of practice; and

5. Effect of federal income tax, reinsurance, and any other relevant factor; **[**-]

(d) Summary of material changes in methods, procedures or assumptions from prior year's asset adequacy analysis;

(e) Summary of results; and

(f) Conclusion.

(11) The memorandum shall include a statement **<u>that</u>[which]** indicates that the memorandum conforms to the appropriate Standards of Practice and **<u>that</u>[which]** shall include language identical or substantially similar to the following: "Actuarial methods, considerations, and analyses used in the preparation of this memorandum conform to the appropriate standards of practice as promulgated by the Actuarial Standards Board, which standards form the basis for this memorandum."

(12) The regulatory asset adequacy issues summary shall include:

(a) Descriptions of the scenarios tested, including whether those scenarios are stochastic or deterministic, and the sensitivity testing done relative to those scenarios.

1. If negative ending surplus results under certain tests in the aggregate, the actuary shall describe those tests and the amount of additional reserve as of the valuate date <u>that[which]</u>, if held, would eliminate the negative aggregate surplus values.

2. Ending surplus values shall be determined by:

a. Extending the projection period until the in-force and associated assets and liabilities at the end of the projection period are immaterial; or

b. Adjusting the surplus amount at the end of the projection period by an amount that appropriately estimates the value that can reasonably be expected to arise from the assets and liabilities remaining in force;

(b) The extent to which the appointed actuary uses assumptions in the asset adequacy analysis that are materially different than the assumptions used in the previous asset adequacy analysis;

(c) The amount of reserves and the identity of the product lines that had been subjected to asset adequacy analysis in the prior opinion but were not subject to analysis for the current opinion;

(d) Comments on any interim results that may be of significant concern to the appointed actuary;

(e) The methods used by the actuary to recognize the impact of reinsurance on the company's cash flows, including both assets and liabilities, under each of the scenarios tested; and

(f) Whether <u>or not</u> the actuary has been satisfied that all options, whether explicit or embedded, in any asset or liability, including those affecting cash flows embedded in fixed income securities, and equity-like features in any investments have been

appropriately considered in the asset adequacy analysis.

(13) The regulatory asset adequacy issues summary shall contain the name of the company for which the regulatory asset adequacy issues summary is being supplied and shall be signed and dated by the appointed actuary rending the actuarial opinion.

(14) The appointed actuary shall retain on file, for at least seven (7) years, sufficient documentation so that it will be possible to determine the procedures followed, the analyses performed, the bases for assumptions, and the results obtained.

Section 6. Additional Considerations for Analysis. (1) An appropriate allocation of assets in the amount of the interest maintenance reserve (IMR), whether positive or negative, shall be used in any asset adequacy analysis.

(2) Analysis of risks regarding asset default may include an appropriate allocation of assets supporting the asset valuation reserve (AVR).

(3) AVR assets shall not be applied for any other risks with respect to reserve adequacy.

(4) Analysis of these and other risks may include assets supporting other mandatory or voluntary reserves available to the extent not used for risk analysis and reserve support.

(5) The amount of the assets used for the AVR shall be disclosed in the Table of Reserves and Liabilities and in the memorandum.

(6) The method used for selecting particular assets or allocated portions of assets shall be disclosed in the memorandum.

Section 7. Effective Date. This administrative regulation will take effect for annual statements for the year 2009.

Section 8.] Incorporation by Reference. (1) The "Table of Reserves and Liabilities", 5/2009, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department of Insurance, 500 Mero Street [215 West Main Street], Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. Forms may also be obtained on the department's internet Web site at: http://insurance.ky.gov.

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PUBLIC PROTECTION CABINET **Department of Insurance Financial Standards and Examination Division** (As Amended at ARRS, October 13, 2020)

806 KAR 7:035. Finance committee of domestic insurers.

RELATES TO: KRS 304.2-205. 304.7-361[, 304.2-205] STATUTORY AUTHORITY: KRS 304.2-110, 304.2-205, 304.3-240, 304.7-367[304.2-110]

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110 authorizes the Commissioner of Insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code defined in KRS 304.1-010. KRS 304.2-205 [of Insurance] to requires[authorizes] the commissioner prescribe additional filings to be made by an insurer, along with its annual statement filing, by March 1 of each year. KRS 304.3-240 requires each authorized insurer to annually file with the commissioner a true statement of its financial condition, transactions, and affairs. KRS 304.7-367 authorizes the commissioner to promulgate administrative regulations implementing the provisions of KRS Chapter 304, Subtitle 7.[KRS 304.2-110 authorizes the Commissioner of Insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code as defined in KRS 304.1-010.] The administrative regulation requires a domestic insurer transacting

business in Kentucky to notify the commissioner [of Insurance] of the names of the members of the finance or executive committees of its company or the board of directors responsible for approval of the insurer's investment policy.

Section 1. (1) Each domestic insurer shall, with each annual statement report, file with the commissioner the names of the members of any finance or executive committee or the board of directors which has, during the preceding year, exercised the authority to approve investments or investment policy.

(2) The filing required by subsection (1) of this section shall be accompanied by an affidavit signed by a financial officer of the insurer or its president, attesting that the members of the executive or finance committee or the board of directors have been advised as to the requirements of Subtitle 7 of KRS Chapter 304, administrative regulations, and other pertinent provisions of law applicable to investments or investment policy submitted for their approval.

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PUBLIC PROTECTION CABINET Department of Insurance **Financial Standards and Examination Division** (As Amended at ARRS, October 13, 2020)

806 KAR 7:090. Custodial accounts for investment securities of insurance companies.

RELATES TO: KRS 304.7-360

STATUTORY AUTHORITY: KRS 304.2-110, 304.7-360

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110 authorizes the Commissioner of Insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code as defined in KRS 304.1-010. KRS 304.7-360 requires the Commissioner [Executive Director] of Insurance to promulgate administrative regulations governing the deposit by insurers of securities with clearing corporations, the Federal Reserve bookentry system, and with[or] custodian banks. This administrative regulation establishes[sets forth the] provisions to be included in an agreement for the custody of an insurance company's securities with a custodian bank and qualifications for a custodian bank.

Section 1. Definitions.

(1) "Certificated security" is defined by[in] KRS 304.7-360(1)(g). (2) "Clearing corporation" is defined by[in] KRS 304[034].7-

360<u>(1)(a).</u>

(3) "Commissioner" is defined by[in] KRS 304.1-050(1).

(4) "Custodian bank" is defined by[in] KRS 304.7-360(1)(b).

(5) "Custodied securities" means securities held by the custodian bank, its nominee, a clearing corporation, the Federal Reserve book-entry system, or in any combination of these entities.

(6) "Direct participant" is defined by[in] KRS 304.7-360(1)(c) (7) "Federal reserve book-entry system" is defined by[in] KRS 304.7-360(1)(d).

(8) "Member bank" is defined by[in] KRS 304.7-360(1)(e).

(9) "Security" is defined by[in] KRS 304.7-360(1)(f).

(10) "Uncertificated security" is defined by[in] KRS 304.7-360(1)(h).[Terms defined in KRS 304.7-360 shall have the same meaning when used herein.]

Section 2. Standards for Custodial Agreements. Pursuant to KRS 304.7-360, an insurance company may provide by agreement for the custody of its securities with a custodian bank meeting the qualifications set forth in Section 3 of this administrative regulation which securities may be held by the custodian bank, its nominee, in a clearing corporation, or in the Federal Reserve book-entry

system. [Such securities, whether held by the custodian bank, its nominee, in a clearing corporation, in the Federal Reserve bookentry system, or in any combination of these entities, are referred to here-in as "custodied securities."] Any [such] agreement shall contain provisions to comply with the following standards:

(1) The agreement shall be in writing and shall be authorized by a resolution of the Board of Directors <u>or an authorized</u> <u>committee</u> of the insurance company [or <u>of an authorized</u> <u>committee thereof</u>].

(2) Certificated securities held by the custodian bank may be [se] held separate from the securities of the custodian bank and of all its other customers or in a fungible bulk of securities as part of a Filing of Securities by Issue (FOSBI) arrangement.

(3) Securities [se] held in a fungible bulk by the custodian bank and securities in a clearing corporation or the Federal Reserve book-entry system shall be separately identified on the custodian bank's official records as being owned by the insurance company. <u>The [Said]</u> records shall identify which custodied securities are held by the custodian bank or by its nominee and which securities are in a clearing corporation or the Federal Reserve book-entry system. If the securities are in a clearing corporation or the Federal Reserve book-entry system, <u>the [said]</u> records shall also identify where the securities are and, if in a clearing corporation, the name of the clearing corporation or, if held in nominee name, the name of the nominee.

(4) All custodied securities that are registered shall be registered in the name of:

(a) The [the] insurance company; [, in]

(b) A [the name of a] nominee of the insurance company; [, in]

(c) The [the] [name of the] custodian bank or its nominee: [,] or[,]

(d) If [if] in a clearing corporation, [in the name of] the clearing corporation or its nominee.

(5) Custodied securities shall be held subject to the instructions of the insurance company and shall be withdrawable upon the demand of the insurance company.

(6) The custodian bank shall arrange for execution of transactions in custodied securities in accordance with the insurance company's instructions and shall not exercise discretionary authority to effect transactions in custodied securities except in such limited or special circumstances as the insurance company may authorize.

(7) The custodian bank shall be required to send or cause to be sent to the insurance company a confirmation of all transfers of custodied securities to or from the account of the insurance company. In addition, the custodian bank shall be required to furnish the insurance company with reports of holdings of custodied securities at such times and containing such information as may be reasonably requested by the insurance company, but not less frequently than monthly.

(8) During the course of the custodian bank's regular business hours, any officer or employee of the insurance company, any independent accountant selected by the insurance company, or any representative of the <u>commissioner</u> [executive director] shall be entitled to examine, on the premises of the custodian bank, the custodian bank's records relating to custodied securities and the custodied securities, but only upon furnishing the custodian bank with written instructions to that effect from an appropriate officer of the insurance company or the <u>commissioner</u> [executive director].

(9) The custodian bank and its nominee shall be required to send to the insurance company:

(a) All reports which they receive from a clearing corporation or the Federal Reserve book-entry system on their respective systems of internal accounting control; and

(b) Reports prepared by outside auditors with respect to the respective systems of internal accounting control of the custodian bank and its nominee pertaining to custodial record keeping as the insurance company may reasonably request from time to time.

(10) The custodian bank shall maintain records sufficient to determine and verify information relating to custodied securities that may be reported in the insurance company's annual statement and supporting schedules as filed with various regulatory authorities and in connection with any audit of the financial statements of the insurance company.

(11) The custodian bank shall provide upon request <u>an affidavit</u> [appropriate affidavits] with respect to custodied securities on the form, ["]Custodian Affidavit[" incorporated by reference in this administrative regulation] or in a substantially similar format. [substantially in the form attached hereto (Appendix A) with respect to custodied securities].

(12) The custodian bank shall be obligated to indemnify the insurance company for any loss of custodied securities, except that the custodian bank shall not be [se] obligated to the extent that the [such] loss was caused by other than the negligence or dishonesty of the custodian bank.

(13) If [In the event that] there is a loss of custodied securities for which the custodian bank shall be obligated to indemnify the insurance company as provided in subsection (12) of this section, the custodian bank shall promptly replace the securities or the value of the securities [thereof] and the value of any loss of rights or privileges resulting from the [said] loss of securities.

(14) The agreement may provide that the custodian bank will not be liable for any failure to take any action required to be taken under the agreement <u>if</u> [in the event and to the extent that] the taking of such action is prevented or delayed by war. [{]whether declared or not and including existing war[]], revolution, insurrection, riot, civil commotion, act of God, accident, fire, explosion, stoppage of labor, strikes or other differences with employees, laws, regulations, orders or other acts of any governmental authority, or any other cause [whatever] beyond its reasonable control.

(15) <u>If</u> [In the event that] entry in a clearing corporation or in the Federal Reserve book-entry system is gained through a direct participant or a member bank, there shall be an agreement between the custodian and the direct participant or member bank under which the direct participant or member bank shall be subject to the same liability for loss of custodied securities as the custodian bank. <u>However</u>, [; provided, however, that,] if the direct participant or member bank shall be subject to regulation which is different from the jurisdiction the laws of a jurisdiction which is different from the jurisdiction the direct participant or member bank which is different from the standard of liability applicable to the custodian bank.

(16) The agreement <u>shall</u> [must] be terminable by the insurance company on not more than thirty (30) days' notice.

Section 3. Qualifications of Custodian Banks. Any custodian bank selected by an insurance company to act as custodian under an agreement authorized by KRS 304.7-360 shall possess the following qualifications:

(1) Its custodial functions for the insurance company shall be carried out under its trust department;

(2) It shall be audited annually by independent public accountants whose audit report, together with the related financial statements, and whose report on internal controls are made available to the insurance company and the <u>commissioner</u> [executive director];

(3) It <u>shall</u> [must] be organized under the laws recognizing that the custodied securities are ["]special deposits["] rather than ["]general deposits,["] remain the specific property of the insurance company, and <u>shall not be</u> [are not] subject to any creditor relationship of the custodian bank.

(4) It <u>shall</u> [must] maintain blanket bond coverage relating to its custodial functions with limits equal to or exceeding those suggested by the American Bankers Association.

(5) Its capital and surplus funds shall equal or exceed \$25,000,000[unless it is licensed and regulated by the Commonwealth of Kentucky, in which case its capital and surplus funds shall equal or exceed \$10,000,000]; and

(6) It <u>shall</u> [must] have demonstrated sufficient experience in handling custodial accounts.

Section **4[5]**. Incorporation by Reference. (1) "Custodian Affidavit", (6/2020), is incorporated by reference.

(2) This material may be inspected, copied, or obtained,

subject to applicable copyright law, at the Kentucky Department of Insurance, 500 Mero Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

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PUBLIC PROTECTION CABINET Department of Insurance Financial Standards and Examination Division (As Amended at ARRS, October 13, 2020)

806 KAR 8:010. Valuation of assets on deposit.

RELATES TO: KRS 304.8-040, <u>304.8-095,</u> 304.8-120 STATUTORY AUTHORITY: KRS 304.2-110

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110 provides that the <u>Commissioner</u> [Executive Director] of Insurance may make reasonable rules and administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code. This administrative regulation sets forth the method of <u>valuation</u> [value] of assets on deposit with the Commissioner [Executive Director] of Insurance.

Section 1. Insurance companies making deposits and revaluations of <u>deposits</u> [the same] with the Custodian of Insurance Securities shall utilize the Insurance Department Form 143, ["]Detailed Listing of Securities Held Under Safekeeping Pursuant to KRS 304.8-095[" incorporated by reference in this administrative regulation].

Section 2. Assets on deposit with the Custodian of Insurance Securities which are obligations having a fixed term, rate and face value, shall be valued as follows:

(1) At face value if acquired at face value; or

(2) If acquired above or below face value, [they shall be valued] on the basis of the purchase price adjusted annually to bring the value to face value on maturity. The [Such] obligations when in default as to either principal or interest are not eligible for deposit, and the <u>commissioner</u> [executive director] shall require replacement of the [such] deposits in accordance with [{]KRS 304.8-120[}].

Section 3. Preferred and common stocks shall be valued, for deposit purposes, at the then market value. Twice each year these classes of securities shall be revalued, once as of the preceding December 31 and again as of June 30. The latter revaluation shall be accompanied by a statement from a recognized securities brokerage firm to the effect that the prices [se] used were the fair market values at June 30.

Section 4. Mortgage loans and [/er] notes shall be valued at the unpaid principal balance of the note at the time of deposit. Each year, before April 1, the mortgage loans on deposit shall be revalued so as to reflect the estimated unpaid principal balances as of the succeeding December 31.

Section 5. Home office real property shall be valued for deposit purposes at the company's book value, or at the fair market value if <u>the appraisal[such]</u> has been established by <u>a licensed</u> <u>appraiser[an appraisal acceptable to the commissioner]</u> [executive director]. Any change in the company's book value or appraised value shall cause a revaluation of this deposit.

Section 6. Incorporation by Reference. (1) "Insurance Department Form 143, Detailed Listing of Securities Held Under Safekeeping Pursuant to KRS 304.8-095", (6/2020), is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department of Insurance, 500 Mero Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

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PUBLIC PROTECTION CABINET Department of Insurance Financial Standards and Examination Division (As Amended at ARRS, October 13, 2020)

806 KAR 49:020. Captive insurer application requirements.

RELATES TO: KRS 304.49-010-304.49-230[304.49]

STATUTORY AUTHORITY: KRS 304.2-110, 304.49-020(3), 304.49-140

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110 provides that the <u>Commissioner</u> [Executive Director] of Insurance may promulgate administrative regulations necessary for or as an aid to the effectuation of any provisions of the Kentucky Insurance Code. KRS 304.49-140 authorizes the <u>Commissioner</u> [Executive Director] of Insurance to establish and amend administrative regulations related to captive insurance companies as necessary to effectuate the provisions of KRS <u>304.49-010 to 304.49-230[304.49]</u>. KRS 304.49-020(3) authorizes the <u>Commissioner</u> [Executive Director] of Insurance to promulgate administrative regulations concerning the application for a certificate of authority for captive insurers. This administrative regulation establishes application requirements for the regulation of captive insurers.

Section 1. Definition. "Company" means the captive insurer.

Section 2. A captive insurer seeking to obtain a certificate of authority to engage in insurance business in Kentucky shall apply to the Kentucky <u>Department</u> [Office] of Insurance by completing and filing the following forms:

(1) Captive Application for Admission, CI-103 [(7/2004)] [(04/01)];

(2) Coverage Limits and Reinsurance, CI-105 [(04/01)];

(3) Irrevocable Letter of Credit CI-130 [(7/2004)] [(04/01)];

(4) Application for Authorization to Certify Loss Reserves and

Loss Éxpense Reserves for Captives CI-110 [[(2/2011)] [(04/01)]; (5) Application for Authorization as an Independent Certified Public Accountant for Captive Insurance Business CI-120

[<u>(2/2011)]</u> [(04/01)]; and (6) Biographical Affidavit CI-501 [<u>(7/2004)]</u> [(04/01)].

Section 3. All documents required by KRS 304.49-020(3)-(6) shall be submitted with a company's application seeking a certificate of authority to engage in insurance business in Kentucky or a statement describing the reason each document is not applicable.

Section 4. (1) In addition to the processing of the application, an organizational investigation or examination may be performed by the <u>department</u> [office] before an applicant <u>receives a</u> <u>certificate of authority[is licensed]</u> as a captive insurer.

(2) The investigation or examination shall consist of a general survey of the company's corporate records, including:

(a) Charter, bylaws, and minute books;

- (b) Verification of capital and surplus;
- (c) Verification of principal place of business;
- (d) Determination of assets and liabilities; and
- (e) A review of investment practice policy and procedures.

Section 5. A person shall not act as an insurance producer, broker, agent, salesman, or reinsurance intermediary for captive business without the authorization of the <u>commissioner</u> [executive director]. Application for that authorization shall be on the Individual Application 8301 [[772014]][(03/01)] form, incorporated by reference in 806 KAR 9:025.

Section 6. Revocation. (1) The <u>commissioner</u> [executive director] may, subject to the provisions of this section, by order revoke the certificate of authority of the company:

(a) If the company has not commenced business according to its plan of operation within two (2) years of being licensed;

(b) If the company ceases to carry on insurance business in Kentucky;

(c) At the request of the company; or

(d) For any reason provided in KRS 304.3-190 or 304.3-200.

(2) Before the <u>commissioner</u> [executive director] revokes the certificate of authority of a company under subsection (1)(a) or (b) of this section, the <u>commissioner</u> [executive director] shall give the company notice in writing of the grounds on which he proposes to cancel the <u>certificate of authority[license]</u>, and shall afford the company an opportunity to make objection in writing within thirty (<u>30</u>) days receipt of the notice. The <u>commissioner</u> [executive director] shall take into consideration any objection timely filed and schedule an administrative hearing on the matter in accordance with KRS Chapter 13B.

Section 7. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) Captive **[Insurer]** Application <u>for Admission</u> CI-103 (6/2020) [(04/01)];

(b) Coverage, Limits and Reinsurance CI-105 (4/2001)[(6/2020)] [(04/01)];

(c) Irrevocable Letter of Credit CI-130 (6/2020) [(04/01)];

(d) Application for Authorization to Certify Loss Reserves and Loss Expense Reserves for Captives CI-110 (6/2020)[(2/2011)] [(04/01)];

(e) Application for Authorization as an Independent Certified Public Accountant for Captive Insurance Business CI-120 (6/2020)[(2/2011)] [(04/01)]; and

(f) Biographical Affidavit CI-501 (4/2001)[(6/2020)] [(04/01)]]; and

(g) Individual Application 8301 (7/2014)] [(03/01)].

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky <u>Department</u> [Office] of Insurance, <u>500 Mero</u> [215 West Main] Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

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PUBLIC PROTECTION CABINET Department of Insurance Financial Standards and Examination Division (As Amended at ARRS, October 13, 2020)

806 KAR 49:030. Captive insurer reporting requirements.

RELATES TO: KRS 304.49-010-304.49-230[304.49]

STATUTORY AUTHORITY: KRS 304.2-110, 304.49-070(2), 304.49-140

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110 provides that the Commissioner [Executive Director] of Insurance may promulgate administrative regulations necessary for or as an aid to the effectuation of any provisions of the Kentucky Insurance Code. KRS 304.49-140 authorizes the Commissioner [Executive Director] of Insurance to establish and amend administrative regulations related to captive insurance companies as necessary to effectuate the provisions of KRS 304.49-010 to 304.49-230[304.49] KRS 304.49-070(2) requires the Commissioner [Executive Director] of Insurance to promulgate administrative regulations concerning the reporting requirements of captive insurers. This administrative regulation establishes financial and reporting requirements for captive insurers.

Section 1. Definition. "Company" means the captive insurer.

Section 2. A consortium[(1) An association] captive insurer,

and a pure or industrial insured captive insurer engaged in insurance in Kentucky shall annually submit to the <u>commissioner</u> [executive director] a report of its financial condition, verified by oath of two (2) of its executive officers <u>on the Annual Statement</u> <u>Convention Blank</u>. The report shall be filed in the same format and content as required by KRS<u>304.2-205 and</u> 304.3-240. [

(2) A pure or industrial insured captive insurer engaged in insurance in Kentucky shall annually submit to the <u>commissioner</u>] [executive director][a report of its financial condition, verified by oath of two (2) of its executive officers on the Annual Statement Convention Blank pursuant to KRS 304.2-205.]

Section 3. (<u>1</u>) A captive insurer shall have an annual audit by an independent certified public accountant, authorized by the <u>commissioner</u> [executive director], and shall file an audited financial report with the <u>commissioner</u> [executive director] on or before <u>July</u> [June] 1 for the year ending December 31 immediately preceding.

(2) The annual audit report shall be considered part of the company's annual report of financial condition except with respect to the date by which it shall be filed with the <u>commissioner</u> [executive director].

(3) The annual audit shall consist of the following:

(a) [(1)] Opinion of independent certified public accountant.

<u>1. [(a)]</u> Financial statements furnished pursuant to this section shall be examined by <u>an</u> independent certified public <u>accountant</u> [accountants] in accordance with generally-accepted auditing standards as determined by the American Institute of Certified Public Accountants.

 $\underline{2.}$ [(b)] The opinion of the independent certified public accountant shall cover all years presented.

3. [(c)] The opinion shall:

<u>a. Be</u> [be] addressed to the company on stationery of the accountant showing the address of issuance; [7]

b. Bear [shall bear] original manual signatures; and

c. Be [shall be] dated.[;]

(b) [(2)] Report of evaluation of internal controls.

1. [(a)] This report shall include an evaluation of the internal controls of the company relating to the methods and procedures used in the securing of assets and the reliability of the financial records, including the controls as the system of authorization and approval, and the separation of duties.

2. [(b)] The review shall be conducted in accordance with generally accepted auditing standards and the report filed with the commissioner [executive director].[:]

(c) [(3)] Accountant's letter. The accountant shall furnish the company, for inclusion in the filing of the audited annual report, a letter stating:

<u>1. [(a)]</u> That he is independent with respect to the company and conforms to the standards of his profession as contained in the Code of Professional Ethics and pronouncements of the American Institute of Certified Public Accountants and pronouncements of the Financial Accounting Standards Board; [-]

2. [(b)] The general background and experience of the staff engaged in audit including the experience in auditing captives or other insurance companies; [-]

<u>3.</u> [(c)] That the accountant understands that the audited annual report and his opinions thereon will be filed in compliance with this administrative regulation with the Kentucky <u>Department</u> [Office] of Insurance: [-]

4. [(d)] That the accountant consents to the requirements of Section 6 of this administrative regulation and that the accountant consents and agrees to make available for review by the commissioner, his designee or his appointed agent, the work papers as defined in Section 6 of this administrative regulation: [.-]

<u>5.</u> [(e)] That the accountant is properly licensed by an appropriate state licensing authority; and

6. That the accountant [that he] is a member in good standing in the American Institute of Certified Public Accountants.

(d) [(4)] Financial statements. The following statements are required:

1. [(a)] Balance sheet; [-]

2. [(b)] Statement of gain or loss from operations; [-]

3. [(c)] Statement of changes in financial position; [-]

<u>4.</u> [(4)] Statement of changes in capital paid up, gross paid in and contributed surplus and unassigned funds or unassigned surplus; and [-]

5. ((e)) Notes to financial statements. The notes to financial statements shall be those required by generally accepted accounting principles, and shall include:

a. [1-] A reconciliation of differences, if any, between the audited financial report and the statement or form filed with the <u>commissioner [executive director]</u>. [-]

<u>b.</u> [2-] A summary of ownership and relationship of the company and all affiliated corporations or companies insured by the captive; and [-]

<u>c.</u> [3-] A narrative explanation of all material transactions and balances with the company. \underline{f}

(e) [(5)] Certification of loss reserves and loss expense reserves.

<u>1. [(a)]</u> The annual audit shall include an opinion as to the adequacy of the company's loss reserves and loss expense reserves.

2. [(b)] The individual who certifies as to the adequacy of reserves shall be approved by the <u>commissioner</u> [executive director] and shall be:

a. A [a] Fellow of the Casualty Actuarial Society; [,]

<u>b.</u> A [a] member in good standing of the American Academy of Actuaries; [,] or

<u>c. An</u> [an] individual who has demonstrated his competence in loss reserve evaluation to the <u>commissioner.[-][executive director.]</u>

<u>3.</u> [(c)] Certification shall be in the form as the <u>commissioner</u> [executive director] deems appropriate.*[: and]*[.]

(f) [(6)] A filing fee for audited financial statements <u>shall be</u> as prescribed by 806 KAR 4:010.

Section 4. A company shall within ninety (90) days report to the <u>commissioner [executive director]</u> in writing, the name and address of the independent certified public accountant retained to conduct the annual audit established in this administrative regulation.

Section 5. A company shall require the certified public accountant to immediately notify, in writing, an officer and all members of the board of directors of the company of any determination by the independent certified public accountant that the company has materially misstated its financial condition in its report to the <u>commissioner</u> [executive director] as required in KRS 304.49-070. The company shall furnish the notification to the <u>commissioner</u> [executive director] within five (5) working days of receipt.

Section 6. Work Papers. (1) Each company shall require the independent certified public accountant to make available for review and inspection by the <u>commissioner</u> [executive director] or his appointed agent the work papers prepared in the conduct of the audit of the company.

(2) The company shall require that the accountant retain the audit work papers for a period of not less than five (5) years after the period reported upon.

(3) Any review by the <u>commissioner</u> [executive director] shall be considered a part of an examination or investigation and all working papers obtained during the course of an examination or investigation shall be confidential.

(4) The company shall require that the independent certified public accountant provide photocopies of any of the working papers the <u>Department</u> [Office] of Insurance requests and the working papers may be retained by the <u>department</u> [office].

(5) Work papers shall include:

(a) Schedules;

- (b) Analyses;
- (c) Reconciliations;
- (d) Abstracts;
- (e) Memoranda;
- (f) Narratives;
- (q) Flow charts;

(h) Copies of company records; or

(i) Other documents prepared or obtained by the accountant and his employees in the conduct of their examination of the company.

Section 7. (1) If [Whenever] the commissioner [executive director] deems that the financial condition of the company warrants additional security, he may require a company to deposit with the Treasurer of this state, cash or securities approved by the commissioner [executive director] or, to furnish the commissioner [executive director] a clean irrevocable letter of credit issued by a bank chartered by the State of Kentucky or a member bank of the Federal Reserve System and approved by the commissioner [executive director].

(2) The company may receive interest or dividends from the deposit or exchange the deposits for others of equal value with the approval of the <u>commissioner [executive director]</u>.

(3) If the company discontinues business, the <u>commissioner</u> [executive director] shall return the deposit only after being satisfied that all obligations of the company have been discharged.

CONTACT PERSON: DJ Wasson, Executive Advisor, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 564-6026, fax +1 (502) 564-1453, email dj.wasson@ky.gov.

CABINET FOR HEALTH AND FAMILY SERVICES Department for Public Health Division of Public Health Protection and Safety (As Amended at ARRS, October 13, 2020)

902 KAR 100:012. Fee schedule.

RELATES TO: KRS 211.840-211.852, 211.990(4), 523.100 STATUTORY AUTHORITY: KRS 194A.050(1), 211.844, 211.848(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.848(1) <u>requires[authorizes]</u> requires] the cabinet to establish a reasonable schedule of fees and charges by administrative regulation. This administrative regulation establishes a schedule of fees and charges for radioactive material licensees; radiation producing <u>machine[machines]</u> registrants; others who may receive, possess, use, transfer, or dispose of sources of radiation; and vendors, service providers, and qualified experts providing services in Kentucky.

Section 1. Radiation Producing Machine Schedule of Annual Fees and Charges. The following schedule, established in subsections (1) through (4) of this section, of annual fees shall apply to radiation producing machine registrants. <u>A "Registration Application for Radiation Producing Machines", RPS 402[An application for registration or annual renewal]</u> shall be accompanied by the appropriate fee established in subsections (1) through (4) of this section.

(1) A diagnostic x-ray <u>machine[tube; therapeutic x-ray tube</u> capable of operating up to 150 kVp] shall be \$<u>131.25[425]</u>.

(2) A therapeutic x-ray <u>machine[tube capable of operating at</u> 150 kVp or above] including particle accelerators shall be \$525[500].

(3) Industrial, dental, and other x-ray <u>machines[tubes]</u> not specified in subsections (1) and (2) of this section shall be <u>\$89.25[eighty-five (85) dollars]</u>.

(4) Shielding evaluation, per room:

(a) Diagnostic facilities shall be \$600; and

(b) Linear accelerator shall be \$1,500.

Section 2. Radioactive Material License Schedule of Annual Fees and Charges. The following schedule, established in subsections (1) through (5) of this section, shall apply to radioactive material licenses. An initial and renewal application, *incorporated by reference in 902 KAR 100:040*, shall be accompanied by the fee established in this section.

(1) A specific radioactive material license initial and annual fee.

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(a) Human use.

1. Nuclear medicine, imaging shall be \$2,205[2,100].

2. Nuclear medicine, radiopharmaceutical therapy shall be \$2,205[2,100].

3. Nuclear medicine, permanent implant shall be \$2,835[2,700].

4. Nuclear medicine, temporary implant shall be \$1,575[1,500].

5. Nuclear medicine, mobile imaging shall be \$2,625[2,500].

6. Teletherapy or Gamma Stereotactic Radiosurgery shall be \$4,200[4,000].

7. Broad scope, medical shall be \$7,875[7,500].

8. Other shall be \$<u>1,312.50</u>[1,250].

(b) Industrial radiography shall be \$4,200[4,000].

(c) Wireline service shall be \$2,625[2,500].

(d) Broad scope, academic shall be \$3,675[3,500].

(e) Nuclear laundry shall be \$7,875[7,500].

(f) Irradiator.

1. Self-contained shall be \$<u>1,837.50</u>[1,750].

2. Unshielded during irradiation shall be \$4,410[4,200].

(g) Manufacturing, processing, or distribution.

1. Industrial gauging devices shall be \$4,725[4,500].

2. In vitro-In vivo kits shall be \$3,780[3,600].

3. Radiopharmaceuticals shall be \$5,460[5,200].

4. Other shall be \$<u>3,780[</u>3,600].

(h) Industrial gauging devices.[:]

1. Fixed shall be \$<u>1,155[1,100].[; and]</u>

2. Portable shall be \$<u>1,365</u> [1,300].

(i) In vitro, academic, environmental, or clinical laboratory shall be \$<u>1,312.50</u>[1,250].

(j) Veterinary use shall be \$2,205[2,100].

(k) Services, such as leak testing shall be \$1,312.50[1,200].

(I) An application for review of a [:

-1.] new sealed source or device [;]or

[2.] custom device shall be 4,600 plus the applicable fee in paragraphs (a) through (k) of this subsection.

(m) An amendment for review of a sealed source or device shall be \$1,575[1,500].

(n) A byproduct, source, or special nuclear material license or other license—authorizing decommissioning, decontamination, reclamation, or site restoration shall be \$7,875[7,500].

(o) The fee shall be \$10,500 for a license specifically authorizing:

<u>1.</u> The receipt of prepackaged byproduct, source material, or special nuclear material from other persons; <u>and</u>

2. [The license authorizes] the disposal of the material by transfer to a person authorized to receive or dispose of the material [, and the fee shall be <u>\$10,500[</u>10,000].

(p) A license specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from a person for the purpose of storage, treatment, and packaging for transfer to a person authorized to receive or dispose of radioactive material shall be \$26,250[25,000].

(2) A general radioactive material license initial and annual fee.(a) In vitro or medical use specified in 902 KAR 100:050,

Sections 4 and 5 shall be \$<u>1,312.50</u>[1,250].

(b) Measuring, gauging, or a controlling device except emergency exit signs shall be \$300 per device not to exceed \$<u>1,260</u>[1,200] per use location.

(3) An application to amend an existing specific license shall be \$210[200].

(4) An application for initial reciprocal recognition of an out-ofstate license as established by 902 KAR 100:065. The fee shall be equal to the applicable fee for an in-state licensee.

(5) A licensee required to pay an annual fee pursuant to this administrative regulation may qualify as a small entity pursuant to form RPS-526, [Certification of] Small Entity Certification[Status]. If a licensee qualifies as a small entity, based on Kentucky Department of Revenue review and approval, and completes and submits form RPS-526 with its annual fee payment each year, the licensee shall pay the reduced annual fee.

Section 3. Inspection Fee. (1) The cost of a routine interval inspection shall be covered in the annual licensing renewal fee.

(2) One (1) or more additional inspections shall be conducted to ensure ongoing public health and safety if any of the conditions established in paragraphs (a) through (d) exist:

(a) Willful neglect or careless disregard that has, or could lead to, a threat to public health and safety;

(b) Failure to take appropriate and timely action to correct documented violations of statutes, regulations, or conditions of the license or permit;

(c) A substantiated violation that indicates a lack of management oversight or that the radiation safety officer is not adequately performing duties; or

(d) Repeated violations from the previous inspection.

(3) The fee for each additional inspection shall be \$525[500].

Section 4. Shipment of Radioactive Material and Waste. The shipper or carrier shall provide full cost reimbursement within thirty (30) days of receipt of the invoice, for all escorts of shipments of radioactive material, spent nuclear fuel, transuranic waste, radioactive waste, and other radioactive material or waste through Kentucky.

Section 5. Site Investigations, Remediation Projects, and Scoping Surveys. The licensee, remediation contractor, or other responsible party shall provide full cost reimbursement for review and oversight of site investigations, remediation projects, and scoping surveys to include project evaluation and planning, sample collection, analysis, and independent validation as applicable.

Section 6. Qualified Experts, Vendors and Service Providers. The schedule established in subsections (1) and (2) of this section shall apply to any entity or individual seeking or maintaining a designation as a qualified expert, vendor, or service provider as defined in 902 KAR 100:010.

(1) Qualified experts.

- (a) Initial application shall be \$105[100].
- (b) Annual fee shall be \$52.50[fifty (50) dollars].
- (2) Vendors and service providers shall be \$315[300].

Section 7. General Requirements. (1) A general radioactive material license shall expire on July 31 following the date of issuance.

(2) A radiation producing machine registration certificate shall expire on the last day of the month, one (1) year after the date of issuance.

(3) A general radioactive material license fee shall be paid on or before July 31.

(4) A specific radioactive material license shall be renewed annually based on the expiration date stated in the license.

(5) A renewal fee shall be paid within forty-five (45) days of the bill date. A payment postmarked more than forty-five (45) days of the bill date shall be subject to a \$100 late payment penalty per license, device, or x-ray <u>machine[tube]</u> in addition to the renewal fee.

(6) Payment of a fee or other charge shall be submitted to the Radiation Health Branch, Cabinet for Health and Family Services, 275 East Main Street, Mailstop HS1C A, Frankfort, Kentucky 40621-0001, in the form of a check or money order payable to the Kentucky State Treasurer or paid online at <u>https://prd.webapps.chfs.ky.gov/rad_epay/</u>

[https://prd.chfs.ky.gov/rad_epay/].

(7) If a check issued for payment of the fee established in this administrative regulation is returned to the state treasurer due to insufficient funds, the payor shall resubmit payment by money order or cashier's check.

(8) A registration and licensing application fee shall be nonrefundable.

(9) Failure to submit an applicable fee established in this administrative regulation shall be deemed a violation and subject to the provisions of 902 KAR 100:170.

Section 8. Incorporation by Reference. <u>The following material</u> <u>is incorporated by reference:</u> (1) "RPS-526, [Certification of] Small Entity <u>Certification[Status,]</u>" edition <u>6/2020[12/2014]</u>, is incorporated by reference: and.

(2) <u>"Registration Application for Radiation Producing</u> Machines" RPS 402, 4/2016.

(3) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Cabinet for Health and Family Services, Department for Public Health, Division of Public Health Protection and Safety, Radiation Health Branch, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8:00 a.m. to 4:30 p.m.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

CABINET FOR HEALTH AND FAMILY SERVICES Department for Community Based Services Division of Family Support (As Amended at Interim Joint Committee on Health and Welfare, September 23, 2020)

921 KAR 3:025. Technical requirements.

RELATES TO: KRS 205.2005, 7 C.F.R. <u>*Parts* 271-285,</u> 273.4, 273.5, 273.7, 273.11, 45 C.F.R. 261.2, 7 U.S.C. 2011, 2014, 2015(d)

STATUTORY AUTHORITY: KRS 194A.050(1), 7 C.F.R. 271.4, Part 272, Part 273

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to implement programs mandated by federal law or to qualify for the receipt of federal funds and necessary to cooperate with other state and federal agencies for the proper administration of the cabinet and its programs. 7 C.F.R. 271.4 requires the cabinet to administer a Supplemental Nutrition Assistance Program (SNAP) within the state. 7 C.F.R. Parts 272 and 273 establish requirements for the cabinet to participate in the SNAP. In addition, 7 U.S.C. 2014 establishes that an otherwise-gualified alien who is blind or receiving a disability benefit, who has lived in the United States for at least five (5) years, or who is under eighteen (18) years of age shall be eligible to participate in SNAP regardless of the date he entered the United States. This administrative regulation establishes the technical eligibility requirements used by the cabinet in the administration of SNAP.

Section 1. Definitions. (1) ["Certification period" means a period of time during which a household shall be eligible to receive SNAP benefits.

(2)] "Exempt" means excused by the department from participation in the Supplemental Nutrition Assistance Program Employment and Training Program (E&T).

(2)[(3)] "Qualified alien" is defined by 7 C.F.R. 273.4.

(3)[(4)] "Student" means a person who is between the ages of eighteen (18) and forty-nine (49), physically and mentally fit, and enrolled at least half-time in an institution of higher education.

Section 2. Technical Eligibility. In accordance with <u>*T C.F.R.*</u> <u>Parts 271 through 285[federal regulations]</u> promulgated by the Food and Nutrition Service (FNS), of the United States Department of Agriculture, the cabinet shall utilize national uniform requirements of technical eligibility for SNAP.

Section 3. Technical Eligibility Criteria. Technical eligibility requirements shall apply to all households and consist of <u>the</u> <u>criteria established in this section.[-;]</u>

(1) Residency. A household:

(a) Shall reside in the county in which the household receives benefits; and

(b) May apply for benefits in any county in accordance with 921 KAR 3:030, Section 3.

(2) Identity.

(a) The applicant's identity shall be verified; and

(b) If an authorized representative applies for the household, the applicant's and the authorized representative's identities shall be verified.

(3) Citizenship and alien status.

(a) An individual shall satisfy the citizenship and alien status requirement if the individual is a:

1. Citizen of the United States;

2. U.S. noncitizen national; or

3. Qualified alien who is lawfully residing in Kentucky.

(b) Except as provided in paragraph (c) of this subsection, an individual whose status is questionable shall be ineligible to participate until verified.

(c) An individual whose status is pending verification from a federal agency shall be eligible to participate for up to six (6) months from the date of the original request for verification.

(d) A single household member shall attest in writing to the citizenship or alien status requirements as established in 921 KAR 3:030 for each household member.

(4) Household size. If information is obtained by the Department for Community Based Services (DCBS) that household size differs from the household's stated size, the size of household shall be verified through readily available documentary evidence or through a collateral contact.

(5) Students. A student shall be ineligible to participate unless the student is:

(a)1. Engaged in paid employment for an average of twenty (20) hours per week; or

2. If self-employed, employed for an average of twenty (20) hours per week and receiving weekly earnings at least equal to the federal minimum wage multiplied by twenty (20) hours;

(b) Participating in a state or federally financed work study program during the regular school year;

(c) Responsible for the care of a dependent household member under the age of six (6);

(d) Responsible for the care of a dependent household member who has reached the age of six (6), but is under age twelve (12) and for whom the cabinet has determined that adequate child care is not available to enable the individual to attend class and to satisfy the work requirements of paragraphs (a) or [and] (b) of this subsection;

(e) Receiving benefits from the Kentucky Transitional Assistance Program (K-TAP);

(f) Assigned to or placed in an institution of higher learning through a program pursuant to:

1. 7 C.F.R. 273.5(a)[29 U.S.C. 2801];

2. 45 <u>C.F.R.[U.S.C.]</u> 261.2; or

3. 19 U.S.C. 2296;

(g) Enrolled in an institution of higher learning as a result of participation in a work incentive program pursuant to 42 U.S.C. 681;

(h) Enrolled in an institution of higher learning as a result of participation in E&T in accordance with 921 KAR 3:042; or

(i) A single parent with responsibility for the care of a dependent household member under age twelve (12).

(6) Social Security number (SSN).

(a) Households applying for or participating in SNAP shall comply with SSN requirements by providing the SSN of each household member or applying for a number prior to certification.

(b) Failure to comply without good cause shall be determined for each household member and shall result in an individual's disqualification from participation in SNAP until this requirement is met.

(7) Work registration. All household members, unless exempt, shall be required to comply with the work registration requirements established in Section 4 of this administrative regulation.

(8) Work requirement.

(a) Except for individuals who may be eligible for up to three (3) additional months in accordance with <u>paragraph (e) of this</u> <u>subsection[Section 4 of this administrative regulation]</u>, an individual shall not be eligible to participate in SNAP as a member of a household if the individual received SNAP for more than three (3) countable months during any three (3) year period, during which the individual did not:

1. Work eighty (80) hours or more per month;

 Participate in and comply with the requirements of the E&T component pursuant to 7 U.S.C. 2015(d) for twenty (20) hours or more per week;

3. Participate in and comply with the requirements of a program pursuant to:

a. 7 C.F.R. 273.5(a)[29 U.S.C. 2801 to 2945]; or

b. 19 U.S.C. 2296;

4. Participate in and comply with the requirements established in 921 KAR 3:042; or

5. Receive SNAP benefits pursuant to paragraph (b), (c), or (d) of this subsection.

(b) Paragraph (a) of this subsection shall not apply to an individual if the individual is:

1. Under eighteen (18) or fifty (50) years of age or older;

Physically or mentally unfit for employment as determined by the cabinet;

3. A parent or other adult member of a household containing a dependent child under the age of eighteen (18);

4. Exempt from work registration pursuant to Section 4(4) of this administrative regulation; or

5. Pregnant.

(c) Paragraph (a) of this subsection shall not apply if, pursuant to an approved waiver by FNS, the county or area in which the individual resides:

1. Has an unemployment rate of over ten (10) percent; or

2. Does not have a sufficient number of jobs to provide employment.

(d) Subsequent eligibility.

1. An individual denied eligibility pursuant to paragraph (a) of this subsection shall regain eligibility to participate in SNAP if, during a thirty (30) day period, the individual meets <u>one of</u> the conditions of paragraph (a)1. through 4. of this subsection, or the individual was not meeting the work requirements in accordance with paragraph (b) of this subsection.

2. An individual who regains eligibility pursuant to subparagraph 1. of this paragraph shall remain eligible as long as the individual meets the requirements of subparagraph 1. of this paragraph.

(e) Loss of employment or training.

1. An individual who regains eligibility pursuant to paragraph (d)1. of this subsection and who no longer meets the requirements of paragraph (a)1. through 4. of this subsection shall remain eligible for a consecutive three (3) month period, beginning on the date the individual first notifies the cabinet that the individual no longer meets the requirements of paragraph (a)1. through 4. of this subsection.

2. An individual shall not receive benefits pursuant to subparagraph 1. of this paragraph for more than a single three (3) month period in any three (3) year period.

(f) If the individual does not meet all other technical and financial eligibility criteria pursuant to 7 U.S.C. 2011, nothing in this section shall make an individual eligible for SNAP benefits.

(9) Quality control. Refusal to cooperate in completing a quality control review shall result in termination of the participating household's benefits.

(10) Drug felons. An individual convicted under federal or state law of an offense classified as a felony by the law of the jurisdiction involved and that has an element of possession, use, or distribution of a controlled substance as defined in 21 U.S.C. 862(a), may remain eligible for SNAP benefits if the individual meets the requirements <u>established in</u> [pursuant to] KRS 205.2005.[

(11) Child Support Arrears.

(a) In accordance with 7 C.F.R. 273.11(q) to disqualify a noncustodial parent for refusing to cooperate, a noncustodial parent of a child under the age of eighteen (18) shall not be eligible to participate in SNAP if the individual is delinquent in payment of court-ordered support as determined by the Department for Income Support, Child Support Enforcement, unless the individual:

1. Is enrolled in a drug treatment program;

2. Is participating in a state or federally funded employment

training program;

3. Meets good cause for nonpayment. Good cause shall include temporary situations of thirty (30) days or less resulting from illness, job change, or pendency of unemployment benefits;

4. Is a member of a SNAP household containing a child under the age of six (6);

5. Is pregnant or three (3) months post-partum; or

6. ls:

a. Within three (3) months of incarceration for a period of at least six (6) months; and

b. Cooperating with the Department for Income Support, Child Support Enforcement.

(b) The disqualification of an individual in accordance with paragraph (a) of this subsection shall be in place as long as the individual remains delinquent as determined by Department for Income Support, Child Support Enforcement.

(c) The income, expenses, and resources of an individual disqualified in accordance with paragraph (a) of this subsection shall be processed in accordance with 921 KAR 3:035, Section 5(4).]

Section 4. Work Registration. (1) Unless a household member is exempt from work requirements as established in subsection (4) of this section, a household member shall register for work:

(a) At the time of initial application for SNAP; and

(b) Every twelve (12) months following the initial application.

(2) Work registration shall be completed by the:

(a) Member required to register; or

(b) Person making application for the household.

(3) Unless otherwise exempt, a household member excluded from the SNAP case shall register for work during periods of disqualification. An excluded person shall be an:

(a) Ineligible alien; or

(b) Individual disqualified for:

1. Refusing to provide or apply for a Social Security number; or 2. An intentional program violation.

(4) An individual meeting the criteria of 7 C.F.R. 273.7(b)(1) shall be exempt from work registration requirements.

(5) A household member who loses exemption status due to a change in circumstances shall register for work in accordance with 7 C.F.R. 273.7(b)(2).

(6) After registering for work, a nonexempt household member shall:

(a) Respond to a cabinet request for additional information regarding employment status or availability for work;

(b) In accordance with 7 C.F.R. 273.7(a)(1)(vi), accept a bona fide offer of suitable employment pursuant to 7 C.F.R. 273.7(h), at a wage not lower than the state or federal minimum wage; or

(c) In accordance with 7 C.F.R. 273.7(a)(1)(ii), participate in the E&T Program if assigned by the cabinet.

(7) A household member making a joint application for SSI and SNAP in accordance with 921 KAR 3:035 shall have work requirements waived in accordance with 7 C.F.R. 273.7(a)(6).

(8) The cabinet's E&T worker shall explain to the SNAP applicant the:

(a) Work requirements for each nonexempt household member;

(b) Rights and responsibilities of the work-registered household members; and

(c) Consequences of failing to comply.

Section 5. Determining Good Cause. (1) A determination of good cause shall be undertaken if a:

(a) Work registrant has failed to comply with work registration requirements as established in Section 4 of this administrative regulation; or

(b) Household member has, pursuant to Section 7 of this administrative regulation, voluntarily:

1. Quit a job; or

2. Reduced the household member's work effort.

(2) In accordance with 7 C.F.R. 273.7(i)(2), good cause shall be granted for circumstances beyond the control of the individual, such as:

(a) Illness of the individual;

(b) Illness of another household member requiring the presence of the individual;

(c) A household emergency;

(d) Unavailability of transportation; or

(e) Lack of adequate care for a child who is six (6) to twelve (12) years of age for whom the individual is responsible.

(3) Good cause for leaving employment shall be granted if:

(a) A circumstance established in subsection (2) of this section exists;

(b) The employment became unsuitable in accordance with 7 C.F.R. 273.7(h); or

(c) A circumstance established in 7 C.F.R. 273.7(i)(3) exists.

Section 6. Disqualification. (1) A participant shall be disqualified from the receipt of SNAP benefits if the participant: (a) Fails to comply with the work registration requirements; or

(b) Is determined to have voluntarily, without good cause, quit a job or reduced the work effort as established in Section 5 of this administrative regulation.

(2) An individual disqualified from participation in SNAP shall be ineligible to receive SNAP benefits until the latter of the:

(a) Date the individual complies; or

(b) Lapse of the following time periods:

1. Two (2) months for the first violation;

2. Four (4) months for the second violation; or

3. Six (6) months for the third or a subsequent violation.

(3) Ineligibility shall continue until the ineligible member:

(a) Becomes exempt from the work registration; or

(b)1. Serves the disqualification period established in subsection (2)(b) of this section; and

2. Complies with the work registration requirements.

(4) A disqualified household member who joins a new household shall:

(a) Remain ineligible for the remainder of the disqualification period established in subsection (2)(b) of this section;

(b) Have income and resources counted with the income and resources of the new household; and

(c) Not be included in the household size in the determination of the SNAP allotment.

Section 7. Disqualification for Voluntary Quit or Reduction in Work Effort. (1) Within thirty (30) days prior to application for SNAP or any time after application, an individual shall not be eligible to participate in SNAP if the individual voluntarily, without good cause:

(a) Quits a job:

1. Of thirty (30) hours or more per week; and

2. With weekly earnings at least equal to the federal minimum wage times thirty (30) hours; or

(b) Reduces the individual's work effort [to]:

1. To less [Less] than thirty (30) hours per week; and

2. <u>So that after [After]</u> the reduction, weekly earnings are less than the federal minimum wage times thirty (30) hours.

(2) The cabinet shall impose a disqualification period established in Section 6(2)(b) of this administrative regulation on an individual meeting subsection (1)(a) or (1)(b) of this section.

Section 8. Curing Disqualification for Voluntary Quit or Reduction in Work Effort. (1) Eligibility and participation may be reestablished by:

(a) Securing new employment with salary or hours comparable to the job quit;

(b) Increasing the number of hours worked to the amount worked prior to the work effort reduction and disqualification; or

(c) Serving the minimum period of disqualification imposed pursuant to Section 6(2)(b) of this administrative regulation.

(2) If the individual applies again and is determined to be eligible, an individual may reestablish participation in SNAP.

(3) If an individual becomes exempt from work registration, the disqualification period shall end, and the individual shall be eligible to apply to participate in SNAP.

Section 9. Hearing Process. If aggrieved by a cabinet action or inaction that affects participation, a SNAP participant may request a hearing in accordance with 921 KAR 3:070.

<u>Section 10. This administrative regulation was found</u> deficient by the Interim Joint Committee on Health and Welfare on September 23, 2020.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091, email CHFSregs@ky.gov.

CABINET FOR HEALTH AND FAMILY SERVICES Department for Community Based Services Division of Protection and Permanency (As Amended at ARRS, October 13, 2020)

922 KAR 1:330. Child protective services.

RELATES TO: KRS 159.140, 194A.005(1), 194A.050(1), 202A.011, 211.684, 214.036, 431.600(1), (8), 503.110(1), 508.125(1), 529.010(5), (13), 532.045, 600.010, 600.020, 605.090(3), 605.130, 605.150(1), 610.010(2)(d), (9), 620.010-620.050, 620.070, 620.072, 620.180(1), 620.350, 620.990, 42 U.S.C. 5106a

STATUTORY AUTHORITY: KRS 194A.050(1), 605.150(1), 620.029(2)(a), 620.180(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the Secretary of the Cabinet for Health and Family Services to promulgate, administer, and enforce administrative regulations necessary to implement programs mandated by federal law or to qualify for the receipt of federal funds and necessary to cooperate with other state and federal agencies for the proper administration of the cabinet and its programs. KRS 605.150(1) authorizes the cabinet to promulgate administrative regulations to implement the provisions of KRS Chapter 605. KRS 620.180(1) authorizes the cabinet to promulgate administrative regulations to implement the provisions of KRS Chapter 620. KRS 620.029(2)(a) requires the cabinet, in consultation with agencies serving victims of human trafficking, to promulgate administrative regulations for the treatment of children who are reported to be victims of human trafficking as dependent, neglected, or abused children, including providing for appropriate screening, assessment, treatment, and services. 42 U.S.C. 5106a(b) establishes eligibility requirements for a state to receive a grant for a child abuse and neglect prevention and treatment program. This administrative regulation establishes cabinet procedures, congruent with eligibility requirements under 42 U.S.C. 5106a(b), for a child protection investigation or assessment of abuse, neglect, or dependency.

Section 1. Definitions. (1) "Assessment" means the collection and analysis of information to inform decision-making about or service provision to a child or a family, including:

(a) An observable threat or threatening condition to the child's safety;

(b) A factor present that increases the likelihood of child abuse, neglect, or dependency; and

(c) Child or family strengths and protective capacities.

(2) "Cabinet" is defined by KRS 194A.005(1) and 600.020(7).

(3) "Caretaker" means a parent, guardian, fictive kin, person in a position of authority or special trust as defined in KRS 532.045(1), or other person exercising custodial control or supervision of a child.

(4) "Child fatality" is defined by KRS 211.684(1)(a).

(5) "Child protective services" means preventive and corrective services directed toward:

(a) Safeguarding the rights and welfare of an abused, neglected, or dependent child;

(b) Assuring for each child a safe and nurturing home;

(c) Improving the abilities of parents to carry out parental

responsibilities;

(d) Strengthening family life; and

(e) Assisting a parent or other person responsible for the care of a child in recognizing and remedying conditions detrimental to the welfare of the child.

(6) "Dependent child" is defined by KRS 600.020(20).

(7) "Female genital mutilation" is defined by KRS 508.125(1).

(8) "Human trafficking" is defined by KRS 529.010(5).

(9)[(8)] "Initial determination" means an evaluation of risk factors to determine immediate safety and risk of harm resulting in a decision whether to proceed with an:

(a) Investigation; or

(b) Assessment.

(10)[(9)] "Investigation" means a process of collecting information and evaluating risk factors to determine if a child:

(a) Has been abused or neglected;

(b) Is dependent; or

(c) Is a victim of human trafficking.

 $\underline{(11)[(10)]}$ "Near fatality" is defined by KRS 600.020(40) and 42 U.S.C. 5106a(b)(4)(A).

(12)[(11)] "No finding" means that the information contained in a report that met criteria to open an investigation has been found to be false or erroneous and no longer meets acceptance criteria.

(13)[(12)] "Preponderance of evidence" means that evidence is sufficient to conclude that it is more likely than not that an alleged perpetrator committed an act of child abuse or neglect as defined by KRS 600.020(1).

(14)[(13)] "Prior involvement" means any assessment or investigation, of which the cabinet has record, with a child or family in the area of protection and permanency prior to the child's fatality or near fatality investigation.

(15)[(14)] "Services needed" means a low risk finding with no perpetrator that indicates a family needs to be linked to community services.

(16)[(15)] "Sexual abuse" is defined by KRS 600.020(61).

(17)[(16)] "Sexual exploitation" is defined by KRS 600.020(62).

(18)[(17)] "Substantiated" means:

(a) An admission of abuse or neglect by the person responsible;

(b) A judicial finding of child abuse or neglect; or

(c) A preponderance of evidence exists that abuse or neglect was committed by the caretaker.

(19)[(18)] "Unable to locate" means that:

(a) Identifying information about the family is insufficient for locating them; or

(b) The family has moved and their new location is not known.

(20)[(19)] "Unsubstantiated" means there is insufficient evidence, indicators, or justification present for substantiation of abuse or neglect.

(21)[(20)] "Victim of human trafficking" is defined by KRS 529.010(13).

Section 2. A Report of Child Abuse, Neglect, or Dependency. (1) In accordance with 42 U.S.C. 5106a(b)(2)(B)(i), the cabinet shall accept reports of alleged child abuse, neglect, or dependency made pursuant to KRS 620.030.

(a) A twenty-four (24) hour on-call response system and the child abuse hotline, for the receipt of emergency reports after normal office hours, shall be made available to those in a community who may have information regarding:

1. Child abuse, neglect, or dependency; or

2. Human trafficking of a child.

(b) Cabinet staff or designee shall attempt to elicit from the person reporting suspected child abuse, neglect, dependency, <u>female genital mutilation</u>, or human trafficking as much information about the child's circumstances as possible, including:

1. Specific information as to the nature and extent of:

a. Abuse, neglect, or dependency; [or]

b. Female genital mutilation; or

c. Human trafficking;

2. The cause of the abuse, neglect, or dependency;

3. The location of the child and family;

4. Knowledge or suspicion of a previous incident;

5. Identifying information regarding a witness to the alleged incident that resulted in the child's condition;

6. An action taken by the reporting person, if applicable;

7. Present danger or threat of danger to the child or cabinet staff; and

8. Information in accordance with KRS 620.030(2) through (4)[and (3)].

(c) The reporting person's identity shall remain confidential, unless ordered to be divulged by a court of competent jurisdiction.

(d) The cabinet shall investigate or accept as an assessment an anonymous report that provides sufficient information regarding an incident involving a child:

1. Who is alleged to be dependent; or

2. And alleged:

a. Abuse or neglect perpetrated by a caretaker; [or]

b. Female genital mutilation, whether the person alleged to have caused it is a caretaker or not; or

c. Human trafficking of the child.

(e) Immunity from liability shall be in accordance with 42 U.S.C. 5106a(b)(2)(B)(vii) and KRS 620.050(1) and (2).

(2) The cabinet shall not undertake an investigation or assessment for a report of abuse or neglect allegedly perpetrated by a non-caretaker, with the exception of a report of human trafficking <u>or female genital mutilation</u> or a joint investigation with law enforcement pursuant to KRS 620.040(3), but shall refer the matter in compliance with KRS 620.030(1).

(3) Pursuant to KRS 620.040(1)(b) and (2)(b), if a report does not meet an acceptance criterion for an investigation or assessment, the cabinet shall:

(a) Not accept the report for investigation or assessment;

(b) Refer the caller to a community resource that may meet family needs if available; and

(c) Keep a record of the report in accordance with 42 U.S.C. 5106a(b)(2)(B)(xii).

(4) Acceptance criteria for an investigation or assessment. The cabinet shall:

(a) Investigate or conduct an assessment upon the receipt of a report of physical abuse if the report alleges:

1. An injury that is, or has been, observed on a child that was allegedly inflicted non-accidentally by a caretaker;

2. Physical abuse if no current observable injury is seen;

3. A child being hit in a critical area of the body, such as the head, neck, genitals, abdomen, or back;

4. Physical injury to a child, as defined by KRS 600.020(49), that is the result of an altercation between the child and the caretaker. The cabinet shall explore the following:

a. Age of the child;

b. Precipitating factors;

c. Degree of appropriateness of force used by the caretaker; and

d. Need for further services to assist in eliminating violent behavior in the home;

5. A situation in which a child is likely to be physically abused; or

6. Physical injury to a child involved in an incident of domestic violence;

(b) Investigate or conduct an assessment upon receipt of a report that alleges neglect of a child perpetrated by a caretaker that may result in harm to the health and safety of a child in the following areas:

1. Hygiene neglect if:

a. A child has physical symptoms that require treatment due to poor care; or

b. The child's physical health and safety are negatively affected due to an act or omission by the caretaker;

2. Supervision neglect if the individual reporting has reason to believe that the physical health and safety of the child is negatively affected by lack of necessary and appropriate supervision;

3. Food neglect if a child shows symptoms of:

a. Malnutrition;

b. Dehydration; or

c. Not having been provided adequate food for a period of time that interferes with the health needs of the child, based on height or weight norms for the child's age;

4. Clothing neglect if a child suffers from:

a. Illness;

b. Exposure; or

c. Frostbite due to inadequate clothing provided to the child or the clothing provided is insufficient to protect the child from the elements;

5. Environmental neglect, if a serious health and safety hazard is present and the caretaker is not taking appropriate action to eliminate the problem;

6. Educational neglect if the:

a. School system has exhausted its resources to correct the problem and complied with its duties pursuant to KRS 159.140; and

b. Caretaker's neglect prevents the child from attending school or receiving appropriate education;

7. Medical neglect, in accordance with 42 U.S.C. 5106a(b)(2)(C), if a child has not received a medical assessment or is not receiving treatment for an injury, illness, or dis-ability that if left untreated may:

a. Be life-threatening;

Result in permanent impairment;

c. Interfere with normal functioning and worsen; or

d. Be a serious threat to the child's health due to the outbreak of a vaccine preventable disease, unless the child is granted an exception to immunization pursuant to KRS 214.036;

8. Neglect due to a caretaker's use of drugs or alcohol that results in:

a. A child born exposed to drugs or alcohol, as documented by a health care provider pursuant to:

(i) 42 U.S.C. 5106a(b)(2)(B)(ii); and

(ii) KRS 620.030(2);

b. A child's facilitated access to and use of drugs or alcohol that may result in a life-threatening situation for the child; or

9. Exploitation neglect if the:

a. Caretaker has used a child or child's financial resources for personal gain;

b. Caretaker has enticed a child to become involved in criminal activities; or

c. Child is a victim of human trafficking;

(c) Investigate or conduct an assessment upon the receipt of a report of sexual abuse if the report:

1. Alleges sexual abuse of a child committed or allowed to be committed by a caretaker. An investigation may be conducted without a specific allegation if a child has a sexually transmitted disease; or

2. Alleges a situation in which the factors provided in the report indicate that:

a. An act of sexual abuse, sexual exploitation, or prostitution involving a child may have occurred; or

b. The child exhibits physical or behavioral indicators of sexual abuse;

(d) Investigate or conduct an assessment upon the receipt of a report that alleges emotional injury or risk of emotional injury to a child by a caretaker pursuant to KRS 600.020(26); and

(e) Investigate or conduct an assessment upon the receipt of a report that alleges dependency if the report alleges that a child is dependent pursuant to KRS 600.020(20).

(5) The following criteria shall be used in identifying a report of abuse, neglect, or dependency not requiring a child protective services investigation or assessment:

(a) The victim of the report of abuse, neglect, or dependency is age eighteen (18) or older at the time of the report;

(b) There is insufficient information to locate the child or to explore leads to locate;

(c) The problem described does not meet the statutory definitions of abuse, neglect, or dependency;

(d) The reporter notifies the cabinet that a child is injured, but the reporter does not allege injuries were the result of abuse or neglect;

(e) The report concerns custody changes, custody related issues, or lifestyle issues, without allegations of abuse, neglect, or dependency;

(f) Pursuant to KRS 503.110(1), corporal punishment

appropriate to the age of the child, without an injury, mark, bruise, or substantial risk of harm; or

(g) An allegation of spouse abuse to a married youth under the age eighteen (18).

(6) An abandoned newborn infant pursuant to KRS 620.350 shall be determined to be dependent unless indicators of child physical abuse or child neglect are present.

Section 3. Initial Investigation or Assessment. (1) Based upon an accepted report of child abuse, neglect, or dependency, the cabinet shall, in accordance with KRS 620.040(1)(b) or (2)(b), and 42 U.S.C. 5106a(b)(2)(B)(iv), make an initial determination as to the immediate safety and risk of harm to a child.

(2) The cabinet shall have face-to-face contact with the child or, in the case of a child fatality, initiate the investigation within four(4) hours after acceptance of the report if a report of child abuse, neglect, or dependency:

(a) Includes a child who is:

1. The alleged victim of a fatality or near fatality; or

2. A surviving child in the care of the alleged perpetrator of a child fatality or near fatality; or

(b)1. Involves a child who is:

a. Under four (4) years of age; or

b. Unable to verbally or nonverbally communicate the child's needs as provided by the reporting source; and

2. Indicates a high risk of harm to the child due to:

a. Physical abuse in accordance with Section 2(4)(a) of this administrative regulation;

b. Supervision neglect in accordance with Section 2(4)(b)2. of this administrative regulation; or

c. Sexual abuse in accordance with Section 2(4)(c) of this administrative regulation, and the alleged:

(i) Perpetrator has access to the child; or

(ii) Perpetrator's access to the child is unknown by the reporting source.

(3) The cabinet shall have face-to-face contact with the child within twenty-four (24) hours after acceptance of the report, if a report of child abuse, neglect, or dependency:

(a)1. Indicates a high risk of harm to the child; or

2. Alleges the child is the victim of human trafficking <u>or female</u> genital mutilation; and

(b) Criteria of subsection (2) of this section are not met.

(4) If the report of child abuse, neglect, or dependency indicates a moderate risk of harm to a child, the cabinet shall have face-to-face contact with the child within forty-eight (48) hours after acceptance of the report.

(5) If the report of child abuse, neglect, or dependency indicates a low risk of harm to a child, the cabinet shall have face-to-face contact with the child within seventy-two (72) hours after acceptance of the report.

(6) Cabinet staff shall be permitted to interview an alleged victim of child abuse or neglect without obtaining the consent of the caretaker in accordance with KRS 620.072.

(7) Cabinet staff shall incorporate an unannounced home visit in accordance with provisions in KRS 620.072.

(8) Cabinet staff shall:

(a) Advise the individual under investigation of the complaints or allegations in accordance with 42 U.S.C. 5106a(b)(2)(B)(xviii); and

(b) Notify the parent or legal guardian of the child alleged to be abused, neglected, or dependent pursuant to KRS 620.050(5).

(9) A written assessment shall:

(a) Be completed by the cabinet on every investigation; and

(b) Document efforts if the cabinet is unable to locate the family.

(10) The cabinet shall provide or make a referral to any community-based service:

(a) Available to a child, caretaker, or a child's family:

1. In accordance with 42 U.S.C. 5106a(b)(2)(B)(v),(vi),(ix),(xi), or (xxi); or

2. Pursuant to KRS 620.029 or 620.040(1)(b) or (2)(b); and

(b) Necessary to:1. Reduce risk to a child; and

2. Provide family support.

(11) The cabinet shall make a referral for early intervention services pursuant to 42 U.S.C. 5106a(b)(2)(B)(xxi) for a child under the age of three (3) who is involved in a substantiated case of abuse or neglect.

(12)(a) The cabinet may develop a plan for services at any point during an investigation or assessment to protect the health and safety of a child.

(b) The plan shall be:

1. Developed in conjunction with a family and the family's identified support system;

2. Agreed upon by the participants;

3. Signed by all parties identified to participate in the plan, unless a party is unwilling or unable to sign; and

4. Provided to all participants.

(13) If an investigation or assessment is conducted as a result of a child being referred pursuant to Section 2(4)(b)8. of this administrative regulation, the cabinet shall develop a plan in accordance with 42 U.S.C. 5106a(b)(2)(B)(iii).

(14) Collateral contact shall be made pursuant to KRS 620.030, 620.040, and 620.050.

(15)(a) A medical or psychological examination may be required if a report of <u>female genital mutilation; *human trafficking*</u>: <u>or</u> child abuse, neglect, or dependency alleges that a child has suffered physical or sexual harm or emotional injury.

(b) A medical examination shall be conducted in accordance with KRS 620.050(14).

(16) Cabinet staff shall coordinate an investigation with a children's advocacy center governed by 922 KAR 1:580, in accordance with KRS 620.040(6) and (7).

(17) Pursuant to KRS <u>620.030(6)[620.030(5)]</u>, an agency, institution, or facility serving the child or family shall provide cooperation, assistance, and information necessary for the cabinet to conduct an investigation or assessment.

(18) Photographs may be taken of a child or a child's environment during a protective services investigation or assessment in accordance with KRS 620.050(14).

(19) An interview with a child shall be conducted pursuant to KRS 620.040(6).

(20)(a) A child sexual abuse, <u>female genital mutilation</u>, or human trafficking investigation shall be conducted jointly with law enforcement and other multidisciplinary team members pursuant to KRS 431.600(1) and (8), 620.040(3), and 42 U.S.C. 5106a(b)(2)(B)(xi).

(b) The cabinet's primary responsibility shall be the protection of the child.

(21) If there is reason to believe a child is in imminent danger, or if a parent or caretaker of a child refuses the cabinet entry to a child's home or refuses to allow a child to be interviewed, the cabinet may request assistance:

(a) From law enforcement; or

(b) Through a request for a court order pursuant to KRS 620.040(5)(a).

(22)(a) If the court issues a search warrant for execution by law enforcement, cabinet staff may accompany law enforcement officers.

(b) Except as provided in KRS 605.090(3), the cabinet shall not remove a committed child from the child's home without a court order.

(23) At the request of law enforcement, the cabinet shall, pursuant to KRS 620.040(3):

(a) Provide assistance in interviewing an alleged child abuse victim in a noncaretaker report; and

(b) Not be the lead investigator in a noncaretaker investigation.

Section 4. Alleged Perpetrators of Abuse or Neglect Age Twelve (12) to Eighteen (18).

(1) A report of child abuse or neglect involving alleged perpetrators in a care-taking role age twelve (12) to eighteen (18) shall be subject to investigation or assessment.

(2) If substantiated, a child age twelve (12) to eighteen (18) shall be identified as the alleged perpetrator.

Section 5. Child Fatality or Near Fatality Investigations. (1) The cabinet shall investigate a report of child fatality or near fatality alleged to be the result of abuse or neglect in accordance with KRS 620.040.

(2) If there is a surviving child in the care of the alleged perpetrator, the cabinet shall determine the safety of the surviving child through immediate assessment in accordance with this administrative regulation.

(3) If a child fatality or near fatality allegedly due to abuse or neglect occurs, cabinet staff shall immediately notify the service region administrator or designee.

(4) If a fatality or near fatality occurs to a child in the custody of the cabinet in an out-of-home placement, the cabinet shall make an immediate effort to notify:

(a) The biological or legal parents; and

(b) The Office of the Director of the Division of Protection and Permanency.

(5) If parental rights have been terminated, and there are special circumstances including ongoing contact with the child, the cabinet shall notify a child's biological or legal parents of the child's fatality or near fatality.

(6) The cabinet shall notify the Department of Public Advocacy, Protection and Advocacy Division, in the Justice and Public Safety Cabinet if:

(a)1. A child identified as a protection and advocacy client dies as a result of alleged abuse or neglect; and

2. The alleged perpetrator is a person exercising custodial control or supervision; or

(b) A child fatality has occurred as a result of:

1. Placement in a seclusion room pursuant to 922 KAR 1:390; or

2. Physical management applied pursuant to 922 KAR 1:300.

(7) The cabinet shall notify the following persons, in writing, of a fatality of a child in the custody of the cabinet:

(a) Judge of the committing court; and

(b) Guardian ad litem for the deceased child.

(8) The cabinet may make public disclosure of a fatality or near fatality in accordance with:

(a) KRS 620.050(5) and (12); and

(b) 42 U.S.C. 5106a(b)(2)(B)(x)[5106a(b)(2)(A)(x)].

(9) If the alleged perpetrator was not a caretaker, notification of the child fatality or near fatality shall be in accordance with KRS 620.030(1).

(10) The cabinet shall:

(a) Be in compliance with KRS 620.050(12) in cases where the cabinet has had prior involvement; and

(b) Provide annual reporting in accordance with 42 U.S.C. 5106a(d)(4)(5)(6)(11).

(11) If a child fatality or near fatality occurs in a licensed facility, the cabinet shall notify the licensing authority in accordance with 42 U.S.C. 5106a(b)(2)(B)(ix)[5106a(b)(2)(A)(ix)].

Section 6. Reports of Child Abuse, Neglect, or Dependency in Cabinet-approved Homes or Licensed Facilities. (1) Pursuant to KRS <u>620.030(6)</u> [620.030(5)], the cabinet shall have the authority to obtain necessary information to complete an investigation in a report of child abuse, neglect, or dependency in a:

(a) Child-caring facility licensed in accordance with 922 KAR 1:300 or its subcontractor;

(b) Child-placing agency licensed in accordance with 922 KAR 1:310 or its subcontractor;

(c) Child-care center licensed in accordance with 922 KAR 2:090:

(d) Family child-care home certified in accordance with 922 KAR 2:100;

(e) Child care provider registered in accordance with 922 KAR 2:180; or

(f) Foster, adoptive, or respite care provider home approved pursuant to 922 KAR 1:350.

(2) If a report of alleged child abuse, neglect, or dependency in a home approved pursuant to 922 KAR 1:310 or 922 KAR 1:350 is accepted, the designated cabinet staff shall:

(a) Immediately contact the service region administrator or

designee; and

(b) Assign staff to conduct the investigation.

(3) If a report of alleged child abuse or neglect in a licensed child-care center, a certified family child-care home, or a registered child care provider is accepted, cabinet staff shall:

(a) Notify the cabinet's Division of Child Care to share information and request assistance in locating alternate care if needed; and

(b) Conduct an investigation.

(4) If a report of alleged child abuse or neglect in a licensed child-caring facility, child-placing agency placement, certified family child-care home, or licensed child-care center is accepted, cabinet staff shall:

(a) Notify the Office of the Inspector General, Division of Regulated Child Care; and

(b) Conduct an investigation.

1. If possible, an investigation shall be coordinated and conducted jointly with the Division of Regulated Child Care. However, if not possible, the cabinet shall proceed with an investigation.

2.a. An entrance interview with the facility administrator or designee shall be conducted; and

b. The nature of the report shall be outlined without disclosing the name of the reporting source.

3. If the cabinet substantiates the report of child abuse or neglect and the alleged perpetrator is an employee of the facility, the cabinet shall notify the provider or program director within thirty (30) working days, unless a necessary extension is granted by the designated cabinet staff in a supervisory role.

(5) The cabinet shall share written findings of an investigation with the Division of Child Care for a:

(a) Licensed child-care center;

(b) Certified family child-care home; or

(c) Registered child care provider.

(6) The cabinet shall share written findings of an investigation with the Office of <u>the</u> Inspector General for a:

(a) Licensed child-care center;

(b) Certified family child-care home;

(c) Registered child care provider;

(d) Licensed child-caring facility; or

(e) Licensed child-placing agency.

(7) As soon as practical after a determination has been made that a child is in imminent danger or that a child needs to be removed, verbal or written notification shall be provided to the Division of Child Care or to the Office of the Inspector General.

Section 7. Interviewing a Child in a School Setting. (1) Pursuant to KRS <u>620.030(6)</u> [620.030(5)] and 620.072(4), the cabinet may, upon receipt of a report of child abuse or neglect, initiate an investigation or assessment at a school, which may include the review and copying of relevant school records pertaining to the child.

(2) If initiating an investigation or assessment at a school, the cabinet shall:

(a) Inform appropriate school personnel of the need to interview a child regarding the report; and

(b) Give necessary information concerning the allegation and investigation only to school personnel with a legitimate interest in the case.

Section 8. Investigation of an Employee of the School System. If a report of child abuse or neglect involving school personnel is accepted, the following shall apply:

(1) An investigation shall be conducted;

(2) If the allegation is made about a school employee in a caretaker role of a child, the cabinet shall, if possible, conduct an interview away from the school grounds, with each of the following persons:

(a) The child;

(b) The parent or legal guardian;

(c) The alleged perpetrator; and

(d) Other collateral source, if any, in accordance with Section 3(14) of this administrative regulation;

(3) The findings shall be shared with the custodial parent or guardian and the alleged perpetrator;

(4) The cabinet shall notify the appropriate supervisor of the alleged perpetrator, in writing, of the following:

(a) That an investigation has been conducted;

(b) The results of the investigation; and

(c) That the alleged perpetrator has the right to appeal pursuant to 922 KAR 1:480; and

(5) A person desiring other information shall employ the open records procedure, as described in 922 KAR 1:510.

Section 9. Written Notice of Findings of Investigation. The cabinet shall provide notification to specified government officials in accordance with KRS 620.040(1) or (2) and 42 U.S.C. 5106a(b)(2)(B)(ix).

Section 10. Substantiation Criteria and Submission of Findings. (1) The cabinet shall use the definitions of "abused or neglected child" in KRS 600.020(1) in determining if an allegation is substantiated.

(2) A finding of an investigation or assessment shall be based upon the:

(a) Information and evidence collected by the cabinet during the report's investigation or assessment; and

(b) Condition that is present, rather than an action taken to remediate an issue or concern pertaining to a child's health, safety, or welfare.

(3) Cabinet staff may find and substantiate abuse or neglect, or make a services needed finding, at any point during an investigation or assessment or prior to case closure and <u>aftercare[after-care]</u> planning in accordance with Section 12 of this administrative regulation, if preponderance of the evidence exists.

(4)(a) At the completion of an investigation or assessment involving a caretaker, the cabinet shall make a finding of:

1. Unsubstantiated child abuse or neglect;

2. Substantiated child abuse or neglect;

3. Child fatality or near fatality related to abuse or neglect;

4. Unable to locate the child;

5. Services needed for the child or child's family, which may include a dependent child;

6. No finding; or

7. Closed, which may include completed service provision.

(b) At the completion of an investigation involving human trafficking <u>or female genital mutilation</u> of a child by a non-caretaker, the cabinet shall make a finding of:

1. Confirmed [human trafficking];

2. Not confirmed [human trafficking]; or

3. Unable to locate the child.

(5) A cabinet finding shall not be a judicial finding.

(6) The cabinet staff's supervisor or designee shall review and approve the final finding of the investigation or assessment.

(7) Upon approval of the finding by designated cabinet staff in a supervisory role, the cabinet shall send a notice of finding and notice of the perpetrator's right to appeal in accordance with 922 KAR 1:480, Section 2, to the alleged or substantiated perpetrator by certified mail to the last known address of the perpetrator.

(8) Upon approval of the finding by designated cabinet staff in a supervisory role, the cabinet shall:

(a) Send a notice of finding to the child's parent or guardian by certified mail; or

(b) Give a notice of finding to the parent or guardian, in person, with the parent or guardian and a witness signature to document receipt of the notice.

(9) The cabinet's notice of a substantiated finding of child abuse or neglect shall include:

(a) The factual basis for the finding of child abuse or neglect;

(b) The results of the investigation;

(c) Information about the perpetrator's right to appeal the substantiated finding in accordance with 922 KAR 1:480; and

(d) A statement informing the perpetrator that the perpetrator's name shall be added to the central registry in accordance with 922 KAR 1:470.

Section 11. Appeals.

(1) The perpetrator of a substantiated finding of child abuse or neglect may request a hearing in accordance with 922 KAR 1:480.

(2) A person may have additional hearing rights as specified in 922 KAR 1:320.

Section 12. Closure. (1)(a) A decision to close a child protective services case shall be based on evidence that the factors resulting in the child abuse, neglect, or dependency have been resolved to the extent that the family is able to:

1. Protect the child; and

2. Meet the needs of the child.

(b) Prior to a case's closure in accordance with paragraph (a) of this subsection, designated cabinet staff in a supervisory role shall review and agree to the decision to close the child protective services case.

(2) If the cabinet does not have the authority to obtain courtordered cooperation from a family, the cabinet shall close the child protective services investigation or assessment.

(3) Unless court-ordered cooperation from the family cannot be obtained in accordance in subsection (2) of this section, a child protective services case shall not be closed if withdrawal of services places a child at risk of abuse, neglect, or dependency.

(4) A family shall be:

(a) Notified in writing of the decision to close the protective services case; and

(b) Advised of the right to a fair hearing in compliance with 922 KAR 1:320, Section 2.

(5) Aftercare planning shall link a family to community resources for the purpose of continuing preventive measures if the cabinet discontinues services in accordance with this section.

(6) An aftercare plan shall be developed upon the completion of an investigation or assessment, if an issue or concern identified by the cabinet falls below the level that triggers a protection services case being opened.

(7)(a) When it is determined that a protective services case is appropriate for closure, the cabinet shall work with the family to develop the aftercare plan.

(b) The focus of the aftercare plan shall be to prevent a recurrence of abuse, neglect, or dependency to the child in the home.

(8) The cabinet may open a child protective services case in accordance with 922 KAR 1:140, 1:400, or 1:430.

(9) The cabinet may request the assistance of a court of competent jurisdiction to protect the child in accordance with KRS 620.070.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

VOLUME 47, NUMBER 5– NOVEMBER 1, 2020

ADMINISTRATIVE REGULATIONS AMENDED AFTER PUBLIC HEARING OR RECEIPT OF WRITTEN COMMENTS

BOARDS AND COMMISSIONS Board of Pharmacy (Amended After Comments)

201 KAR 2:105 Requirements for wholesalers, medical gas wholesalers, wholesale distributors, and virtual [Licensing and drug distribution requirements for] wholesale distributors.

RELATES TO: KRS 315.010, <u>315.350</u>, 315.402, 315.406 STATUTORY AUTHORITY: KRS 315.010, 315.191(1)(a), 315.350, 315.402, 315.406

NECESSITY, FUNCTION, AND CONFORMITY: KRS <u>315.350</u>, 315.402 and 315.406 authorizes the board to promulgate administrative regulations to regulate <u>wholesalers</u>, <u>medical gas</u> <u>wholesalers</u>, <u>wholesale</u> distributors, <u>and virtual wholesale</u> <u>distributors</u> of <u>prescription</u> drugs <u>and related devices</u>. This administrative regulation establishes the requirements for the regulation of <u>wholesalers</u>, <u>medical gas wholesalers</u>, wholesale distributors, <u>and virtual wholesale</u> distributors.

Section 1. Definitions[Definition].

(1) "Distribution" or "distribute" has the same meaning given in KRS 315.400(5).

(2) "Drug sample" means \underline{a} unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(3) "Medical gas wholesaler" has the same meaning given in KRS 315.400(13).

(4) "Suspect product" means a product for which there is reason to believe that such product:

(a) Is potentially counterfeit, diverted, or stolen;

(b) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans or animals;

(c) Is potentially the subject of a fraudulent transaction; or

(d) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans or animals.

(5) "Wholesale distribution" has the same meaning given in KRS 315.400(20).

(6) "Wholesale distributor" has the same meaning given in KRS 315.400(21).

(7) "Wholesaler" has the same meaning given in KRS 315.010(28) and includes medical gas wholesalers, wholesale distributors, and virtual wholesale distributors.

(8) "Virtual wholesale distributor" has the same meaning given in KRS 315.400(21).

Section 2. Requirements.

(1) A <u>wholesaler[wholesale distributor]</u> engaged in wholesale distribution in the Commonwealth shall apply for a license from the <u>Board[beard]</u> of <u>Pharmacy</u> in accordance with KRS <u>315.350</u>, 315.402, 315.406, and this administrative regulation.

(2) A surety bond of not less than \$25,000 or other equivalent means of security acceptable to the Board of Pharmacy or a third party recognized by the Board of Pharmacy such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution, to secure payment of any administrative penalties imposed by the Board of Pharmacy and any fees or costs incurred by the Board of Pharmacy regarding that licensee when those penalties, fees, or costs are authorized under state law and the licensee fails to pay thirty (30) days after the penalty, fee, or costs becomes final. A separate surety bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies/groups when such separate locations or affiliated companies/groups are required to apply for or renew their wholesaler license with the Board of Pharmacy. The Board of Pharmacy may make a claim against such bond or other equivalent means of security until one year after wholesaler's license closes, lapses or expires, or until sixty (60) days after any administrative or legal proceeding before or on behalf of the Board of Pharmacy that involves the wholesaler is concluded, including any appeal, whichever occurs later. The Board of Pharmacy may waive the bond requirement, if the wholesaler:

(a) has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the wholesaler possesses a valid license in good standing;

(b) is a publicly held company;

(c) is a medical gas wholesaler; or

(d) has a license for the sole purpose of distribution within a health care entity under common ownership.

(3)[(2)] <u>A</u> separate license shall be required for each <u>wholesaler's</u> [wholesale distributor's] facility that <u>engages in</u> <u>wholesale distribution</u> [distributes] within the Commonwealth regardless of whether joint ownership or control exists.

(4)[(3)] An agent or employee of a licensee shall not be required to obtain a license under this section when the agent or employee is acting in the usual course of business or employment.

(5)[(4)] A license shall not be issued or renewed unless the applicant demonstrates or continues to demonstrate acceptable operational procedures, including:

(a) Adequate <u>operational</u>, maintenance, and storage conditions to ensure proper lighting, ventilation, temperature and humidity control, sanitation, space, and security as per label requirements or official United States Pharmacopoeia (USP) compendium requirements. Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs and related devices;

(b) <u>Separation[Physical separation]</u> and quarantine of deteriorated, damaged, outdated, misbranded, adulterated or otherwise recalled <u>prescription drugs and related devices</u> [merchandise] until they are destroyed or returned;

(c) Providing accurate and precise records of all <u>prescription</u> drugs and related devices sold, purchased, traded, delivered, handled, stored, or received and any other information pertinent to the distribution or disposition [goods shipped or received including source or recipient, date, quantity, itemized description, and any other information pertinent to the transaction]; and

(d) Providing proof of registration [with the state controlled substance authority, and] with the U.S. Drug Enforcement Administration (DEA) and shall comply with all DEA regulations, if applicable.

(6) Wholesale distributors and virtual wholesale distributors shall comply with all requirements outlined in the Drug Supply Chain Security Act (DSCSA).

(7) Wholesalers shall establish a system to:

a. Quarantine and investigate suspect product to determine if it is illegitimate; and

b. Notify U.S. Food and Drug Administration (FDA), if applicable, the Board of Pharmacy and recipient(s) of illegitimate product, if illegitimate product is found.

(8) A virtual wholesale distributer shall be exempt from the following, Section 2(5)(a) and (b) and Section 5(1)(a) and (b) and (2)(a) and (b).

<u>Section</u> 3. Qualifications for License. (1) [The minimum qualifications shall include:

(a)] The [Kentucky] Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs and related devices within the Commonwealth:

(a)[4.] Any convictions of the applicant under any federal, state, or local laws relating to <u>drugs to include</u> drug samples and [wholesale or retail drug distribution of] controlled substances;

(b)[2-] Any felony convictions of the applicant under federal, state, or local laws;

(c)[3-] The applicant's past experience in the [wholesale] distribution of prescription drugs_and related devices, including

drug samples and controlled substances;

(d)[4.] The furnishing by the applicant of false or fraudulent material in any application made in connection with the <u>distribution</u> of prescription drugs and related devices [wholesale distribution];

(e)[5-] Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant for [wholesale] distribution of any prescription drugs and related devices, including drug samples and controlled substances;

(f)[6-] Compliance with the requirements under any previously granted license or permit, if any; and

(g)[7.] Compliance with requirements to maintain or make available to the [Kentucky] Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this regulation[section].

(2)[(b)] The [Kentucky] Board of Pharmacy shall have the right to deny a license to an applicant if it determines that the granting of that license would not be in the public interest based on health and safety considerations.

(3)[(2)] A license shall not be issued pursuant to this administrative regulation unless the applicant has furnished proof satisfactory to the Board of Pharmacy:

(a) That the applicant is in compliance with all applicable federal. [and] state, and local laws and regulations relating to drugs; and

(b) That the applicant is equipped as to land, buildings, and security to properly carry on the business described in <u>the</u> [his] application.

(4) [(3)] A license issued pursuant to this administrative regulation [may be suspended or revoked for failure] failing to comply with the provisions of KRS <u>315.350</u>, 315.400, 315.402, 315.404, 315.406, 315.408, 315.410, 315.412, or this administrative regulation may result in action under KRS <u>315.121</u>.

Section 4. Application, Fees, Renewals.

(1) An application for a license shall be submitted to the Board of Pharmacy on "Application for a License to Operate as a <u>Wholesaler [Wholesale Distributor (KBP W 9:08)]</u>".

(2) An application shall be accompanied by the annual fee set forth in 201 KAR 2:050.

(3) An application shall include:

(a) The name, full business address, and telephone number of the licensee;

(b) All trade or business <u>names[name]</u> used by the licensee;

(c) Addresses, telephone numbers, and the names of contract persons for all facilities used by the licensee for the storage,

handling, and distribution of prescription drugs <u>and related devices;</u> (d) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship);

(e) The name(s) of the owner and operator of the licensee, including;

1. If a person, the name and Social Security number of the person;

2. If a partnership, the name and Social Security number of each partner, and the name of the partnership;

3. If a corporation, the name, Social Security number and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

4. If a sole proprietorship, the full name and Social Security number of the sole proprietor and the name of the business entity; [and]

(f) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs <u>and related devices; and[-]</u>

(g) Proof of surety bond or equivalent.

(4) All licenses shall:

(a) Expire on September 30 following date of issuance; and

(b) Be renewable annually thereafter upon renewal application accompanied by the renewal fee set forth in 201 KAR 2:050 and shall be nontransferable.

Section 5. Standards. (1) Facilities.

(a) All <u>facilities</u>[buildings] in which <u>prescription</u>[legend] drugs and <u>related devices</u> are held for wholesale distribution, [repackaged,] stored, [held,] sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.

(b) <u>All facilities</u>[Buildings] shall meet all applicable federal, state, and local standards. The facility shall [have a] quarantine [area for storage of] prescription drugs and related devices that are outdated, damaged, deteriorated, misbranded, recalled, or adulterated, or that are in immediate or sealed secondary containers that have been opened.

(c) A facility shall not be located in a residence.

(d) A facility shall be located apart and separate from a pharmacy permitted by the Board of Pharmacy, with the exception of a medical gas wholesaler.

(2) Security.

(a) A <u>wholesaler[wholesale distributor]</u> shall be equipped with an alarm system to detect entry after hours.

(b) A <u>wholesaler[wholesale distributor]</u> shall ensure that access from outside their premises is well controlled and reduced to a minimum. This includes the installation of adequate lighting at the outside perimeter of the premises.

(c) Internal security policies shall be developed to provide reasonable protection against theft and diversion by limiting access to areas where legend prescription drugs and related devices are held to authorized personnel. These policies shall provide protection against tampering with computers or electronic records.

(d) A licensee shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution [or virtual wholesale distribution] of prescription drugs and related devices.

(3) Recordkeeping.

(a) Inventories and other records [of transactions] regarding the receipt <u>and distribution or</u> [and] disposition of <u>prescription[legend]</u> drugs <u>and related devices</u> shall be maintained and readily available for inspection or photocopying by <u>the Board</u> of <u>Pharmacy and</u> authorized law enforcement officials for a period of <u>six (6)</u> years)[two (2) following disposition of the drugs]. These records shall include:[

1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other distribution of the drugs.]

<u>1. The proprietary and established name of the prescription</u> drug and/or related device;

2. The dosage, if applicable;

3. The size of the container, if applicable;

4. The number of containers;

5. The lot number or control number of the prescription drug and/or related device, if applicable;

6. The business name and address of all parties involved in each receipt and distribution or disposition of the prescription drug and/or related device, starting with the manufacturer; and

7. the date of each receipt and distribution or disposition of the prescription drug and/or related device.

(b) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by <u>the Board of Pharmacy or an</u> authorized of a federal, state, or local law enforcement agency.

(c) Wholesalers shall maintain an ongoing list of verified persons or businesses with whom they do business.

(d) A wholesaler may sell or distribute prescription drugs and related devices only to the following, except as provided in KRS 315.0351(2) and KRS 315.404:

1. A currently licensed wholesaler;

2. A currently licensed third party logistics provider;

3. A currently permitted pharmacy;

4. A currently licensed outsourcing facility;

5. A currently licensed practitioner;

6. A currently permitted repackager;

7. A currently licensed hospital, but only for use by or in that hospital;

8. A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes; or

<u>9. Any other appropriately licensed or permitted facility in</u> the jurisdiction in which it is located.

(e) A wholesaler may acquire prescription drugs and related devices only from the following, except as provided in KRS 315.404:

1. A currently permitted manufacturer;

2. A currently permitted repackager;

3. A currently licensed wholesaler; or

4. A currently licensed third-party logistics provider.

(f) Wholesalers shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion, or other significant loss of any prescription drug and related device to the Board of Pharmacy, and where applicable, the FDA and DEA.

(4) Written policies and procedures.

(a) A <u>wholesaler[Wholesaler</u> Distributor distributors] shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, [and] distribution<u>and disposition</u> of prescription drugs<u>and related</u> <u>devices[.</u>, including policies and procedures for identifying, recording, and reporting losses or thefts and to assure that the wholesale distributor prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.]

(b) There shall be written policies and procedures for identifying, recording, and reporting losses or thefts.

(c)There shall be written policies and procedures to assure that the wholesaler prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

(d)[(b)] There shall be written policies and procedures for managing and correcting all errors or inaccuracies in inventories.

(e)[(c)] There shall be written policies and procedures to assure that any outdated stock or any stock with an expiration date that, in the <u>wholesaler's[wholesale_distributor's]</u> view, does not allow sufficient time for repacking or resale shall be segregated from other stock and shall be prepared for return to the manufacturer or otherwise destroyed, and this shall be documented.

(f)((d)] There shall be written policies and procedures by which the <u>wholesaler[wholesale distributor]</u> exercises control over the shipping and receiving of all stock within the operation.

(g) There shall be written policies and procedures for investigating suspect product and reporting illegitimate product to the Board of Pharmacy and the FDA pursuant to the DSCSA, where applicable.

(5) Returned, damaged, and outdated prescription drugs and related devices. A wholesaler-[wholesale distributor] shall maintain and follow a written policy and procedure to assure the proper handling and disposal of returned goods. If conditions under which a prescription drug or related device has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug or related device shall be destroyed, or returned, unless examination, testing, or other investigation proves that the drug or related device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a prescription drug or related device has been returned cast doubt on the drug's or related device's safety, identity, strength, quality, or purity, the wholesaler[wholesale distributor] shall consider, among other things, the conditions under which the drug or related device has been held, stored, or shipped before or during its return and the condition of the drug or related device and its container, carton, or labeling, as a result of storage

or shipping.

(6) Handling recalls. A <u>wholesaler[wholesale distributor]</u> shall <u>establish</u>, maintain, and <u>adhere to a[follow]</u> written policy <u>and</u> <u>procedure</u> for handling recalls and withdrawals of [products] <u>prescription drugs and related devices</u>. The policy <u>and procedure</u> shall cover all recalls and withdrawals of <u>drugs[drug products] and</u> related devices due to:

(a) Any voluntary action on the part of the manufacturer;

(b) The direction of the <u>FDA[Food and Drug Administration]</u>, or any other federal, state, or local government agency; and

(c) Replacement of existing [merchandise with an improved product or new package design prescription drug and related device].

(7) <u>Procedures (a)</u> A visual examination of all materials received or shipped shall be made to guarantee product identity and to reasonably guard against acceptance or delivery of damaged, contaminated, tampered, or otherwise unfit stock.

(b) Procedures for distribution of approved stock shall provide for a rotation whereby <u>the expiration date is taken into</u> <u>consideration when distributing inventory[the oldest inventory is</u> <u>distributed first]</u>.

(c) A <u>wholesaler[wholesale distributor]</u> shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug <u>and related</u> <u>device[product]</u> salvaging or reprocessing. [

Section 6. Pedigree.

(1) Effective July 1, 2009 and in accordance with KRS 315.406, each person or entity engaged in the wholesale distribution of prescription drugs that leave or that have ever left the normal distribution channel shall, prior to the distribution of the prescription drug, provide a pedigree to the person receiving the prescription drug.

(2) The pedigree shall include the following information concerning the prescription drug:

(a) The proprietary and established name of the prescription drug;

(b) The dosage;

(c) The size of the container;

(d) The number of containers;

(e) The lot number of control number of the prescription drug;

(f) The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and

(g) The date of each previous transaction.

(3) Pedigree records shall be maintained and readily be available for inspections or photocopying by authorized law enforcement officials for a period of two (2) years.]

Section 6.[7] Violations.

(1) A <u>wholesaler[wholesale_distributor]</u> shall not distribute <u>prescription[legend]</u> drugs <u>and related devices</u> directly to a consumer or a patient <u>except as provided in KRS 315.0351(2)</u>. [or operate in a manner that endangers the public health.]

(2) A wholesaler shall not operate in a manner that endangers the public health.

(3)[(2)] <u>Violations</u> of any of these provisions shall be grounds for <u>action under KRS 315.121[the suspension or revocation of the license]</u>.

Section 7[8]. Incorporation by Reference.

(1) "Application for a License to Operate as a <u>Wholesaler"</u>, <u>May 2020, [Wholesale Distributor (KBP W 9:08)]</u> is incorporated by reference.

(2) <u>"Renewal Application to Operate as a Wholesaler", May 2020, is incorporated by reference.</u>

(3) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, <u>State Office Building Annex, Suite 300, 125 Holmes</u> <u>Street, Frankfort, Kentucky 40601-8024, [Spindletop Administration Building Suite 302, 2624 Research Park Drive, Lexington, Kentucky 40511]</u>, Monday through Friday, 8 a.m. to 4:30 p.m.

LARRY A. HADLEY, R.Ph., Executive Director

APPROVE BY AGENCY: October 7, 2020

FILED WITH LRC: October 7, 2020 at 10:54 a.m.

CONTACT PERSON: Larry Hadley, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Larry.Hadley@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Larry Hadley

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements for the regulation of wholesalers, medical gas wholesalers, wholesale distributors and virtual wholesale distributors.

(b) The necessity of this administrative regulation: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations with minimum requirements for the permitting of those entities that provide pharmacy services. This administrative regulation establishes the requirements for the regulation of wholesalers, medical gas wholesalers, wholesale distributors and virtual wholesale distributors.

(c) How this administrative regulation conforms to the content of the authorizing statues: This administrative regulation establishes the requirements for the regulation of wholesalers, medical gas wholesalers, wholesale distributors and virtual wholesale distributors.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: Retitle this regulation and cleanup language to be consistent with Federal Regulations.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of: How the amendment will change this existing administrative regulation: Retitle this regulation; Retitle this regulation and cleanup language to be consistent with Federal Regulations.

(a) The necessity of the amendment to this administrative regulation: The criteria needed to be updated.(b) How the amendment conforms to the content of the authorizing statutes: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies.

(b) How the amendment will assist in the effective administration of the statutes: The amendment will further promote, preserve, and protect public health through effective regulation of pharmacists and pharmacies by retitling this regulation and cleanup language to be consistent with Federal Regulations.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates pharmacies and pharmacists will be affected minimally by this regulation amendment.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Pharmacies and pharmacists will have to familiarize themselves with amended language. The board will help to educate pharmacists and pharmacies in these changes.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no expected costs for the identities to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This amendment will clarify previous statutory language.

(5) Provide an estimate of how much it will cost to implement this administrative Regulation:

(a) Initially: There will be no costs incurred.

(b) On a continuing basis: There will be no costs incurred.

(6) What is the source of the funding to be used for the

implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: The fee for wholesale distributor permit will be increased by \$25.00.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does establish fees and this amendment increases the fee for wholesale distributors from \$100.00 to \$125.00.

(9) TIERING: Is tiering applied? Tiering is not applied because the regulation is applicable to all entities wishing to distribute pharmaceuticals in Kentucky.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Pharmacy will be the only entity impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(1)(a).

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? It is estimated this administrative regulation will generate an annual increase in revenue in the amount of \$106,800.00 for the Board in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? It is estimated this administrative regulation will generate an annual increase in revenue in the amount of \$106,800.00 for the Board in the first year.

(c) How much will it cost to administer this program for the first year? No costs are required to administer this program for the first year.

(d) How much will it cost to administer this program for subsequent years? No costs are required to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation. N/A

Revenues (+/-): regulation will provide an annual 106,800 increase in revenue

Expenditures (+/-): 0

BOARDS AND COMMISSIONS Board of Pharmacy (Amended After Comments)

201 KAR 2:320. <u>Requirements</u> [Permit] or manufacturers and virtual manufacturers.

RELATES TO: KRS <u>315.010</u>, 315.020(2), 315.036, [and] 315.191(1)(<u>a)</u>, <u>315.400</u>, and <u>315.404</u>. STATUTORY AUTHORITY: KRS <u>315.020(2)</u>, <u>315.036</u>,

STATUTORY AUTHORITY: KRS 315.020(2), 315.036, 315.191(1), 315.400.

NECESSITY, FUNCTION, AND CONFORMITY: KRS <u>315.020</u>, 315.036 and 315.191(1)(a) authorizes the board to promulgate administrative regulations to regulate the manufacturers <u>and virtual manufacturers</u> of drugs <u>and related</u> <u>devices</u>. [KRS <u>315.036</u> authorizes the board to promulgate administrative regulations regarding manufacturer permits and the

maintenance and reporting of accurate records of all drugs manufactured, received and sold. KRS 315.020(2) authorizes the Board to promulgate administrative regulations regarding the pharmacist-in-charge.] This administrative regulation establishes the requirements for [a] the regulation of manufacturers and virtual manufacturers [manufacturer permit

and for functioning as a manufacturer].

Section 1. Definitions [Requirements].

(1) "Component" means any raw material, ingredient or article intended for use in the manufacture of a drug and related device.

(2) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(3) "Manufacturer or virtual manufacturer" means, in addition to KRS 315.010(13), any person, except a pharmacist compounding in the normal course of professional practice, within the Commonwealth engaged in the commercial production, preparation, propagation, conversion, or processing of a drug either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both and includes any packaging or repackaging of a drug or the labeling or relabeling of its container.

(4) "Relabeler" means any person who owns or operates an establishment that changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. This does not include establishments that do not change the original labeling but merely add their own name.

(5) "Repackager" has the same meaning as in KRS 315.400(16).

(6) "Suspect product" means a product for which there is reason to believe that such product:

(a) Is potentially counterfeit, diverted, or stolen;

(b) Is potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans or animals;

(c) Is potentially the subject of a fraudulent transaction; or

(d) Appears otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans or animals.

Section 2. Requirements.

(1) A manufacturer or virtual manufacturer engaging in manufacturing in the Commonwealth shall apply for a permit from the Board of Pharmacy in accordance with KRS 315.036 and this administrative regulation.

(2) A separate permit shall be required for each facility within the Commonwealth regardless of whether joint ownership or control exists.

(3) An agent or employee of a permit holder shall not be required to obtain a permit under this section when the agent or employee is acting in the usual course of business or employment.

(4) A permit shall not be issued or renewed unless the applicant [or its officers] demonstrates or continues to demonstrate acceptable operational procedures, including:

(a) Adequate <u>operation</u>, maintenance, and storage conditions to ensure proper lighting, ventilation, temperature and humidity control, sanitation, space, and security as per label requirements or <u>official [current year</u>] United States Pharmacopoeia (USP) compendium requirements. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of <u>components and [prescription</u>] drugs<u>and related</u> <u>devices</u>;

(b) <u>Separation</u> [Physical separation] and quarantine of deteriorated, damaged, outdated, misbranded, adulterated, or otherwise recalled <u>components and drugs and related devices</u> [merchandise] until they are destroyed or returned;

(c) Providing accurate and precise records of all <u>components</u> and <u>drugs and related devices [goods</u>] shipped or received including source or <u>and</u> recipient, date, quantity, itemized description, and any other information pertinent to the [transaction] receipt and distribution or disposition;

(d) Providing proof of registration [with the state controlled substance authority, and] with the U.S. Food and Drug Administration (FDA) and the U.S. Drug Enforcement Administration (DEA) and compliance with all [DEA] federal, state, and local laws and regulations; and

(5) Manufacturers and virtual manufacturers must comply with all requirements as outlined in the Drug Supply Chain Security Act (DSCSA), if applicable.

(6) Manufacturers and virtual manufacturers shall establish a system to:

(a) Quarantine and investigate suspect product to determine if it is illegitimate; and

(b) Notify FDA, the Board of Pharmacy, and recipient(s) of illegitimate product, if illegitimate product is found.

(7) All virtual manufacturers shall be exempt from the requirements of Section 2(4)(a) and (b), Section 5(1)(a) and (b) and (2)(a) and (b).

Section [2]3. Qualifications for Permit.

(1)[(a)] The [Kentucky] Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in <u>manufacture</u> or virtual manufacture[manufacturer] of [prescription] drugs <u>and related</u> <u>devices</u> within the Commonwealth:

(a)[4-] Any convictions of the officers of the applicant under any federal, state, or local laws<u>relating to drugs</u>, to include drug samples and controlled substances;

(b) Any felony convictions of the applicant or its officers under federal, state or local laws;

(c)[2-] The applicant's <u>and its officers'</u> past experience in the manufacture <u>or virtual manufacture</u>of_[prescription] drugs <u>and</u> related devices, including <u>drug samples and</u> controlled substances;

(d)[3-] The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or virtual drug manufacturing;

[4.](d) Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant or its officers for the manufacture or virtual manufacture of any drugs and related devices, including drug samples and controlled substances;

(e)[5-] Compliance with the requirements under any previously granted license or permit, if any; and

[6-](f) Compliance with requirements to maintain or make available to the [Kentucky] Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this regulation [section].

(2)[(+)] The [Kentucky] Board of Pharmacy shall have the right to deny a permit to an applicant or its officers if it determines that the granting of that permit would not be in the public interest <u>based</u> on health and safety considerations-[for any reason established in KRS 315.121].

[(2)](<u>3</u>) A permit shall not be issued pursuant to this administrative regulation unless the applicant [or its officers] has furnished proof satisfactory to the Board of Pharmacy:

(a) That the applicant <u>is</u> [and its officers are] in compliance with all applicable federal, [and] state, <u>and local</u> laws and regulations relating to drugs <u>and related devices</u>; and

(b) That the applicant is [and its officers are] equipped as to land, buildings, and security to properly carry on the business described in the application. [

(3) A permitted manufacturer may sell or distribute federal legend drugs only to the following:

(a) A currently permitted manufacturer;

(b) A currently licensed wholesale distributor;

(c) A currently permitted pharmacy;

(d) A currently licensed practitioner;

(c) A currently licensed hospital, but only for use by or in that hospital; or

(f) A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes.]

(4) A permit <u>issued pursuant to this administrative regulation</u> [holder] may be disciplined, <u>suspended or revoked</u> for failure to comply with the provisions of KRS <u>315.020</u>, 315.036, <u>315.400</u> [pursuant to KRS <u>315.121</u>], or this administrative regulation.

(5) No permit shall fail to designate a pharmacist-in-charge.

Section <u>4[</u>3]. Application, Fees[;], Renewals.

(1) An application for a permit shall be submitted to the Board of Pharmacy on "Application for a Permit to Operate as a Manufacturer <u>or Virtual Manufacturer [(KBP M 5:09)]</u>."

(2) An application shall be accompanied by the annual fee set forth in 201 KAR 2:050.

(3) An application shall include:

(a) The name, full business address, and telephone number of the applicant;

(b) All trade or business names used by the applicant;

(c) Addresses, telephone numbers, and the names of the [contact] persons for the facility used by the <u>permit holder</u> [permittee] for the storage, handling, and manufacturing <u>or virtual</u> <u>manufacturing</u> of <u>drugs and related devices</u> [prescription drugs];

(d) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship);

(e) The name(s) of the owner and operator of the <u>permit</u> <u>holder</u> [permittee], including;

1. If a person, the name and Social Security number of the person;

2. If a partnership, the name and Social Security number of each partner, and the name of the partnership;

3. If a corporation, the name, Social Security number and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

4. If a sole proprietorship, the full name and social security number of the sole proprietor and the name of the business entity; and

(f) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to manufacture. <u>virtual manufacture</u> or possess [prescription] drugs and related devices.

(4) All permits shall:

(a) Expire on September 30 following the date of issuance; and

(b) Be:

1. Renewable annually thereafter upon-renewal [proper] application accompanied by the renewal fee set forth in 201 KAR 2:050; and

2. Nontransferable.

Section [4]5. Standards.

(1) Facilities.

(a) All <u>facilities</u> [<u>buildings</u>] in which <u>components and</u> [<u>legend</u>] drugs <u>and related devices</u> are <u>labeled</u>, <u>relabeled</u>, <u>packaged</u>, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.

(b) <u>All facilities [Buildings]</u> shall meet all applicable federal, state, and local standards. The facility shall [have a] quarantine <u>components and [area for storage of prescription]</u> drugs <u>and</u> <u>related devices</u> that are outdated, damaged, deteriorated, misbranded, <u>recalled</u>, or adulterated, [or that are in immediate or sealed secondary containers that have been opened].

(c) A facility shall not be located in a residence.

(2) Security.

(a) A manufacturer shall be equipped with an alarm system to detect entry after hours.

(b) A manufacturer shall ensure that access from outside their premises is well-controlled and reduced to a minimum. This includes the installation of adequate lighting at the outside perimeter of the premises.

(c) Internal security policies shall be developed to provide reasonable protection against theft and diversion by limiting access to areas where <u>components [legend]</u> and drugs <u>and related devices</u> are held to authorized personnel. These policies shall provide protection against tampering with computers or electronic records.

(d) A permit holder shall employ adequate personnel with the education and experience necessary to safely and lawfully engage

in the manufacture <u>or virtual manufacture[manufacturer]</u> of [prescription] drugs <u>and related devices</u>.

(e) Lists of officers, directors, managers and other persons in charge of <u>manufacture or virtual manufacture</u>, distribution <u>or</u> <u>disposition</u>, storage, and handling of <u>components and [prescription]</u> drugs <u>and related devices</u>, including a description of their duties and summary of their qualifications, shall be maintained for purpose of review.

(3) Recordkeeping.

(a) Inventories and other records [of transactions] regarding the receipt and <u>distribution or</u> disposition of <u>components</u> [legend] and drugs <u>and related devices</u> shall be maintained and readily available for inspection or photocopying by <u>the Board of Pharmacy</u> and authorized law enforcement officials for a period <u>six (6) [of two</u> (2)] years following disposition of the drugs]. These records shall include:

1. The <u>business name and address of the</u> source of the <u>components and</u> drugs <u>and related devices</u> including the [name and principal address of the] seller or transferor and the address of the location from which the <u>components and</u> drugs <u>and related</u> <u>devices</u> were shipped;

2. The business name and address to whom components and drugs and related devices were shipped including the purchaser and the address of the location where the components and drugs and related devices were shipped;

<u>3[2]</u>. The identity and quantity of the <u>components and</u> drugs and <u>related devices</u> received and distributed or disposed of; and

3[4]. The dates of receipt and distribution or <u>disposition</u>-[other distribution] of the <u>components and</u> drugs <u>and related devices</u>.

(b) The manufacturer or virtual manufacturer shall keep production and process control records for a period of six (6) years following completion of manufacturing.

(c[b]) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by the Board of Pharmacy or an authorized official of a federal, state, or local law enforcement agency.

(d) Manufacturers and virtual manufacturers shall maintain an ongoing list of verified persons and businesses with whom they do business.

(e) A permitted manufacturer and virtual manufacturer may sell or distribute drugs and related devices only to the following:

1. A currently permitted manufacturer or virtual manufacturer;

2. A currently licensed third-party logistics provider;

3. A currently licensed wholesaler;

4. A currently permitted pharmacy;

5. A currently licensed outsourcing facility;

6. A currently licensed practitioner;

7. A currently permitted repackager or relabeler;

8. A currently licensed hospital, but only for use by or in that hospital; or

9. A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes.

10. Any other appropriately licensed or permitted facility in the jurisdiction in which it is located.[

(d)](f) Manufacturers and virtual manufacturers shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion, or other significant loss of any component or drug or related device to the Board of Pharmacy and where applicable the FDA and DEA.

(4) Written policies and procedures.

(a) A manufacturer <u>or virtual manufacturer</u> shall establish, maintain, and adhere to written policies and procedures for [the] <u>all</u> <u>operations including production, process controls,</u> receipt, security, storage, inventory, and distribution<u>or disposition of components</u> <u>and [prescription]</u> drugs <u>and related devices.</u>, [including policies and procedures for identifying, recording, and reporting losses or thefts and to ensure that the manufacturer prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency].

(b) There shall be written policies and procedures for identifying, recording, and reporting losses or thefts.

(c) There shall be written policies and procedures to assure that the manufacturer and virtual manufacturer prepares for, protects against, and handles crisis situations that affect the security, or operation, and records of the facility permit holder. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

(d) ((b)) There shall be written policies and procedures for managing and correcting all errors or inaccuracies in inventories.

(e) [(c)] There shall be written policies and procedures to assure that any outdated stock_components or drugs or related devices or any [stock] components or drugs or related devices with an expiration date that, in the manufacturer's <u>or virtual</u> <u>manufacturer's</u> view, does not allow sufficient time for repacking or resale shall be segregated from other stock and shall be prepared for return or otherwise destroyed, and this shall be documented.

(f) [(d)] There shall be written policies and procedures by which the manufacturer <u>or virtual manufacturer</u> exercises control over the shipping and receiving of all-[steck] <u>components and drugs and related devices</u> within the operation.

(g) There shall be written policies and procedures for investigating suspect product and reporting illegitimate product to the Board of Pharmacy, FDA and recipient(s) of illegitimate product.

(5) Returned, damaged, and outdated [prescription] drugs and related devices. A manufacturer [manufacturer's] or virtual manufacturer [operation] shall maintain and follow a written procedure to assure the proper handling and disposal of returned components or drugs or related devices [goods]. If conditions under which a-[prescription] drug or related device has been returned cast doubt on the drug's or related device's safety, identity, strength, quality, or purity, then the drug or related device shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug or related device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug or related device has been returned cast doubt on the drug [drug's] or related device's safety, identity, strength, quality, or purity, the manufacturer or virtual manufacturer shall consider, among other things, the conditions under which the drug or related device has been held, stored, or shipped before or during its return and the condition of the drug or related device and its container, carton, or labeling, as a result of storage or shipping.

(6) Handling recalls. A manufacturer <u>or virtual manufacturer</u> shall adopt, maintain, and follow a written policy <u>and procedure</u> for handling recalls and withdrawals of [products] <u>components or</u> <u>drugs or related devices</u>. The policy shall cover all recalls and withdrawals [of drug products] due to:

(a) Any voluntary action on the part of the manufacturer or virtual manufacturer;

(b) The direction of the <u>FDA</u> [Food and Drug Administration], or any other federal, state, or local government agency; and

(c) Replacement, <u>relabeling</u>, <u>or repackaging</u> of existing <u>component or drug or related devices</u> [merchandise with an improved product or new package design].

(7) Procedures.

(a) A visual examination of all materials received or shipped shall be made to guarantee product identity and to reasonably guard against acceptance or delivery of damaged, contaminated, tampered, or otherwise unfit stock. [

(b) Procedures for distribution of approved stock shall provide for a rotation whereby the first expiration inventory is distributed first.]

(b)[(c)] A manufacturer or virtual manufacturer shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to [prescription] drug product <u>and related</u> <u>devices</u> salvaging or reprocessing.

Section 6[5]. Pharmacist-in-charge. A manufacturer or virtual

<u>manufacturer</u> shall designate a pharmacist-in-charge of the facility [who shall be responsible to the board for security and recordkeeping]. The pharmacist-in-charge shall review the security and records by conducting <u>and documenting</u> an on-site inspection not less than quarterly.

Section 7[6]. Violations.

(1) A drug manufacturer <u>or virtual manufacturer</u> shall not distribute [legend] <u>prescription</u> drugs <u>and related devices</u> directly to a consumer or a patient [or operate in a manner that endangers the public health].

(2) A manufacturer or virtual manufacturer shall not operate in a manner that endangers the public health.

(3) [(2)] Violation of any of these provisions shall be grounds for the discipline, suspension, or revocation of the permit [pursuant to KRS 315.121].

Section <u>8[</u>7]. Incorporation by Reference.

(1) "Application for a Permit to Operate as a Manufacturer <u>or</u> <u>Virtual Manufacturer</u>", [6/09], is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, <u>State Office Building Annex</u>, <u>Suite 300</u>, 125 Holmes <u>Street, Frankfort, Kentucky 40601-8024</u>, [Spindletop Administrative Building, Suite 302, 2624 Research Park Drive, Lexington, <u>Kentucky 40511</u>,]Monday through Friday, 8 a.m. through 4:30 p.m.

LARRY A. HADLEY, R.Ph., Executive Director

APPROVED BY AGENCY: October 1, 2020

FILED WITH LRC: October 14, 2020 at 11:15 a.m.

CONTACT PERSON: Larry Hadley, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Larry.Hadley@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Larry Hadley

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements for Manufacturers and virtual manufacturers.

(b) The necessity of this administrative regulation: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations with minimum requirements for the permitting of those entities that provide non-dispensing pharmacy services. This administrative regulation establishes the requirements for Manufacturers and virtual manufacturers

(c) How this administrative regulation conforms to the content of the authorizing statues: This administrative regulation establishes the requirements for Manufacturers and virtual manufacturers.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: Retitle this regulation and cleanup language to be consistent with Federal law

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: Retitle this regulation; Retitle this regulation and cleanup language to be consistent with Federal law.

(b) The necessity of the amendment to this administrative regulation: The criteria needed to be updated.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will further promote, preserve, and protect public health through effective regulation of pharmacists and pharmacies by retitling this regulation and cleanup language to be consistent with Federal law

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this

administrative regulation: The board anticipates pharmacies and pharmacists will be affected minimally by this regulation amendment.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Pharmacies and pharmacists will have to familiarize themselves with amended language. The board will help to educate pharmacists and pharmacies in these changes.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no expected costs for the identities to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This amendment will clarify previous statutory language.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: No costs will be incurred.

(b) On a continuing basis: No costs will be incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: The fee for wholesale distributor permit will be increased by \$25.00

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: The administrative regulation does establish fees and this amendment increases the fee for wholesale distributors from \$100.00 to \$125.00.

(9) TIERING: Is tiering applied? Tiering is not applied because the regulation is applicable to all entities wishing to manufacture pharmaceuticals into Kentucky.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Pharmacy will be the only entity impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(1)(a).

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? It is estimated this administrative regulation will generate an annual increase in revenue in the amount of \$106,800.00 for the Board in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? It is estimated this administrative regulation will generate an annual increase in revenue in the amount of \$106,800.00 for the Board in the first year.

(c) How much will it cost to administer this program for the first year? No costs are required to administer this program for the first year.

(d) How much will it cost to administer this program for subsequent years? No costs are required to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined,

provide a brief narrative to explain the fiscal impact of the administrative regulation. $\ensuremath{\mathsf{N/A}}$

Revenues (+/-): Regulation will provide an annual \$106,800.00 increase in revenue.

Expenditures (+/-): There will be no expenditures.

KENTUCKY COMMUNITY AND TECHNICAL COLLEGE SYSTEM Kentucky Board of Emergency Medical Services (Amended After Comments)

202 KAR 7:201. <u>Emergency Medical Responders</u> [First responders]

RELATES TO: KRS 311A.010, KRS 311A.025, KRS 311A.030, KRS 311A.060, KRS 311A.095, KRS 311A.110, KRS 311A.140, KRS 311A.145, KRS 311A.160

STATUTORY AUTHORITY: KRS 311A.020, KRS 311A.025, KRS 311A.110, KRS 311A.160

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311A.020 requires the board to promulgate administrative regulations relating to first responders. KRS 311A.025 and KRS 311A.160 require the board to establish standards relating to emergency medical responders.

Section 1. <u>Emergency Medical Responder</u> [First Responder] Student Eligibility. (1) Individuals shall be eligible to enroll as a student in an <u>Emergency Medical Responder</u> [first responder] training program if the applicant:

(a) Is at least fifteen (15) years of age; and

(b) [4-] Is currently enrolled in grades 9-12 with a minimum GPA of 2.0; or

<u>(c)[2-]</u> Holds a high school diploma. [er] GED, or home school diploma.

(2) The student applicant shall:

(a) [Understand, read, speak, and write the English language with a comprehension and performance level equal to at least the ninth grade of education, otherwise known as Level 4, verified by testing as necessary;

(b)] Not currently be subject to disciplinary action pursuant to KRS Chapter 311A that would prevent certification; [and]

(b) Pass a criminal background check through the Kentucky Administrative Office of the Courts (AOC) meeting the requirements of KRS 311A.050; and[

(c) Pass a drug test using criteria established by the EMS Training and Educational Institution (TEI); and

(d) (c) Meet all additional requirements established by the EMS Training and Educational Institution (TEI) [EMS-TEI].

Section 2. Certification Requirements. (1) Individuals desiring initial certification as an Emergency Medical Responder [first responder] shall:

(a) [Meet all of the requirements of Section 1 of this administrative regulation;

(b)] Be at least sixteen (16) years of age;[

(c) Be currently enrolled as a student in grades 9-12 with a minimum GPA of 2.0 or hold a high school diploma or GED;

(d)] (b) Successfully complete a board approved training program which conforms to the United States Department of Transportation, National Highway Traffic Safety Administration, National Emergency Medical Services Educational Standards-Instructional Guidelines for the Emergency Medical Responder; [1995 National Standard Curriculum, NREMT-FR as the curriculum for education, which]

<u>1. The educational curriculum</u> shall not be satisfied by the completion of refresher or transition courses alone;

(c) Meet all educational standards established in 202 KAR 7:601;

(d) [(e)] Obtain certification [NREMT's registration] as a[n] NREMT-Emergency Medical Responder [NREMT-FR];

(e) [(f)] Submit a completed <u>application for EMR Initial in</u> <u>KEMSIS</u> [and signed "First Responder Initial Certification Application"];

(f) [(g) Present written evidence of completion of current HIV/AIDS training required by KRS 311A.110;

(h)] Pay the fee required for certification pursuant to [by] 202 KAR 7:030; [and

(i) Present written evidence of completion of current training in CPR that:

1. Shall be taught by an individual who holds instructor certification at an appropriate level from:

a. The American Red Cross;

b. The AHA;

c. The National Safety Council;

d. The ASHI; or

e. Another board approved organization; [and

2. Shall provide instruction and testing in:

a. One (1) rescuer CPR;

b. Two (2) rescuer CPR;

c. Techniques of changing from one (1) to two (2) rescuers during the performance of CPR;

d. Techniques of changing rescuers during the performance of two (2) rescuer CPR;

e. Techniques for relief of obstruction of the airway;

f. CPR of infants and small children;

g. Barrier-to-mouth, barrier-to-nose, or barrier-to-stoma resuscitation for adults, small children, and infants;

h. Use of oral and nasal airways;

i. Use of bag-valve-mask or other ventilation device;

j. Use of supplemental oxygen; and

k. Use and operation of an AED.

(2) An applicant for certification as a first responder shall successfully complete all NREMT testing and become Kentucky certified within two (2) years after the completion date of the first responder course.]

(g) Undergo a background check pursuant to KRS 311A.050 and 311A.100; and

1. The background check required shall be:

a. National in scope for an applicant not currently certified at any level in Kentucky;

b. Statewide in scope for an applicant with current certification in Kentucky;

c. Less than six (6) months old when the applicant submits to the board all requirements for certification; and

d. Provided by a vendor that has been contracted through the board.

2. The applicant shall not directly submit a background check to meet the requirements of this section. The background check shall be submitted to the board by the company that conducts the background check;

(h) Be a citizen of the United States, a permanent resident of the United States, or otherwise lawfully present in the United States, as evidenced by submission to the board of:

1. A social security card;

2. Birth certificate;

<u>3. A United States Citizenship and Immigration Services</u> (U.S.C.IS) Permanent Resident Card (form I-551/Green Card); or

4. Other legal authorization to live and work in the United States.

Section 3. <u>Renewal of Certification</u> [Recertification] and Continuing Education Requirements. (1) An Emergency Medical <u>Responder</u> [first responder] shall be eligible for <u>certification</u> renewal [recertification] if:

(a) The applicant submits a [signed and] completed ["Universal] Application for <u>EMR Renewal in KEMSIS</u> [Recertification/Relicensure"];

(b) The applicant maintains written evidence of: [current completion of training in CPR meeting the requirements as outlined in Section 2 of this administrative regulation;]

1. Completion of a cardiopulmonary resuscitation (CPR) course that:

a. Meets all guidelines established by the International Liaison Committee (ILCOR) on Resuscitation for CPR [standards of the American Heart Association (AHA) Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC); and

b. Includes a psychomotor and a cognitive assessment.

2. Completion of current HIV/AIDS training required by KRS 311A.110;

<u>3. Pediatric Abusive Head Trauma required by KRS 311A.127;</u> and

4. Awareness of Sexual Violence Training required by KRS 311A.120;

(c) [The applicant maintains written evidence of completion of current HIV/AIDS training required by KRS 311A.110;

(d)] The applicant pays the fee <u>pursuant to</u> [established in] 202 KAR 7:030; and

(d) [(e)] The applicant maintains evidence of either:

1. <u>Current certification by the NREMT as an Emergency</u> <u>Medical Responder</u> [Current registration by the NREMT as an NREMT-FR]; or

a. If this option is used the board may request, through a continuing education audit, proof of continuing education to verify compliance with the continuing education requirements of this section.

2. Successful completion of the NREMT Emergency Medical Responder National Continued Competency Program for Continuing Education, which shall be validated by entities authorized to conduct continuing education pursuant to 202 KAR 7:601. [Successful completion of continuing education that:

<u>7:601. [Successive completion of continuing education that:</u>

a. Includes seventeen (17) contact hours of continuing education, of which:

(i) One (1) shall be in disaster management or mass casualty incidents; and

(ii) Two (2) may be in HIV/AIDS; and

b. Shall be validated by:

(i) The instructor, medical director, training officer, course coordinator, or provider of the continuing education offering; or

(ii) A medical director, service director, or training officer of the first responder's ambulance service, first response agency, fire department, or rescue squad.]

(2) An application for <u>certification renewal</u> [recertification] shall be denied if:

(a) Prior to the certification expiration date, the <u>Emergency</u> <u>Medical Responder</u> [first responder] applicant has not met the applicable requirements of [Section 3 of] this <u>section</u> [administrative regulation]; or

(b) <u>The a[A]pplicant has been subjected to disciplinary action</u> that prevents <u>certification renewal</u> [recertification] at the time of application.

(3) A <u>certified Emergency Medical Responder</u> [first responder], in good standing, who is a member of a National Guard or a military reserve unit who is called to active duty by presidential order pursuant to 10 U.S.C. <u>§§</u> 121 and 673b, <u>shall be renewed</u> <u>according to KRS 12.355 upon submission of the Military</u> <u>Extension Application</u> [may be given a one (1) year extension following release from active duty to meet the applicable requirements for recertification listed in this Administrative Regulation. The first responder shall submit a written request for this extension within sixty (60) days of release from active duty].

(4) The <u>board [KBEMS</u>] office may audit an <u>Emergency</u> <u>Medical Responder's</u> [first responder's] continuing education and continuing education records. <u>The Emergency Medical Responder</u> <u>shall submit the documentation requested within ten (10) business</u> <u>days of receipt of the board's request.</u>

(5) The first responder shall maintain documentation of all continuing education for <u>three (3)</u> [four (4)] years from the date of completion.

(6) If documentation of continuing education hours consistent with this administrative regulation are not received by the office of the board within ten (10) business days of receipt of the board's request, the Emergency Medical Responder certification for the individual shall be summarily revoked and the individual shall reapply for certification through Reinstatement, if eligible.

(7) The ten (10) business days for submission shall not apply to investigations pursuant to KRS Chapter 311A.

Section 4. <u>Emergency Medical</u> [First] Responder Reciprocity. (1) <u>An individual who is</u> [person] certified in [another] <u>a contiguous</u> <u>state to the Commonwealth of Kentucky</u> or [territory of the United States or member of the United States military who is registered] by the NREMT as an NREMT-<u>Emergency Medical Responder[FR]</u> or any member of the United States Armed Forces, or veteran who has transitioned within the past six (6) years from the United States Armed Forces, and has been registered by the National Registry as an <u>NREMT-Emergency Medical</u> <u>Responder or EMT</u> shall be eligible for [direct] reciprocity for [initial] Kentucky certification as an <u>Emergency Medical Responder</u> [first responder] if the <u>applicant submits</u> [individual]:

(a) <u>A completed EMR Reciprocity Application in KEMSIS</u> [Is at least sixteen (16) years of age]; <u>and</u>

(b) <u>Proof of the applicant's</u> [Holds current] unrestricted certification [registration] as an NREMT-<u>Emergency Medical</u> <u>Responder or Emergency Medical Responder certification in a</u> <u>contiguous state to the Commonwealth of Kentucky.[FR; and</u>

(c)1. Is currently enrolled in grades 9-12 with a minimum GPA of 2.0: or

2. Holds a high school diploma or GED.

(2) The individual shall:

(a) Understand, read, speak, and write the English language with a comprehension and performance level equal to at least the ninth grade of education, otherwise known as Level 4, verified by testing as necessary;

(b) Have successfully completed a training program, which utilized the United States Department of Transportation, National Highway Traffic Safety Administration, 1995 National Standard Curriculum, Emergency Medical Technician--First-Responder as the curriculum for education if any individual initially certified after January 1, 1986. An earlier edition of the National Standard Curriculum which has been supplemented by the completion of the First Responder Transition Course shall be considered to meet this requirement, which shall not be satisfied by the completion of refresher or transition courses alone;

(c) Submit a completed and signed "First Responder Initial Certification Application";

(d) Present written evidence of completion of current HIV/AIDS training required by KRS 311A.110;

(e) Present written evidence of completion of current training in CPR that meets the requirements of Section 2(1)(i) of this administrative regulation;

(f) Pay the fee required by 202 KAR 7:030;

(g) Not have been convicted of, entered a guilty plea or Alford plea to a felony offense, or have completed a diversion program for a felony offense; and

(h) Not have been subjected to discipline that would prevent reciprocity at the time of application.]

(2) An applicant shall pay the fee required for reciprocity pursuant to 202 KAR 7:030.

(3) An applicant for Emergency Medical Responder reciprocity shall undergo a national background check provided by a vendor that has been contracted through the board.

(a) An applicant shall not directly submit a background check to meet the requirements of this section. The background check shall be submitted to the board by the company that conducts the background check; and

(b) Background checks that are older than six (6) months shall not be considered current, and the applicant shall undergo another national background check prior to approval of certification through reciprocity.

(4) An applicant shall not have been convicted of offenses described in KRS 311A.050.

(5) An applicant shall not have been subjected to discipline that would prevent reciprocity at the time of application.

(6) An Emergency Medical Responder certified pursuant to Section 2 of this administrative regulation shall not perform any procedures or skill on which the Emergency Medical Responder has not been trained. An Emergency Medical Responder who performs a skill for which the Emergency Medical Responder does not have documented training shall have exceeded the scope of practice and shall be in violation of KRS 311A.050. (7) An Emergency Medical Responder certified pursuant to Section 4 of this administrative regulation shall complete the Kentucky supplemental Emergency Medical Responder curricula for the procedures listed in 202 KAR 7:701 prior to beginning work for a licensed agency in Kentucky.

(a) Kentucky supplemental Emergency Medical Responder curricula consistent with 202 KAR 7:701 shall be provided during employee orientation, or by entities authorized to conduct continuing education pursuant to 202 KAR 7:601.

(b) Verification of competency on the supplemental curricula procedures in 202 KAR 7:701 shall be maintained by the Emergency Medical Responder for a minimum of three (3) years. Failure to submit the EMR Supplemental Curriculum Training Verification Report upon request shall result in revocation of the Emergency Medical Responder certification.

(c) If an Emergency Medical Responder certified pursuant to this section fails to supply verification of competency as required by subsection (7) of this section, the Emergency Medical Responder shall be ineligible to apply for and receive Emergency Medical Responder reciprocity certification until the applicant has submitted the EMR Supplemental Curriculum Training Verification Report as required by 202 KAR 7:701, and shall reapply for Reciprocity through the process listed in Section 4 of this administrative regulation.

Section 5. Exemptions from <u>Emergency Medical</u> [First] Responder Administrative Regulations. (1) [The Kentucky] <u>C[</u>e]ertification requirements for an <u>Emergency Medical Responder</u> [first responder] shall not apply to:

(a) [(1)] United States military personnel or state National Guard or employees of the United States government while providing services on a United States government-owned or operated facility, while engaged in the performance of their official duties under federal law, or while providing assistance in mass casualty or disaster type situation; or

(b) [(2)] An Emergency Medical Responder [first responder] certified in another state or territory of the United States who:

<u>1.</u> [(a)] Comes into Kentucky to transport a patient from another state into Kentucky; or

<u>2.</u> [(b)] Is transporting a patient through the state of Kentucky to an out-of-Kentucky location.

Section 6. Reinstatement of Certification. (1) An Emergency Medical Responder whose certification has lapsed may reinstate their certificate by submitting to the board:

(a) A completed Application for EMR Reinstatement in KEMSIS:

(b) Evidence of previous certification as an Emergency Medical Responder in the Commonwealth of Kentucky;

(c) Proof of current training in:

1. HIV/AIDS training required by KRS 311A.110;

2. Pediatric Abusive Head Trauma as required by KRS 311A.127;

3. Awareness of Sexual Violence Training required by KRS 311A.120;

4. A cardiopulmonary resuscitation (CPR) course that:

<u>a. Meets all standards of the American Heart Association Basic</u> <u>Life Support for Healthcare Provider or Professional Rescuer</u> <u>course; and</u>

b. Includes a psychomotor examination component and a cognitive assessment;

(d) Evidence of successful completion of the NREMT Emergency Medical Responder National Continued Competency Program for Continuing Education within twelve (12) months preceding their application for reinstatement of Emergency Medical Responder; and

(e) Evidence of current skills by completing and submitting validation of those skills on the Kentucky Emergency Medical Responder Skills Verification Report prior to beginning work for a licensed agency in Kentucky. The verification report shall be completed by entities authorized to conduct continuing education pursuant to 202 KAR 7:601.

(2) The applicant shall pay fee required for reinstatement

pursuant to 202 KAR 7:030.

(3) The applicant shall undergo a national background check provided by a vendor that has been contracted through the board. The applicant shall not directly submit a background check to meet the requirements of this section. The background check shall be submitted to the board by the company that conducts the background check.

(a) Background checks that are older than six (6) months shall not be considered current, and the applicant shall undergo another national background check prior to approval of reinstatement of certification;

(4) The applicant for reinstatement of certification shall bear the burden of proof of previous certification in Kentucky if the previous certification is in issue or dispute.[

(1) A first responder whose certification has lapsed for a period not exceeding five (5) years, may reinstate their certificate by submitting to the board:

(a) A completed and signed "First Responder Certification Reinstatement Application";

(b) Written evidence of current completion of training in CPR meeting the requirements as outlined in Section 2(1)(i) of this administrative regulation;

(c) Written evidence of completion of current HIV/AIDS training required by KRS 311A.110:

(d) Payment of the fee established in 202 KAR 7:030;

(e) Evidence of previous certification as a first responder in Kentucky;

(f) Evidence of successful completion of continuing education within twelve (12) months preceding their application for reinstatement that includes seventeen (17) contact hours of continuing education, of which:

1. One (1) shall be in disaster management or mass casualty incidents; and

2. Two (2) may be in HIV/AIDS; and

(g) Evidence of successful completion of the National Standard Curriculum for EMT- First Responder Refresher Course within twelve (12) months preceding their application for reinstatement or continuing education hours that meet the requirements of the curriculum.]

(5) An applicant ineligible for certification pursuant to KRS 311A.050 through 311A.090 shall be ineligible for reinstatement. [A first responder, whose certification has lapsed for a period that exceeds five (5) years, may reinstate their certificate by complying with Sections 1 and 2 of this administrative regulation.

(3) An application for reinstatement of certification shall not be considered if:

(a) The applicant is subject to disciplinary action pursuant to KRS Chapter 311A;

(b) The applicant is an individual who has been convicted of, entered a guilty plea or Alford plea to a felony offense, or has completed a diversion program for a felony offense; or

(c) The applicant has been subjected to discipline that would prevent reinstatement at the time of application.]

Section 7. Public Notice of Negative Action. (1) The board office shall cause to be published on the board website the name of an Emergency Medical Responder that:

(a) Is fined;

(b) Is placed on probationary status;

(c) Is placed on restricted status;

(d) Is suspended; or

(e) Has had their certification revoked. [The KBEMS office shall cause to be published, in the KBEMS News or similar publication of the board, or otherwise disseminate the name of a first responder that is fined, is placed on probationary status, is placed on a restricted status, is suspended, or has had their certification revoked.]

Section 8. <u>Expiration of Certification. (1) Certification periods</u> and expiration dates shall be pursuant to KRS 311A.095.

(2) If an Emergency Medical Responders certification lapses or expires, the Emergency Medical Responder shall cease provision of emergency medical services. (3) An Emergency Medical Responder who has allowed their certification to lapse or expire shall reinstate certification pursuant to Section 6 of this administrative regulation.[Temporary Certificate. (1) KBEMS staff may issue a temporary certificate to an individual who:

(a) Submits a completed "Application for Temporary Certificate";

(b) Is at least sixteen (16) years of age;

(c) Understands, reads, speaks, and writes the English language with a comprehension and performance level equal to at least the 9th grade of education, otherwise known as Level 4, verified by testing as necessary;

(d) Provides proof of being currently certified or licensed in another state or territory of the United States or is currently registered by the NREMT;

(e) Presents written evidence of completion of current HIV/AIDS training required by KRS 311A.110;

(f) Presents written evidence of completion of current training in CPR that meets the requirements of Section 2 of this administrative regulation;

(g) Pays the fee required by 202 KAR 7:030;

(h) Provides the board with a copy of a statewide criminal background check from their state of residence;

(i) Is not an individual who has been convicted of, entered a guilty plea or Alford plea to a felony offense, or has completed a diversion program for a felony offense; and

(j) Has not been disciplined by or has action pending against or had a certificate or license in the field of health care denied, limited, suspended, or probated by a certifying or licensing entity in Kentucky or other state or territory under the jurisdiction of the United States.

(2) A temporary certificate may be issued for a period which shall not exceed six (6) months and shall not be reissued or renewed.]

Section 9. Scope of Practice. (1) An Emergency Medical Responder shall provide emergency medical services consistent with the skills and procedures in the National EMS Scope of Practice Model and 202 KAR 7:701.

(2) If providing emergency medical services during a disaster or emergency that qualifies as part of the Emergency Management Assistance Compact pursuant to KRS 39A.050, or if acting pursuant to another agreement made pursuant to KRS Chapter 39, an Emergency Medical Responder certified in another state may perform the skills and procedures approved by the certifying state.

Section 10. Surrender of Certification. (1) An Emergency Medical Responder surrendering certification shall:

(a) Submit a completed Application for EMR Surrender of Certification in KEMSIS; and

(b) Pay the fee pursuant to 202 KAR 7:030.

(2) The applicant shall notify the board's licensed service director(s) with whom the applicant is affiliated immediately upon surrendering their certification.

Section 11. Reporting Requirements. (1) An Emergency Medical Responder shall maintain current demographic information in KEMSIS including:

(a) Legal name;

1. Any changes to an Emergency Medical Responder's legal name shall be submitted using the Name Change application in KEMSIS; and

2. One of the following documents as verification of name change:

a. Social Security Card;

b. Driver's license; or

c. Passport;

(b) Mailing address;

(c) Email address; and

(d) Phone number.

(2) An Emergency Medical Responder that does not comply with this section shall be subject to disciplinary action pursuant to KRS Chapter 311A.

Section <u>12</u> [9]. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) <u>"National Emergency Medical Services Education</u> <u>Standards-Emergency Medical Responder Instructional</u> <u>Guidelines", The United States Department of Transportation,</u> <u>National Highway Traffic Safety Administration, DOT HS 811 077B,</u> <u>January 2009</u> ["First Responder Initial Certification Application" (June 2003)];

(b) <u>"EMR Initial Certification Application" in KEMSIS, July 2019</u> ["Universal Application for Recertification/Relicensure" (June 2003)];

(c) <u>"EMR Certification Renewal Application" in KEMSIS, July</u> <u>2019:</u> ["First Responder Certification Reinstatement Application" (June 2003); and]

(d) <u>"EMR Reciprocity Certification Application" in KEMSIS, July</u> <u>2019:</u> [The United States Department of Transportation, National Highway Traffic Safety Administration, 1995 National Standard Curriculum, Emergency Medical Technician-First Responder.]

(e) "EMR Reinstatement Certification Application" in KEMSIS, July 2019;

(f) "National EMS Scope of Practice Model", National Highway Traffic Safety Administration, DOT HS 810 657, February 2007;

(g) "National EMS Scope of Practice Model", National Highway Traffic Safety Administration, DOT HS 812 666, February 2019;

(h) "EMR Skills Verification Report", July 2019;

(i) "EMR Supplemental Curriculum Training Verification Report", July 2019;

(j) "EMR Certification Surrender Application" in KEMSIS, July 2019;

(k) "National Registry of Emergency Medical Technicians National Continued Competency Program EMR", October 2016;

(I) "American Heart Association Guidelines for CPR and Emergency Cardiovascular Care", November 2018;

(m) "National Registry of Emergency Medical Technicians Emergency Medical Responder Psychomotor Examination Users Guide", September 2016;

(n) "Name Change Application" in KEMSIS, July 2019;

(o) "Military Extension Application" in KEMSIS, July 2019; and

(p) "United States Citizenship and Immigration Services (U.S.C.IS) Permanent Resident Card (form I-551/Green Card)", July 2019.

(2) This material may be inspected, obtained, or copied, subject to applicable copyright law, at the Office of the Kentucky Board of Emergency Medical Services, <u>118 James Court</u>, <u>Lexington, Kentucky 40505, by appointment</u>, [2545 Lawrenceburg Road, Frankfort, Kentucky 40601,] Monday through Friday, 8 a.m. to 4:30 p.m.

PHILIP DIETZ, Chairperson

APPROVED BY AGENCY: September 17, 2020

FILED WITH LRC: October 1, 2020 at noon

CONTACT PERSON: Jeffrey S. Walther, Legal Counsel, Kentucky Board of Emergency Medical Services, Walther, Gay & Mack, PLC; 163 East Main Street, Suite 200, Lexington, Kentucky 40588, phone (859) 225-4714, fax (859) 225-1493, email: administrativeregulations@wgmfirm.com.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Jeffrey S. Walther

(1) Provide a brief summary of:

(a) What this administrative regulation does: KRS 311A.020 requires the board to promulgate administrative regulations relating to first responders. KRS 311A.025 and KRS 311A.160 require the board to establish standards relating to emergency medical responders. This administrative regulation establishes standards relating to emergency medical relating to emergency medical responders.

(b) The necessity of this administrative regulation: KRS 311A.020 requires the board to promulgate administrative regulations relating to first responders. KRS 311A.025 and KRS 311A.160 require the board to establish standards relating to emergency medical responders. This administrative regulation establishes standards relating to emergency medical responders.

The amendment provides terminology updates such as the categorization change from "First Responder" to "Emergency Medical Responder." Additionally, these amendments are necessary to allow Kentucky Emergency Medical Responders the opportunity to become certified and maintain certification to protect the citizens of the Commonwealth of Kentucky. Educational and certification processes are streamlined, and unnecessary or repetitive language across other administrative regulations have been removed.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 311A.020, KRS 311A.025 and KRS 311A.160 by establishing standards relating to emergency medical responders.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: KRS 311A.020 requires the board to promulgate administrative regulations relating to first responders. KRS 311A.025 and KRS 311A.160 require the board to establish standards relating to emergency medical responders. This administrative regulation will effectively establish the standards relating to emergency medical Responders in becoming certified utilizing more simplistic guidelines and processes and provides additional guidance on effective customer service to applicants for certification.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment streamlines certification application processes for Emergency Medical Responders and provides additional guidance on application processes and responsibilities of the Emergency Medical Responder. Additionally, unnecessary and dated requirements and terminology have been removed.

(b) The necessity of the amendment to this administrative regulation: The amendment provides terminology updates such as the categorization change from "First Responder" to "Emergency Medical Responder." Additionally, these amendments are necessary to allow Kentucky Emergency Medical Responders the opportunity to become certified and maintain certification to protect the citizens of the Commonwealth of Kentucky. Educational and certification processes are streamlined, and unnecessary or repetitive language across other administrative regulations have been removed.

(c) How the amendment conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 311A.020, KRS 311A.025 and KRS 311A.160 by establishing standards relating to emergency medical responders.

(d) How the amendment will assist in the effective administration of the statutes: KRS 311A.020 requires the board to promulgate administrative regulations relating to first responders. KRS 311A.025 and KRS 311A.160 require the board to establish standards relating to emergency medical responders. This administrative regulation establishes standards relating to emergency medical responders. This administrative regulation amendment streamlines processes for administrative body processing and removes barriers to certification for the Emergency Responder. Streamlined processes Medical allow the administrative body to more effectively and efficiently certify applicants.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The Kentucky Board of Emergency Medical Services, its members, and staff, emergency medical services providers, emergency medical responders, and local governments will be affected by this administrative regulation.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The Kentucky Board of Emergency Medical Services, its members, and staff, emergency medical services providers, emergency medical responders, and local governments shall implement and satisfy the standards and requirements of this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost to any entity identified in question (3).

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Applicants seeking certification as an Emergency Medical Responder will benefit from decreased certification requirements and processing time.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation. There will be no cost to the administrative body to implement this administrative regulation.

(a) Initially: There will be no cost to the administrative body to implement this administrative regulation.

(b) On a continuing basis: There will be no cost to the administrative body to implement this administrative regulation.

(6) What is the source of funding to be used for the implementation and enforcement of this administrative regulation: No funding source is necessary to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This regulation did not establish any fees.

(9) TIERING: Is tiering applied? Tiering is not applied to this administrative regulation because this amendment applies equally to all licensed agencies.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Emergency Medical Services, its members, and staff, emergency medical services providers, emergency medical responders, and local governments will be affected by this administrative regulation.

2. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 311A.020 requires the board to promulgate administrative regulations relating to first responders. KRS 311A.025 and KRS 311A.160 require the board to establish standards relating to emergency medical responders. This administrative regulation establishes standards relating to emergency medical responders.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will generate no revenue for the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will generate no revenue for subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not impose any costs on state or local government.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not impose any costs on state or local government.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): This administrative regulation will not generate revenue.

Expenditures (+/-): This administrative regulation will not impose any costs.

Other Explanation:

KENTUCKY COMMUNITY AND TECHNICAL COLLEGE SYSTEM Kentucky Board of Emergency Medical Services (Amended After Comments)

202 KAR 7:301. Emergency Medical Technician[EMT].

RELATES TO: KRS 311A.010, 311A.025, 311A.060, 311A.095, 311A.110, 311A.130, 311A.140, 311A.145, 311A.165 STATUTORY AUTHORITY: KRS 311A.020, 311A.025, 311A.030, 311A.110, 311A.140, 311A.165

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311A.025 requires the board to promulgate administrative regulations relating to Emergency Medical Technicians. This administrative regulation establishes requirements for Emergency Medical Technicians.

Section 1. <u>Emergency Medical Technician</u> [EMT] Student Eligibility. (1) Individuals shall be eligible to enroll as a student in an <u>Emergency Medical Technician</u> [EMT] education and training program if the applicant:

(a) Is at least seventeen (17) [sixteen (16)] years of age; and

(b)[4.] Is currently enrolled in grades 9-12 with a minimum GPA of 2.0; or

(c) [2-] Holds a high school diploma, [er] GED, or home school diploma.

(2) The student applicant shall:

(a) [Understand, read, speak, and write the English language with a comprehension and performance level equal to at least the ninth grade of education, otherwise known as Level 4, verified by testing as necessary;

(b)] Not currently be subject to disciplinary action pursuant to KRS Chapter 311A that would prevent certification;

(b) Pass a criminal background check through the Kentucky Administrative Office of the Courts (AOC) meeting the requirements of KRS 311A.050; and[

(c) Pass a drug test using criteria established by the EMS Training and Educational Institution (TEI); and

(d) (c) Meet all additional requirements established by the EMS Training and Educational Institution (EMS-TEI). [EMS-TEI; and

(d) Hold a valid motor vehicle operator's license or learners permit from a state or territory in the United States.]

Section 2. Certification Requirements. (1) Individuals desiring initial certification as an <u>Emergency Medical Technician</u> [EMT] shall:

(a) [Meet all of the requirements of Section 1 of this administrative regulation:

(b)] Be at least eighteen (18) years of age;

[(c) Hold a high school diploma or GED;

(d)] (b) Successfully complete a[n] <u>board approved</u> education and training program that conforms to the curriculum of the United States Department of Transportation, National Highway Traffic Safety Administration <u>National Emergency Medical Services</u> <u>Educational Standards-Instructional Guidelines for the Emergency</u> <u>Medical Technician</u>; [1994 National Standard Curriculum for <u>Emergency Medical Technician-Basic, which</u>]

(c) The educational curriculum shall not be satisfied by the completion of refresher or transition courses alone;

(d) Meet all educational standards established by 202 KAR 7:601;

(e) Obtain <u>certification</u> [NREMT_registration] as an <u>NREMT-</u> Emergency Medical Technician [NREMT-B];

(f) Submit a completed EMT Initial Certification Application in

<u>KEMSIS:</u> [and signed "Emergency Medical Technician Initial Certification Application,"]

(g) [Present written evidence of completion of current HIV/AIDS training required by KRS 311A.110;

(h)] Pay the fee required for certification pursuant to [by] 202 KAR 7:030; [and

(i) Present written evidence of completion of current training in CPR that:

1. Shall be taught by an individual who holds instructor certification at an appropriate level from:

a. The American Red Cross;

b. The AHA;

c. The National Safety Council;

d. The ASHI; or

e. Another board approved organization; and

2. Provides instruction and testing in:

a. One (1) rescuer CPR;

b. Two (2) rescuer CPR;

c. Techniques of changing from one (1) to two (2) rescuers during the performance of CPR;

d. Techniques of changing rescuers during the performance of two (2) rescuer CPR;

e. Techniques for relief of obstruction of the airway;

f. CPR of infants and small children;

g. Barrier-to-mouth, barrier-to-nose, or barrier-to-stoma resuscitation for adults, small children, and infants;

h. Use of oral and nasal airways;

i. Use of bag-valve-mask or other ventilation device;

j. Use of supplemental oxygen; and

k. Use and operation of an AED.

(2) An applicant for certification as an EMT shall successfully complete all NREMT testing and become Kentucky certified within two (2) years after the completion date of their EMT course.]

(h) An applicant shall undergo a background check pursuant to KRS 311A.050 and 311A.100. The background check shall be:

1. National in scope for an applicant not currently certified at any level in Kentucky;

2. Statewide in scope for an applicant with current certification in Kentucky;

3. Less than six (6) months old when the applicant submits to the board all requirements for certification; and

4. Provided by a vendor that has been contracted through the board.

a. An applicant shall not directly submit a background check to meet the requirements of this section. The background check shall be submitted to the board by the company that conducts the background check; and

(j) Be a citizen of the United States, a permanent resident of the United States, or otherwise lawfully present in the United States, as evidenced by submission to the board of:

1. A social security card;

2. Birth certificate;

3. A United States Citizenship and Immigration Services (U.S.C.IS) Permanent Resident Card (form I-551/Green Card); or

4. Other legal authorization to live and work in the United States.

Section 3. <u>Renewal of Certification</u> [Recertification] and Continuing Education Requirements. (1) An <u>Emergency Medical</u> <u>Technician</u> [EMT] shall be eligible for <u>certification renewal</u> [recertification] if:

(a) The applicant submits a completed <u>EMT Certification</u> <u>Renewal Application in KEMSIS [and signed "Universal Application</u> for Recertification/Relicensure"];

(b) The applicant maintains written evidence of: [current completion of training in CPR meeting the requirements as outlined in Section 2(1)(i) of this administrative regulation;]

1. Completion of a cardiopulmonary resuscitation (CPR) course that:

a. Meets all guidelines established by the International Liaison Committee (ILCOR) on Resuscitation for CPR [standards of the American Heart Association (AHA) Cardiopulmonary Resuscitation (CPR)] and Emergency Cardiovascular Care (ECC); and

b. Includes a psychomotor and a cognitive assessment;

2. Completion of current HIV/AIDS training required by KRS 311A.110;

<u>3. Pediatric Abusive Head Trauma required by KRS 311A.127;</u> and

4. Awareness of Sexual Violence Training required by KRS 311A.120.

(c) [The applicant maintains written evidence of completion of current HIV/AIDS training required by KRS 311A.110;

(d)] The applicant pays the fee required for renewal pursuant to [established in] 202 KAR 7:030; and

(d) The applicant maintains evidence of either:

1. Current <u>certification</u> [registration] by the NREMT as an Emergency Medical Technician: [NREMT-B; or]

a. If this option is used, the board may request through a continuing education audit proof of continuing education to verify compliance with the continuing education requirements listed in this section of the administrative regulation; or

2. Successful completion of the <u>NREMT</u> <u>Emergency Medical</u> Technician National Continued Competency Program for <u>Continuing Education which shall be validated by:</u> ["<u>EMT Basic</u> <u>Minimum Continuing Education Requirement" that:</u>

a. Includes twenty-four (24) structured contact hours of continuing education, of which sixteen (16) hours shall be within mandatory topic areas and eight (8) hours may be electives to include the following minimum contact hours and topics:

(i) One (1) in disaster management or mass casualty incidents;

(ii) Two (2) in airway management;

(iii) Three (3) in patient assessment;

(iv) Four (4) in medical or behavioral emergencies;

(v) Four (4) in trauma; and

(vi) Two (2) in obstetrics or gynecology, infants and children; and

b. Shall be validated by:

(i)] <u>a. Entities authorized to conduct continuing education</u> <u>pursuant to 202 KAR 7:601.</u> [The instructor, medical director, training officer, course coordinator, or provider of the continuing <u>education offering; or</u>

(ii) A medical director, service director, or training officer of the EMT's ambulance service, first response agency, fire department, rescue squad or other medical employer.]

(2) An application for [renewal of] certification renewal shall be denied if:

(a) Prior to the certification expiration date, the <u>Emergency</u> <u>Medical Technician</u> [EMT] applicant has not met the applicable requirements of this section; or

(b) The applicant has been subjected to disciplinary action that prevents <u>certification renewal</u> [recertification] at the time of application.

(3) A certified <u>Emergency Medical Technician</u> [EMT], in good standing, who is a member of a National Guard or a military reserve unit <u>who</u> [and] is called to active duty by presidential order pursuant to 10 U.S.C. <u>§§</u> 121 and 673b, <u>shall be renewed</u> according to KRS 12.355 upon submission of the Military <u>Extension Application</u>. [may be given a one (1) year extension following release from active duty to meet the applicable requirements for recertification listed in this administrative regulation. The EMT shall submit a written request for this extension within sixty (60) days of release from active duty.]

(4) The <u>board [KBEMS</u>] office may audit an <u>Emergency</u> <u>Medical Technician's [EMT's]</u> continuing education and continuing education records. <u>The Emergency Medical Technician shall</u> <u>submit the documentation requested within ten (10) business days</u> <u>of receipt of the board's request.</u>

(5) If documentation of continuing education hours consistent with this administrative regulation are not received by the office of the board within ten (10) business days of receipt of the board's request, the Emergency Medical Technician certification for the individual shall be summarily revoked and the individual shall reapply for certification through Reinstatement if eligible.

(6) The ten (10) business days for submission shall not apply to investigations pursuant to KRS Chapter 311A.

(7) The <u>Emergency Medical Technician</u> [EMT] shall maintain documentation of all continuing education for <u>three (3)</u> [four (4)] years from the date of completion.

Section 4. <u>Emergency Medical Technician</u> [EMT] Reciprocity. (1) <u>An individual who is</u> [A person] certified in [another] <u>a</u> contiguous state to the Commonwealth of Kentucky or [territory of the United States or member of the United States military who is certified registered] by the NREMT as an <u>Emergency Medical</u> <u>Technician</u> [NREMT-B] <u>or any member of the United States</u> <u>Armed Forces, or veteran who has transitioned within the past</u> <u>six (6) years from the United States Armed Forces, and has</u> <u>been registered by the National Registry as an NREMT-<u>Emergency Medical Technician</u> shall be eligible for [direct] reciprocity for [initial] Kentucky certification as an <u>Emergency</u> <u>Medical Technician if the applicant submits a completed EMT</u> <u>Reciprocity Certification Application in KEMSIS and proof of:</u> [EMT]</u>

(a) [Is at least eighteen (18) years of age;

(b)] <u>The applicant's</u> [Holds current] unrestricted <u>certification</u> [registration] as an <u>NREMT- Emergency Medical Technician or</u> <u>Emergency Medical Technician certification in a contiguous state</u> to the Commonwealth of Kentucky [NREMT-B];[

(c) Completes a training program that conforms to the curriculum of the United States Department of Transportation, National Highway Traffic Safety Administration, 1994 National Standard Curriculum for Emergency Medical Technician-Basic, which shall not be satisfied by the completion of refresher or transition courses alone:

(d) Holds a high school diploma or GED; and

(e) Holds a valid motor vehicle operators license from a state or territory in the United States.

(2) The individual shall:

(a) Understand, read, speak, and write the English language with a comprehension and performance level equal to at least the ninth grade of education, otherwise known as Level 4, verified by testing as necessary:

(b) Submit a completed and signed "Emergency Medical Technician Initial Certification Application":

(c) Present written evidence of completion of current HIV/AIDS training required by KRS 311A.110;

(d) Present written evidence of completion of current training in CPR that meets the requirements of Section 2(1) (i) of this administrative regulation;

(e)] (2) An applicant shall pay the fee required for certification through reciprocity pursuant to [by] 202 KAR 7:030. [;

(f) Not have been convicted of, entered a guilty plea or Alford plea to a felony offense, or have completed a diversion program for a felony offense; and]

(3) An applicant for Emergency Medical Technician reciprocity shall undergo a national background check provided by a vendor that has been contracted through the board.

(a) An applicant shall not directly submit a background check to meet the requirements of this section. The background check shall be submitted to the board by the company that conducts the background check; and

(b) Background checks that are older than six (6) months shall not be considered current, and the applicant shall undergo another national background check prior to approval of certification through reciprocity.

(4) An applicant shall not have been convicted of offenses described in KRS 311A.050.[

(g)] (5) An applicant shall n[N]ot have been subjected to discipline that would prevent reciprocity at the time of application.[; and]

(6) An Emergency Medical Technician certified pursuant to Section 2 of this administrative regulation shall not perform any procedures or skill on which the Emergency Medical Technician has not been trained. An Emergency Medical Technician who performs a skill for which the Emergency Medical Technician does not have documented training shall have exceeded the scope of practice and shall be in violation of KRS 311A.050.

(7) An Emergency Medical Technician certified pursuant to Section 4 of this administrative regulation shall complete the Kentucky supplemental Emergency Medical Technician curricula for the procedures listed in 202 KAR 7:701 prior to beginning work for a licensed agency in Kentucky.

(a) Kentucky supplemental Emergency Medical Technician curricula consistent with 202 KAR 7:701 shall be provided during employee orientation, or by entities authorized to conduct continuing education pursuant to 202 KAR 7:601.

(b) Verification of competency on the supplemental curricula procedures in 202 KAR 7:701 shall be maintained by the Emergency Medical Technician for a minimum of three (3) years. Failure to submit the EMT Supplemental Curriculum Training Verification Report upon request shall result in revocation of the Emergency Medical Technician certification.

(c) If an Emergency Medical Technician certified pursuant to this section fails to supply verification of competency as required by subsection (7) of this section, the Emergency Medical Technician shall be ineligible to apply for and receive Emergency Medical Technician reciprocity certification until the applicant has submitted the EMT Supplemental Curriculum Training Verification Report as required by 202 KAR 7:701, and shall reapply for Reciprocity through the process listed in Section 4 of this administrative regulation.[

(h) Have successfully completed a training program, which utilized the United States Department of Transportation, National Highway Traffic Safety Administration 1994 National Standard Curriculum, Emergency Medical Technician-Basic as the curriculum for education if any individual initially certified after January 1, 1986. An earlier edition of the National Standard Curriculum which has been supplemented by the completion of the EMT -Basic transition course shall be considered to meet this requirement.]

Section 5. Exemptions from <u>Emergency Medical Technician</u> [EMT] Administrative Regulations. Certification requirements for an <u>Emergency Medical Technician</u> [EMT] shall not apply to:

(1) United States military personnel or state National Guard or employees of the United States government while providing services on a United States government owned or operated facility, while engaged in the performance of their official duties under federal law, or while providing assistance in mass casualty or disaster type situation; or

(2) An <u>Emergency Medical Technician</u> [EMT] certified in another state or territory of the United States who:

(a) Comes into Kentucky to transport a patient from another state into Kentucky; or

(b) Is transporting a patient through the state of Kentucky to an out-of-Kentucky location.

Section 6. Reinstatement of Certification. (1) An <u>Emergency</u> <u>Medical Technician</u> [EMT] whose certification has lapsed [for a period not exceeding five (5) years,] may reinstate their certificate by submitting to the board:

(a) A completed <u>EMT Reinstatement Certification Application in</u> <u>KEMSIS</u> [and signed "Emergency Medical Technician Certification Reinstatement Application"];

(b) Evidence of previous certification as an Emergency Medical Technician in the Commonwealth of Kentucky; and

(c) Current training in:

1. HIV/AIDS training required by KRS 311A.110;

2. Pediatric Abusive Head Trauma as required by KRS

<u>311A.127;</u> <u>3. Awareness of Sexual Violence Training required by KRS</u> 311A.120; and a

4. Cardiopulmonary resuscitation (CPR) course that:

a. Meets all standards of the American Heart Association (AHA) Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC); and

b. Includes a psychomotor and a cognitive assessment.

(b) Written evidence of current completion of training in CPR meeting the requirements as outlined in Section 2(1) (i) of this administrative regulation;

(c) Written evidence of completion of current HIV/AIDS training required by KRS 311A.110;]

(d) Payment of the fee <u>pursuant to</u> [established in] 202 KAR 7:030;

(e) <u>The applicant for reinstatement of certification shall</u> <u>undergo a national background check provided by a vendor that</u> <u>has been contracted through the board.</u>

1. An applicant shall not directly submit a background check to meet the requirements of this section. The background check shall be submitted to the board by the company that conducts the background check; and

2. Background checks that are older than six (6) months shall not be considered current, and the applicant shall undergo another national background check prior to approval of reinstatement of certification. [Evidence of previous certification as an EMT in Kentucky;]

(f) Evidence of [additional] successful completion of the <u>NREMT</u> Emergency Medical Technician National Continued <u>Competency Program for Continuing Education</u> within twelve (12) months preceding their application for reinstatement of the <u>Emergency Medical Technician</u>. ["EMT Basic Minimum Continuing Education Requirement" that includes twenty-four (24) structured contact hours of continuing education, of which sixteen (16) hours shall be within mandatory topic areas and eight (8) hours may be electives to include the following minimum contact hours and toppics:

1. One (1) in disaster management or mass casualty incidents;

2. Two (2) in airway management;

3. Three (3) in patient assessment;

4. Four (4) in medical or behavioral emergencies;

5. Four (4) in trauma; and

6. Two (2) in obstetrics or gynecology, infants and children;]

(g) <u>The applicant for reinstatement of certification shall bear</u> the burden of proof of previous certification in Kentucky if the previous certification is in issue or dispute: [Evidence of successful completion of the National Standard Curriculum for Emergency Medical Technician Refresher Course or continuing education hours that meet the requirements of the Curriculum;] and

(h) An applicant for reinstatement of a lapsed certification shall provide evidence of current skills by completing and submitting validation of those skills on the Kentucky Emergency Medical Technician Skills Verification Report. The verification report shall be completed by entities authorized to conduct continuing education pursuant to 202 KAR 7:601. [Evidence of validation of skills maintenance by completing the EMT Recertification Report.]

(2) [An EMT, whose certification has lapsed for a period that exceeds five (5) years, may reinstate their certificate by complying with Sections 1 and 2 of this administrative regulation.

(3)] An applicant ineligible for certification pursuant to KRS 311A.050 through 311A.090 shall be ineligible for reinstatement. [An application for reinstatement of certification shall not be considered if:

(a) The applicant is subject to disciplinary action pursuant to KRS Chapter 311A;

(b) The applicant is an individual who has been convicted of, entered a guilty plea or Alford plea to a felony offense, or has completed a diversion program for a felony offense; or

(c) The applicant has been subjected to discipline that would prevent reinstatement at the time of application.]

Section 7. Public Notice of Negative Action. (1) The board office shall cause to be published[,] on the board Web site [in the KBEMS News or similar publication of the board, or otherwise disseminate] the name of an Emergency Medical Technician [EMT] that:

(a) Is fined;

(b) Is placed on probationary status;

(c) Is placed on restricted status;

(d) Is suspended; or

(e) Has had their certification revoked.[is fined, is placed on probationary status, is placed on a restricted status, is suspended, or has had their certification revoked.]

Section 8. <u>Expiration of Certification. (1) Certification periods</u> and expiration dates shall be pursuant to KRS 311A.095. (2) If an Emergency Medical Technician's certification lapses or expires, the Emergency Medical Technician shall cease provision of emergency medical services.

(3) An Emergency Medical Technician who has allowed their certification to lapse or expire shall be required to reinstate certification pursuant to Section 6 of this administrative regulation.[Temporary Certificate. (1) KBEMS staff may issue a temporary certificate to an individual who:

(a) Submits a completed "Application for Temporary Certificate";

(b) Is at least eighteen (18) years of age;

(c) Understands, reads, speaks, and writes the English language with a comprehension and performance level equal to at least the 9th grade of education, otherwise known as Level 4, verified by testing as necessary;

(d) Provides proof of being currently certified or licensed in another state or territory of the United States or is currently registered by the NREMT;

(e) Presents written evidence of completion of current HIV/AIDS training required by KRS 311A.110;

(f) Presents written evidence of completion of current training in CPR that meets the requirements of Section 2 of this administrative regulation;

(g) Pays the fee required by 202 KAR 7:030;

(h) Provides the board with a copy of a statewide criminal background check from their state of residence;

(i) Is not an individual who has been convicted of, entered a guilty plea or Alford plea to a felony offense, or has completed a diversion program for a felony offense; and

(j) Has not been disciplined by or has action pending against or had a certificate or license in the field of health care denied, limited, suspended, or probated by a certifying or licensing entity in Kentucky or other state or territory under the jurisdiction of the United States.

(2) A temporary certificate may be issued for a period which shall not exceed six (6) months and shall not be reissued or renewed.]

Section 9. <u>Scope of Practice. (1) An Emergency Medical</u> Technician shall provide emergency medical services consistent with the skills and procedures in the National EMS Scope of Practice Model and 202 KAR 7:701.

(2) If providing emergency medical services during a disaster or emergency that qualifies as part of the Emergency Management Assistance Compact, pursuant to KRS 39A.050, or if acting pursuant to another agreement made pursuant to KRS Chapter 39, an Emergency Medical Technician certified in another state may perform the skills and procedures approved by the certifying state.

Section 10. Downgrading Certification. (1) An Emergency Medical Technician currently certified as an Emergency Medical Technician by the board shall be eligible for certification downgrade if:

(a) The certification is in good standing with no pending disciplinary action;

(b) The applicant submits a completed EMT Certification Downgrade Application in KEMSIS; and

(c) The applicant pays the fee pursuant to 202 KAR 7:030;

(2) An Emergency Medical Technician shall only be eligible to downgrade their certification to an Emergency Medical Responder certification.

(3) Certification periods and expiration dates shall be pursuant to KRS 311A.095.

(4) An applicant shall undergo a background check pursuant to KRS 311A.050 and 311A.100. The background check shall be:

(a) Statewide in scope for an applicant with current certification in Kentucky;

(b) Less than six (6) months old when the applicant submits to the board all requirements for certification; and

(c) Provided by a vendor that has been contracted through the board.

(5) The applicant provides proof of:

(a) Current certification by the NREMT as an Emergency

Medical Technician; or

(b) Successful completion of the NREMT Emergency Medical Technician National Continued Competency Program for Continuing Education which shall be validated by entities authorized to conduct continuing education pursuant to 202 KAR 7:601.

(c) Completion of a cardiopulmonary resuscitation (CPR) course that:

<u>1. Meets all standards of the American Heart Association</u> (AHA) Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC); and

2. Includes a psychomotor and a cognitive assessment.

(d) Completion of current HIV/AIDS training required by KRS 311A.110;

(e) Pediatric Abusive Head Trauma required by KRS 311A.127; and

(f) Awareness of Sexual Violence Training required by KRS 311A.120.

(6) Downgrade shall be denied if the applicant has not met the requirements of this section or has been subject to disciplinary action that prevents certification at the time of application.

(7) The applicant shall be responsible for meeting the renewal requirements of the downgraded certification level issued prior to expiration of that certification.

(8) To reinstate the certification or license that was previously held, the applicant shall meet the regulatory requirements for that level of certification or licensure.

(9) The applicant shall notify the board's licensed service director(s) with whom the applicant is affiliated immediately upon downgrading their certification.

(10) Once the applicant has downgraded their certification or license, the applicant shall no longer be permitted to provide emergency medical services at the previous certification or license level held.

(11) An applicant applying for downgrade that does not comply with this section of the administrative regulation shall be subject to disciplinary action pursuant to KRS Chapter 311A.

(12) All endorsements, certifications, or licenses held at the previous certification or license level shall be void at the completion of the downgrade.

Section 11. Surrender of Certification. (1) An Emergency Medical Technician surrendering certification shall:

(a) Submit a completed EMT Certification Surrender Application in KEMSIS; and

(b) Pay the fee pursuant to 202 KAR 7:030.

(2) The applicant shall notify the board's licensed service director(s) with whom the applicant is affiliated immediately upon surrendering their certification.

Section 12. Reporting Requirements. (1) An Emergency Medical Technician shall maintain current demographic information in KEMSIS including:

(a) Legal name;

1. Any changes to your legal name shall be submitted using the Name Change application in KEMSIS; and

2. One of the following documents as verification of name change:

a. Social Security Card;

b. Driver's license; or

c. Passport;

(b) Mailing address;

(c) Email address; and

(d) Phone number.

(2) An Emergency Medical Technician that does not comply with this section of this administrative regulation shall be subject to disciplinary action pursuant to KRS Chapter 311A.

Section 13. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) <u>"National Emergency Medical Services Education</u> <u>Standards-Emergency Medical Technician Instructional</u> <u>Guidelines"</u>, <u>The United States Department of Transportation</u>, National Highway Traffic Safety Administration, DOT HS 811 077C, January 2009: [The United States Department of Transportation, National Highway Traffic Safety Administration, "1994 National Standard Curriculum, Emergency Medical Technician" (1994 Edition);]

(b) <u>"EMT Initial Certification Application" in KEMSIS, July 2019;</u> [The "Emergency Medical Technician Initial Certification Application" (June 2003);]

(c) <u>"EMT Certification Renewal Application" in KEMSIS, July</u> 2019; [The "Universal Application Recertification/Relicensure" (June 2003);]

(d) "EMT Reciprocity Certification Application" in KEMSIS July 2019;[

(d) "The Kentucky Board of Emergency Medical Services Emergency Medical Technician Minimum Continuing Education Requirements. Total Contact Hours" (June 2003); and]

(e) <u>"EMT Reinstatement Certification Application" in KEMSIS,</u> July 2019; [The "Emergency Medical Technician Reinstatement Application" (June 2003).]

(f) "National EMS Scope of Practice Model", National Highway Traffic Safety Administration, DOT HS 810 657, February 2007;

(g) "National EMS Scope of Practice Model", National Highway Traffic Safety Administration, DOT HS 812 666, February 2019;

(h) "EMT Skills Verification Report", July 2019;

(i) "EMT Supplemental Curriculum Training Verification Report", July 2019;

(j) "EMT Certification Downgrade Application" in KEMSIS, July 2019;

(k) "EMT Certification Surrender Application" in KEMSIS, July 2019;

(I) "National Registry of Emergency Medical Technicians National Continued Competency Program EMT", October 2016;

(m) "American Heart Association Guidelines for CPR and Emergency Cardiovascular Care", November 2018;

(n) "National Registry of Emergency Medical Technicians Emergency Medical Technician Psychomotor Examination Users Guide", September 2016;

(o) "Name Change Application" in KEMSIS, July 2019;

(p) "Military Extension Application" in KEMSIS, July 2019; and

(q) "United States Citizenship and Immigration Services (U.S.C.IS) Permanent Resident Card (form I-551/Green Card)", July 2019.

(2) This material may be inspected, obtained, or copied, subject to applicable copyright law, at the Office of the Kentucky Board of Emergency Medical Services, <u>118 James Court</u>, <u>Lexington, Kentucky 40505, by appointment</u>, [2545 Lawrenceburg Road, Frankfort, Kentucky 40601,] Monday through Friday, 8 a.m. to 4:30 p.m.

PHILIP DIETZ, Chairperson

APPROVED BY AGENCY: September 17, 2020

FILED WITH LRC: October 1, 2020 at noon

CONTACT PERSON: Jeffrey S. Walther, Legal Counsel, Kentucky Board of Emergency Medical Services, Walther, Gay & Mack, PLC; 163 East Main Street, Suite 200, Lexington, Kentucky 40588, phone (859) 225-4714, fax (859) 225-1493, email: administrativeregulations@wgmfirm.com.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Jeffrey S. Walther

(1) Provide a brief summary of:

(a) What this administrative regulation does: KRS 311A.025 requires the board to promulgate administrative regulations relating to Emergency Medical Technicians. This administrative regulation establishes requirements for Emergency Medical Technicians.

(b) The necessity of this administrative regulation: KRS 311A.025 requires the board to promulgate administrative regulations relating to Emergency Medical Technicians. This administrative regulation establishes requirements for Emergency Medical Technicians. These amendments are necessary to allow Kentucky Emergency Medical Technicians the opportunity to become certified and maintain certification to protect the citizens of

the Commonwealth of Kentucky. Educational and certification processes are streamlined, and unnecessary or repetitive language across other administrative regulations have been removed.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 311A.025 by establishing requirements for Emergency Medical Technicians

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: KRS 311A.025 requires the board to promulgate administrative regulations relating to Emergency Medical Technicians. This administrative regulation establishes requirements for Emergency Medical Technicians. This administrative regulation will assist Emergency Medical Technicians in becoming certified utilizing more simplistic guidelines and processes and provides additional guidance on educational requirements, and will allow the board to provide more effective customer service to applicants for certification.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment streamlines certification application processes for Emergency Medical Technicians and provides additional guidance on application processes and responsibilities of the Emergency Medical Technician. Additionally, unnecessary and dated requirements and terminology have been removed.

(b) The necessity of the amendment to this administrative regulation: These amendments are necessary to allow Kentucky Emergency Medical Technicians the opportunity to become certified and maintain certification to protect the citizens of the Commonwealth of Kentucky. Educational and certification processes are streamlined, and unnecessary or repetitive language across other administrative regulations have been removed.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of KRS 311A.025 by establishing requirements for Emergency Medical Technicians.

(d) How the amendment will assist in the effective administration of the statutes: KRS 311A.025 requires the board to promulgate administrative regulations relating to Emergency Medical Technicians. This administrative regulation establishes requirements for Emergency Medical Technicians. This amendment streamlines processes for administrative body processing and removes barriers to certification for the Emergency Medical Technician. Streamlined processes allow the board to certify applicants more effectively and efficiently.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The Kentucky Board of Emergency Medical Services, its members, and staff, local governments, emergency medical services providers, and Emergency Medical Technicians will be affected by this administrative regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The Kentucky Board of Emergency Medical Services, its members, staff, and licensed agencies shall implement the standards relating to Emergency Medical Technicians pursuant to this administrative regulation and shall execute their duties consistent with this amendment.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost to any entity identified in question (3).

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Applicants seeking certification as an Emergency Medical Technician will benefit from decreased

certification requirements and processing time.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation: There will be no cost to the administrative body to implement this administrative regulation.

(a) Initially: There will be no cost to the administrative body to implement this administrative regulation.

(b) On a continuing basis: There will be no cost to the administrative body to implement this administrative regulation.

(6) What is the source of funding to be used for the implementation and enforcement of this administrative regulation: No funding source is necessary to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. This regulation did not establish any fees.

(9) TIERING: Is tiering applied? Tiering is not applied to this administrative regulation because this amendment applies equally to all licensed agencies.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Emergency Medical Services, its members, and staff, local governments, emergency medical services providers, and Emergency Medical Technicians will be affected by this administrative regulation.

2. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 311A.025 requires the board to promulgate administrative regulations relating to Emergency Medical Technicians. This administrative regulation establishes requirements for Emergency Medical Technicians.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will generate no revenue for the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will generate no revenue for subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not impose any costs on state or local government.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not impose any costs on state or local government.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): This administrative regulation will not generate revenue.

Expenditures (+/-): This administrative regulation will not impose any costs.

Other Explanation:

KENTUCKY COMMUNITY AND TECHNICAL COLLEGE SYSTEM Kentucky Board of Emergency Medical Services (Amended After Comments)

202 KAR 7:330. <u>Advanced Emergency Medical</u> <u>Technician</u>[Requirements for examination, certification, and recertification of the advanced emergency medical technician].

RELATES TO: KRS 38.030, KRS Chapter 39, KRS 39A.050, KRS 311A.010, KRS 311A.020, KRS 311A.025, KRS 311A.050, KRS 311A.090, KRS 311A.095, KRS 311A.100, KRS 311A.110, KRS 311A.127, KRS 311A.140, KRS 311A.145, KRS 311A.150, KRS 311A.195, 10 U.S.C. §§ 121, 672(b)

STATUTORY AUTHORITY: KRS 311A.020, KRS 311A.025, KRS 311A.030

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311A.025(2) requires the Kentucky Board of Emergency Medical Services to promulgate administrative regulations relating to the standards for training, education, examination, certification, practice, and recertification of the advanced emergency medical technician (AEMT). This administrative regulation establishes requirements for Advanced Emergency Medical Technician.

Section 1. Advanced Emergency Medical Technician Student Eligibility. (1) Individuals shall be eligible to enroll as a student in an Advanced Emergency Medical Technician education and training program if the applicant:

(a) Is at least eighteen (18) years of age;

(b) Holds a high school diploma, GED, or home school diploma; and

(c) Is currently certified at a minimum of an Emergency Medical Technician by the board or the NREMT.

(2) The student applicant shall:

(a) Not currently be subject to disciplinary action pursuant to KRS Chapter 311A that would prevent certification; and

(b) Meet all additional requirements established by the EMS Training and Educational Institution (EMS-TEI).

Section <u>2[</u>4]. Certification Requirements. (1) <u>Individuals</u> desiring initial certification as an Advanced Emergency Medical <u>Technician shall:</u> [An applicant for initial certification as an AEMT shall complete an educational course that:]

(a) Successfully complete a board approved education and training program that conforms to the curriculum of the United States Department of Transportation, National Highway Traffic Safety Administration National Emergency Medical Services Educational Standards-Instructional Guidelines for the Advanced Emergency Medical Technician. The educational curriculum shall not be satisfied by the completion of refresher or transition courses alone; [Meets or exceeds the National Emergency Medical Services Educational Standards Instructional Guidelines for an AEMT; and]

(b) Meet[s] all educational standards established in 202 KAR 7:601:[-]

(c) Obtain certification as an NREMT-Advanced Emergency Medical Technician;

(d) Be a citizen of the United States, a permanent resident of the United States, or otherwise lawfully present in the United States, as evidenced by submission to the board of:

1. A social security card;

2. Birth certificate;

3. A United States Citizenship and Immigration Services (U.S.C.IS) Permanent Resident Card (form I-551/Green Card); or

4. Other legal authorization to live and work in the United States.

(e) Submit a completed AEMT Initial Certification Application in KEMSIS; and

(f) Pay the fee pursuant to 202 KAR 7:030 for certification as an Advanced Emergency Medical Technician.[

(2) An applicant for initial certification as an AEMT in Kentucky shall pass the examination required to obtain the National Registry

of Emergency Medical Technicians certification for an AEMT.

(3) An applicant for initial certification as an AEMT shall provide proof that the applicant has:

(a) Completed a college degree; or

(b)1. Obtained a high school diploma; or

2. Successfully taken the General Educational Development (GED) test.

(4) An applicant for AEMT shall complete and submit a signed EMS Responder Application.

(5) An applicant for AEMT shall submit valid evidence of completion of the following courses:

(a) HIV/AIDS training required by KRS 311A.110; and

(b) Pediatric Abusive Head Trauma required by KRS 311A.127.

(6) An applicant for AEMT shall pay to KBEMS the fee established in 202 KAR 7:030 for certification as an AEMT.

(7) An applicant for AEMT shall submit to KBEMS an unexpired cardiopulmonary resuscitation (CPR) card or other current evidence of completion of a CPR course that:

(a) Meets all standards of the American Heart Association Basic Life Support for Healthcare Provider course; and

(b) Includes a psychomotor examination component and a cognitive assessment.

(8)] (2) An applicant shall undergo a background check pursuant to KRS 311A.050 and 311A.100. The background check required shall be:

(a) National in scope for an applicant not currently certified at any level in Kentucky;

(b) Statewide in scope for an applicant with current certification in Kentucky;

(c) Less than six (6) months old when the applicant submits to the board [KBEMS] all requirements for certification; and

(d) Provided by a vendor that has been contracted through <u>the</u> <u>board [KBEMS or an official federal entity]</u>.

(3) [(9)] An applicant shall not directly submit a background check. The background check shall be submitted to the <u>board</u> [Kentucky Board of Emergency Medical Services] by the company [or federal entity] that conducts the background check.[

(10) An applicant shall have two (2) years from the completion date appearing on the course completion form for the applicant's AEMT course to:

(a) Pass the National Registry exam for AEMT certification; and

(b) Fulfill all requirements for certification as an AEMT established in this section.]

Section <u>3</u> [2]. Scope of Practice. (1) An <u>Advanced Emergency</u> <u>Medical Technician</u> [AEMT] shall provide emergency medical services consistent with the skills and procedures in the National EMS Scope of Practice Model <u>and 202 KAR 7:701.</u>

(2) [In addition to the skills and procedures in the National EMS Scope of Practice Model, the scope of practice of a Kentucky AEMT shall include the following procedures:

(a) Quantitative and qualitative capnography and capnometry;

(b) Bilevel Positive Airway Pressure and Continuous Positive Airway Pressure (BIPAP/CPAP) devices;

(c) End tidal Carbon Dioxide (ETCO2) Detection;

(d) Acquisition of a non-interpretive twelve (12) lead electrocardiogram (ECG);

(e) Transmission of a non-interpretive twelve (12) lead electrocardiogram (ECG); and

(f) Establish and maintain adult intraosseous infusion.

(3) Eligibility to perform the supplemental procedures shall require an AEMT to complete education on and training for the skill performed. The supplemental curriculum required shall consist of:

(a) Kentucky Ambulance Service Specific Supplemental Curriculum for the AEMT using a noninvasive monitoring device – Application of 12 lead electrocardiogram electrodes and monitor;

(b) Kentucky Ambulance Service Specific Supplemental Curriculum for the AEMT using a noninvasive monitoring device – Application and interpretation of quantitative capnography and end tidal carbon dioxide monitoring;

(c) Kentucky Ambulance Service Specific Supplemental

Curriculum for the AEMT using Bilevel Positive Airway Pressure and Continuous Positive Airway Pressure Devices; and

(d) Kentucky Ambulance Service Specific Supplemental Curriculum for the AEMT using intraosseos infusion in the adult.

(4) An AEMT shall adhere to the protocols the employing service's medical director submitted to KBEMS for approval. Deviation from the protocols shall only occur if:

(a) The AEMT's medical director or designated on-line medical control orders otherwise;

(b) Compliance with approved protocols is not in the patient's medical best interest; or

(c) The AEMT does not have the equipment or medication to adhere to the protocol.

(5) An AEMT shall document deviation from an approved protocol as part of the patient care report.

(6)] If providing emergency medical services during a disaster or emergency that qualifies as part of the Emergency Management Assistance Compact[-] pursuant to KRS 39A.050, or if acting pursuant to another agreement made pursuant to KRS Chapter 39, an <u>Advanced Emergency Medical Technician</u> [AEMT] certified in another state may perform the skills and procedures approved by the certifying state.

Section $\underline{4}$ [3]. Expiration of Certification. (1) Certification periods and expiration dates shall be pursuant to KRS 311A.095.

(2) If an <u>Advanced Emergency Medical Technician's [AEMT's]</u> certification lapses or expires, the <u>Advanced Emergency Medical</u> <u>Technician</u> [AEMT] shall cease provision of emergency medical services.

(3) [If the AEMT has chosen to maintain certification at the EMT level, the AEMT shall apply for renewal of EMT certification prior to the expiration date.

(4)] An Advanced Emergency Medical Technician [AEMT] who has allowed his [all levels of] certification to lapse or expire shall be required to reinstate certification pursuant to Section <u>8</u> [7] of this administrative regulation.

Section <u>5</u> [4]. Renewal of Certification and Continuing Education Requirements. (1) To be eligible for renewal of certification, an <u>Advanced Emergency Medical Technician</u> [AEMT] shall submit to the board:

(a) A completed <u>AEMT Certification Renewal Application in</u> <u>KEMSIS [and signed EMS Responder Application];</u> and

(b) The fee pursuant to [established in] 202 KAR 7:030.

(2) The applicant shall maintain written evidence of:

(a) Current training in HIV/AIDS treatment and recognition required by <u>KRS 311A.110;</u> [Section 1(5) (a) of this administrative regulation; and]

(b) Current training in Pediatric Abusive Head Trauma as required by KRS 311A.127;

(c) Awareness of Sexual Violence Training required by KRS 311A.120; and

(d) Current training in a cardiopulmonary resuscitation (CPR) course that:

1. Meets all guidelines established by the International Liaison Committee (ILCOR) on Resuscitation for CPR and Emergency Cardiovascular Care (ECC) [standards of the American Heart Association Basic Life Support for Healthcare Provider or Professional Rescuer course]; and

2. Includes a psychomotor [examination component] and a cognitive assessment.

(3) <u>The [An] applicant [for renewal of certification as an AEMT]</u> shall maintain evidence of <u>either</u>:

(a) Current certification by the National Registry of Emergency Medical Technicians as an <u>Advanced Emergency Medical</u> <u>Technician [AEMT]</u>; or

1. If this option is used the board may request, through a continuing education audit, proof of continuing education to verify compliance with the continuing education requirements of this section.

(b) <u>Successful</u> completion of the <u>NREMT Advanced</u> <u>Emergency Medical Technician National Continued Competency</u> <u>Program for Continuing Education, which shall be validated by</u> entities authorized to conduct continuing education pursuant to 202 KAR 7:601. [AEMT continuing education requirement of forty-eight (48) total instructional hours. The forty-eight (48) instructional hours shall be composed of twelve (12) elective hours in subject areas chosen by the AEMT and thirty-six (36) hours that include the following minimum contact hours for the following subject areas:

1. Twelve (12) hours in airway, breathing, and cardiology, with a minimum of one (1) hour in each topic;

2. Six (6) hours in medical emergencies, excluding cardiology;

3. Five (5) hours in trauma;

4. Six (6) hours in obstetrics;

5. Six (6) hours in pediatrics; and

6. One (1) hour in disaster management.

(c) The twelve (12) elective hours required for an AEMT to recertify shall not include more than four (4) hours in a single category in the list provided in paragraph (b)1. through 6. of this subsection.

(4) To be used for renewal of certification, the AEMT's continuing education hours shall be certified as valid by:

(a) The course's instructor, medical director, training officer, coordinator, or provider that offered the hours; or

(b) A medical director, service director, or training officer of the AEMT's ambulance service, first response agency, fire department, rescue squad, or other medical employer.]

(4) [(5)] An <u>application</u> [applicant] for [AEMT shall not be eligible for renewal of] certification renewal shall be denied if: [if the applicant does not complete all hours required by the end of the AEMT's certification period.]

(a) Prior to the certification expiration date, the Advanced Emergency Medical Technician applicant has not met the applicable requirements of this section; or

(b) The applicant has been subjected to disciplinary action that prevents certification renewal at the time of application.[

(6) An applicant's certification that is based upon completion of continuing education hours that are subsequently proven untrue, inaccurate, or fraudulent through a board audit shall be invalid pursuant to [KRS 311A.140(4) and] 311A.050(2)(b).]

(5) [(7)] An applicant who is subject to pending administrative action pursuant to KRS 311A.050 through 311A.090 shall be eligible to renew certification unless the applicant:

(a) Is temporarily suspended pursuant to KRS 311A.075;

(b) Has failed to perform an action ordered by the board pursuant to KRS 311A.055 or 311A.060; or

(c) Is delinquent on fines or fees owed to the board pursuant to KRS 311A.055, KRS 311A.060, or 202 KAR 7:030.

(6) [(8)] A certified Advanced Emergency Medical Technician, in good standing, who is a member of a branch of the United States National Guard or a military reserve unit and is called to active duty by presidential order pursuant to 10 U.S.C. §§ 121 and 673b, shall be renewed in accordance with KRS 12.355 upon submission of the Military Extension Application. [AEMT who is not undergoing disciplinary action with the board and who is a member of a branch of the United States military or a National Guard or military reserve unit shall be eligible for an extension of the time limit to renew certification if the AEMT:

(a)1. Is called to federal active duty by presidential order pursuant to 10 U.S.C. 121 and 673b during the current certification period; or

2. Is called to state active duty for an extended period of time by order of the governor pursuant to KRS 38.030;

(b) Because of the call to active duty, is unable to complete the continuing education hours required for renewal of certification; and

(c) Submits a written request for an extension within thirty (30) days prior to or sixty (60) days after release from active duty.

(9) The extension granted pursuant to subsection (8) of this administrative regulation shall not exceed one (1) year beyond the effective date of release from active duty for the AEMT. The AEMT shall be required to provide a DD 214 or other relevant federal documents as proof of the release date.]

(7) [(10)] The board office may audit an Advanced Emergency Medical Technician's continuing education and continuing education records.

(8) [If asked by the office of the board to provide the documentation of continuing education hours an AEMT used as a basis for renewal of certification,] <u>T[t]he Advanced Emergency</u> <u>Medical Technician</u> [AEMT] shall submit the documentation requested within ten (10) business days of receipt of the board's request. <u>If documentation of continuing education hours consistent</u> with this administrative regulation are not received by the office of the board within ten (10) business days of receipt of the board's request, the Advanced Emergency Medical Technician certification for the individual shall be summarily revoked and the individual shall reapply for certification through Reinstatement if eligible.

(9) The ten (10) business days for submission shall not apply to investigations pursuant to KRS Chapter 311A.

(10) The Advanced Emergency Medical Technician shall maintain documentation of all continuing education for three (3) years from the date of completion.

Section <u>6[5]</u>. <u>Advanced Emergency Medical Technician</u> [AEMT] Reciprocity. (1) An individual who is certified <u>in a</u> contiguous state to the Commonwealth of Kentucky or by the NREMT as an <u>Advanced Emergency Medical Technician</u> [AEMT] or any member of the United States Armed Forces, or veteran who has transitioned within the past six (6) years from the United States Armed Forces, and has been registered by the National Registry as an <u>Advanced Emergency Medical</u> <u>Technician or EMT and has successfully completed the Army</u> <u>68 Whiskey course</u> shall be eligible for [direct] reciprocity for [initial] certification as an Advanced Emergency Medical Technician in Kentucky if the applicant submits:

(a) <u>A</u> [a] completed <u>AEMT Reciprocity Certification Application</u> in <u>KEMSIS; and</u> [and signed EMS Responder Application and proof of:]

(b) [(a)] <u>Proof of the applicant's unrestricted NREMT</u> certification as an <u>Advanced Emergency Medical Technician or</u> <u>Advanced Emergency Medical Technician certification in a</u> <u>contiguous state to the Commonwealth of Kentucky.</u> [AEMT; and

(b) Completion of current training in:

1. HIV/AIDS training required by KRS 311A.110;

2. Pediatric Abusive Head Trauma training required by KRS 311A.127; and

3. CPR that meets the requirements of Section 1(7) of this administrative regulation; and

(c) Submission of the Kentucky Required Mandatory Supplemental Curriculum for AEMT Initial Training Verification Report.]

(2) An applicant shall pay the fee required for [initial] certification through reciprocity pursuant to 202 KAR 7:030.

(3) An applicant for <u>Advanced Emergency Medical Technician</u> [AEMT direct] reciprocity shall undergo a national background check <u>provided by a vendor that has been contracted through the</u> <u>board</u>. An applicant shall not directly submit a background check. The background check shall be submitted to the board by the <u>company that conducts the background check</u>. [and have the results submitted to the board.] Background checks that are older than six (6) months shall not be considered current, and the applicant shall [be required to] undergo another national background check prior to approval of certification through reciprocity.

(4) An applicant shall not have been convicted of offenses described in KRS 311A.050.

(5) An applicant shall not have been subjected to discipline that would prevent reciprocity at the time of application.

(6) [(4)] An <u>Advanced Emergency Medical Technician</u> [AEMT] certified pursuant to Section <u>2</u> [4] of this administrative regulation shall not perform any procedures or skill on which the <u>Advanced</u> <u>Emergency Medical Technician</u> [AEMT] has not been trained. An <u>Advanced Emergency Medical Technician</u> [AEMT] who performs a skill for which the <u>Advanced Emergency Medical Technician</u> [AEMT] who performs a skill for which the <u>Advanced Emergency Medical Technician</u> [AEMT] does not have documented training shall have exceeded the scope of practice and shall be in violation of KRS 311A.050[60].

(7) [(5)] An Advanced Emergency Medical Technician [AEMT]

certified pursuant to Section <u>6</u> [4] of this administrative regulation shall complete the Kentucky supplemental <u>Advanced Emergency</u> <u>Medical Technician</u> [AEMT] curricula for the procedures listed in 202 KAR 7:701 prior to beginning work for a licensed agency in <u>Kentucky</u> [Section 2(3) of this administrative regulation within six (6) months of receiving certification through direct reciprocity].

(8) Kentucky supplemental Advanced Emergency Medical Technician curricula consistent with 202 KAR 7:701 shall be provided during employee orientation, or by entities authorized to conduct continuing education pursuant to 202 KAR 7:601.

(9) [(6)] Verification of competency on the supplemental curricula procedures in 202 KAR 7:701 [Section 2(3) of this administrative regulation] shall be maintained by the Advanced Emergency Medical Technician for a minimum of three (3) years. [submitted to the board within six (6) months of receiving certification.] Failure to submit the AEMT Supplemental Curriculum Training Verification Report [verification] shall result in revocation of Advanced Emergency Medical Technician [AEMT] certification [and the board shall issue a new certificate at the level of EMT for the remaining certification period].

(10) [(7)] If an Advanced Emergency Medical Technician [AEMT] certified pursuant to this section fails to supply verification of competency as required by subsection (7) of this section the Advanced Emergency Medical Technician shall be ineligible to apply for and receive Advanced Emergency Medical Technician reciprocity certification until the applicant has submitted the AEMT Supplemental Curriculum Training Verification Report as required pursuant to 202 KAR 7:701, and shall reapply for Reciprocity through the process set forth in this section. [and the AEMT's certificate is reissued at the EMT level of certification, the AEMT shall be ineligible to apply for and receive AEMT reciprocity certification until the applicant has submitted verification of competency in the supplemental procedures in Section 2(3) of this administrative regulation].

Section <u>7[6]</u>. Exemptions from <u>Advanced Emergency Medical</u> <u>Technician</u> [AEMT] Administrative Regulations. Certification requirements for an <u>Advanced Emergency Medical Technician</u> [AEMT] shall not apply to:

(1) United States military members, state National Guard personnel, or employees of the United States government if the individual provides emergency medical services:

(a)[1.] On land owned by the United States government; [or]

(b) [2-] In facilities owned by the United States government; [er] (c) [(b)1.] In the performance of official duties under federal law; [er]

(d) [2-] As part of assistance for a mass casualty or disaster incident pursuant to federal law or official state assistance request; or

(2) An <u>Advanced Emergency Medical Technician</u> [AEMT] certified in another state or territory of the United States who:

(a) Enters Kentucky with a patient being transported to a medical facility or other final destination in Kentucky; or

(b) Travels through Kentucky during the course of a patient transport from an out-of-state location to a destination outside of Kentucky.

Section <u>8</u>[7]. Reinstatement of Certification. (1) An <u>Advanced</u> <u>Emergency Medical Technician</u> [AEMT] whose Kentucky certification has lapsed shall be eligible for reinstatement of certification if <u>the applicant submits</u>:

(a) [The lapse in certification has not exceeded a period of three (3) years; and

(b) The applicant submits:

1.] A completed <u>AEMT Reinstatement Certification Application</u> in KEMSIS [and signed EMS Responder Application]; and

[2.] (b) Evidence of:

<u>1. Previous certification as an Advanced Emergency Medical</u> <u>Technician in the Commonwealth of Kentucky; and [a. Current</u> certification at the AEMT level or higher with the National Registry; er]

2. [b.] Current training in:

a. [(ii)] HIV/AIDS training required by KRS 311A.110;

<u>b.</u> [(iii)] Pediatric Abusive Head Trauma as required by KRS 311A.127;

c. Awareness of Sexual Violence Training required by KRS 311A.120; and a

d. Cardiopulmonary resuscitation (CPR) course that:

(i) Meets all standards of the American Heart Association Basic Life Support for Healthcare Provider or Professional Rescuer course; and

(ii) Includes a psychomotor examination component and a cognitive assessment.

(2) The applicant shall pay the fee pursuant to 202 KAR 7:030.

(3) <u>The applicant for reinstatement of certification shall</u> <u>undergo a national background check provided by a vendor that</u> <u>has been contracted through the board.</u>

(a) An applicant shall not directly submit a background check to meet the requirements of this section. The background check shall be submitted to the board by the company that conducts the background check; and

(b) Background checks that are older than six (6) months shall not be considered current, and the applicant shall undergo another national background check prior to approval of reinstatement of certification. [The applicant shall undergo a national background check and have the results presented to the office of the board. If the background check is older than six (6) months, the applicant shall be required to undergo and have new results submitted to the board.]

(4) The applicant for reinstatement of certification shall bear the burden of proof of previous certification in Kentucky if the previous certification is in issue or dispute.

(5) An applicant for reinstatement of an <u>Advanced Emergency</u> <u>Medical Technician</u> [AEMT] certification shall submit evidence of formal completion of continuing education hours as required in Section <u>5</u> [4] of this administrative regulation. Completion of the hours shall have occurred within the twelve (12) months preceding application for reinstatement of the <u>Advanced Emergency Medical</u> Technician [AEMT].

(6) An applicant for reinstatement of a lapsed certification shall provide evidence of current skills by completing and submitting validation of those skills on the Kentucky Advanced <u>Emergency</u> <u>Medical Technician</u> [EMT] Skills Verification Report. <u>The Advanced</u> <u>Emergency Medical Technician Skills Verification Report shall be completed by entities authorized to conduct continuing education pursuant to 202 KAR 7:601.</u>

(7) [An AEMT whose certification has lapsed for longer than three (3) years shall not be eligible for reinstatement but shall be considered an initial certification and shall meet all requirements in Section 1 of this administrative regulation.

(8)] An applicant ineligible for certification pursuant to KRS 311A.050 through 311A.090 shall be ineligible for reinstatement.

Section 9. Downgrading Certification. (1) An Advanced Emergency Medical Technician currently certified as an Advanced Emergency Medical Technician by the board shall be eligible for certification downgrade if:

(a) The certification is in good standing with no pending disciplinary action;

(b) The applicant submits a completed AEMT Certification Downgrade Application in KEMSIS;

(c) The applicant pays the fee established in 202 KAR 7:030;

(2) An Advanced Emergency Medical Technician is only eligible to downgrade their certification to an Emergency Medical Technician or Emergency Medical Responder certification.

(3) Certification periods and expiration dates shall be pursuant to KRS 311A.095.

(4) An applicant shall undergo a background check pursuant to KRS 311A.050 and 311A.100. The background check required shall be:

(a) Statewide in scope for an applicant with current certification in Kentucky;

(b) Less than six (6) months old when the applicant submits to the board all requirements for certification; and

(c) Provided by a vendor that has been contracted through the board.

(5) The applicant shall provide proof of:

(a) Current certification by the NREMT as an Advanced Emergency Medical Technician; or

(b) Successful completion of the NREMT Emergency Medical Technician National Continued Competency Program for Continuing Education which shall be validated by entities authorized to conduct continuing education pursuant to 202 KAR 7:601.

(c) Completion of a cardiopulmonary resuscitation (CPR) course that:

<u>1. Meets all standards of the American Heart Association</u> (AHA) Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC); and

Includes a psychomotor and a cognitive assessment.

(d) Completion of current HIV/AIDS training required by KRS 311A.110;

(e) Pediatric Abusive Head Trauma required by KRS 311A.127; and

(f) Awareness of Sexual Violence Training required by KRS 311A.120.

(6) Downgrade shall be denied if the applicant has not met the requirements of this section or has been subject to disciplinary action that prevents certification at the time of application.

(7) The applicant shall be responsible for meeting the renewal requirements of the downgraded certification level issued prior to expiration of that certification.

(8) To reinstate the certification or license that was previously held, the applicant shall meet the regulatory requirements for that level of certification or licensure.

(9) The applicant shall notify the board's licensed service director(s) with whom the applicant is affiliated immediately upon downgrading their certification.

(10) Once the applicant has downgraded their certification or license, the applicant is no longer permitted to provide emergency medical services at the previous certification or license level held.

(11) An applicant applying for downgrade that does not comply with this section of the administrative regulation shall be subject to disciplinary action pursuant to KRS Chapter 311A.

(12) All endorsements, certifications, or licenses held at the previous certification or license level shall be void at the completion of the downgrade.

Section 10. Surrender of Certification. (1) An Advanced Emergency Medical Technician surrendering certification shall:

(a) Submit a completed AEMT Certification Surrender Application in KEMSIS; and

(b) Pay the fee established in 202 KAR 7:030.

(2) The applicant shall notify the board's licensed service director(s) with whom the applicant is affiliated immediately upon surrendering their certification.

Section 11. Reporting Requirements. (1) An Advanced Emergency Medical Technician shall maintain current demographic information in KEMSIS including:

(a) Legal name;

1. Any changes to your legal name shall be submitted using the Name Change application in KEMSIS; and

2. One of the following documents as verification of name change:

a. Social Security card;

b. Driver's license; or

c. Passport;

(b) Mailing address;

(c) Email address; and

(d) Phone number.

(2) An Advanced Emergency Medical Technician that does not comply with this section of this administrative regulation shall be subject to disciplinary action pursuant to KRS Chapter 311A.

Section 12. Public Notice of Negative Action. (1) The board office shall cause to be published on the board website the name of an Advanced Emergency Medical Technician that:

(a) Is fined;

(b) Is placed on probationary status;
 (c) Is placed on restricted status;
 (d) Is suspended; or
 (e) Has had their certification revoked.[

Section 8. AEMT certification through previous pilot projects.

(1) An AEMT who obtained certification as an AEMT through training in a pilot project previously approved by the board shall maintain certification until the end of the current certification period without the completion of additional requirements.

(2) An AEMT certified through a previously approved pilot project who applies for renewal at the end of the current certification period shall meet all requirements for renewal of certification in Section 4 of this administrative regulation.

(3) An applicant certified as an AEMT in a previously approved pilot project and who meets the requirements for renewal of certification as an AEMT in Section 4 of this administrative regulation shall not be limited to the geographic boundaries established in the original pilot project but shall be considered fully certified and geographically unrestricted to practice as an AEMT in the state of Kentucky.]

Section <u>13.[9-]</u> Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "National Emergency Medical Services Education Standards-<u>Advanced Emergency Medical Technician</u> Instructional Guidelines", <u>The United States Department of Transportation</u>, <u>National Highway Traffic Safety Administration</u>, <u>DOT HS 811</u> <u>077D</u>, January 2009 [National Highway Traffic Safety Administration, DOT HS 811 077A, January 2009];

 (b) <u>"AEMT Initial Certification Application" in KEMSIS, July</u> <u>2019</u> ["EMS Responder Application", KBEMS E-1, September 2012];

(c) <u>"AEMT Certification Renewal Application" in KEMSIS, July</u> <u>2019</u> ["American Heart Association's Basic Life Support for Healthcare Providers Course", American Heart Association, 2011];

(d) <u>"AEMT Reciprocity Certification Application" in KEMSIS.</u> July 2019 ["National EMS Scope of Practice Model", National Highway Traffic Safety Administration, DOT HS 810 657, February 2007];

(e) <u>"AEMT Reinstatement Certification Application" in KEMSIS.</u> July 2019 ["Kentucky Ambulance Service Specific Supplemental Curriculum for the AEMT using a noninvasive monitoring device -Application of 12 lead electrocardiogram electrodes and monitor", KBEMS E-29, March 2013];

(f) <u>"AEMT Supplemental Curriculum Training Verification</u> <u>Report", July 2019;</u>

(g) "AEMT Skills Verification Report", July 2019;

(h) "National EMS Scope of Practice Model", National Highway Traffic Safety Administration, DOT HS 810 657, February 2007;

(i) "National EMS Scope of Practice Model", National Highway Traffic Safety Administration, DOT HS 812 666, February 2019;

(j) "AEMT Certification Downgrade Application" in KEMSIS, July 2019;

(k) "AEMT Certification Surrender Application" in KEMSIS, July 2019:

(I) "National Registry of Emergency Medical Technicians National Continued Competency Program AEMT", October 2016;

(m) "American Heart Association Guidelines for CPR and Emergency Cardiovascular Care", November 2018;

(n) "National Registry of Emergency Medical Technicians Advanced Emergency Medical Technician Psychomotor Examination Use<u>rs Guide</u>", September 2016;

(o) "Name Change Application" in KEMSIS, July 2019;

(p) "Military Extension Application" in KEMSIS, July 2019; and

(q) "United States Citizenship and Immigration Services (U.S.C.IS) Permanent Resident Card (form I-551/Green Card)", July 2019.["Kentucky Ambulance Service Specific Supplemental Curriculum for the AEMT using a noninvasive monitoring device – Application and interpretation of quantitative capnography and end tidal carbon dioxide monitoring", KBEMS E-30, March 2013;

(g) "Kentucky Ambulance Service Specific Supplemental Curriculum for the AEMT using Bilevel Positive Airway Pressure and Continuous Positive Airway Pressure Devices", KBEMS E-32, March 2013;

(h) "Kentucky Ambulance Service Specific Supplemental Curriculum for the AEMT using intraosseous infusion in the adult", KBEMS E-31, March 2013;

(i) "Kentucky Required Mandatory Supplemental Curriculum for AEMT Initial Training Verification Report", KBEMS E-26, March 2013; and

(j) "Kentucky Advanced EMT Skills Verification Report", KBEMS E-28, March 2013.]

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of the Kentucky Board of Emergency Medical Services, <u>118 James Court</u>, <u>Lexington, Kentucky 40505, by appointment</u>, [KCTCS, 300 N. Main Street, Versailles, Kentucky 40383] Monday through Friday, 8 a.m. to 4:30 p.m.

PHILIP DIETZ, Chairperson

APPROVED BY AGENCY: September 17, 2020

FILED WITH LRC: October 1, 2020 at noon

CONTACT PERSON: Jeffrey S. Walther, Legal Counsel, Kentucky Board of Emergency Medical Services, Walther, Gay & Mack, PLC; 163 East Main Street, Suite 200, Lexington, Kentucky 40588, phone (859) 225-4714, fax (859) 225-1493, email: administrativeregulations@wgmfirm.com.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Jeffrey S. Walther

(1) Provide a brief summary of:

(a) What this administrative regulation does: KRS 311A.025(2) requires the Kentucky Board of Emergency Medical Services to promulgate administrative regulations relating to the standards for training, education, examination, certification, practice, and recertification of the advanced emergency medical technician (AEMT). This administrative regulation establishes requirements for Advanced Emergency Medical Technicians.

(b) The necessity of this administrative regulation: KRS 311A.025(2) requires the Kentucky Board of Emergency Medical Services to promulgate administrative regulations relating to the standards for training, education, examination, certification, practice, and recertification of the advanced emergency medical technician (AEMT). This administrative regulation establishes requirements for Advanced Emergency Medical Technicians. These amendments are necessary to allow Kentucky Advanced Emergency Medical Technicians the opportunity to become certified and maintain certification to protect the citizens of the Commonwealth of Kentucky. Educational and certification processes are streamlined, and unnecessary or repetitive language across other administrative regulations have been removed.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 311A.025 by establishing the requirements for Advanced Emergency Medical Technicians.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: KRS 311A.025(2) requires the Kentucky Board of Emergency Medical Services to promulgate administrative regulations relating to the standards for training, education, examination, certification, practice, and recertification of the advanced emergency medical technician (AEMT). This administrative regulation establishes requirements for Advanced Emergency Medical Technician. This administrative regulation will assist Advanced Emergency Medical Technicians in becoming certified utilizing more simplistic guidelines and processes and provides additional guidance on effective customer service to applicants for certification.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment streamlines certification application processes for Advanced Emergency Medical Technicians and

provides additional guidance on application processes and responsibilities of the Advanced Emergency Medical Technician. Additionally, unnecessary and dated requirements and terminology have been removed.

(b) The necessity of the amendment to this administrative regulation: These amendments are necessary to allow Kentucky Advanced Emergency Medical Technicians the opportunity to become certified and maintain certification to protect the citizens of the Commonwealth of Kentucky. Educational and certification processes are streamlined, and unnecessary or repetitive language across other administrative regulations have been removed.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 311A.025(2) requires the Kentucky Board of Emergency Medical Services to promulgate administrative regulations relating to the standards for training, education, examination, certification, practice, and recertification of the advanced emergency medical technician (AEMT). This administrative regulation establishes requirements for Advanced Emergency Medical Technician.

(d) How the amendment will assist in the effective administration of the statutes: KRS 311A.025(2) requires the Kentucky Board of Emergency Medical Services to promulgate administrative regulations relating to the standards for training, education, examination, certification, practice, and recertification of the advanced emergency medical technician (AEMT). This administrative regulation establishes requirements for Advanced Emergency Medical Technician. This administrative body processing and removes barriers to certification for the Advanced Emergency Medical Technician. Streamlined processes allow the administrative body to certify applicants more effectively and efficiently.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The Kentucky Board of Emergency Medical Services, its members, staff, and licensed agencies will be affected by this administrative regulation.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The Kentucky Board of Emergency Medical Services, its members, staff, and licensed agencies shall implement the standards relating to Advanced Emergency Medical Technicians pursuant to this administrative regulation and shall execute their duties consistent with this amendment.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost to any entity identified in question (3).

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Applicants seeking certification as an Advanced Emergency Medical Technician will benefit from decreased certification requirements and processing time.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation: There will be no cost to the administrative body to implement this administrative regulation.

(a) Initially: There will be no cost to the administrative body to implement this administrative regulation.

(b) On a continuing basis: There will be no cost to the administrative body to implement this administrative regulation.

(6) What is the source of funding to be used for the implementation and enforcement of this administrative regulation: No funding source is necessary to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be necessary. (8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This regulation did not establish any fees.

(9) TIERING: Is tiering applied? Tiering is not applied to this administrative regulation because this amendment applies equally to all licensed agencies.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Emergency Medical Services, its members, staff, and licensed agencies will be affected by this administrative regulation.

2. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 311A.025 requires the board to promulgate administrative regulations relating to Advanced Emergency Medical Technicians. This administrative regulation establishes requirements for Advanced Emergency Medical Technicians.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will generate no revenue for the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will generate no revenue for subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not impose any costs on state or local government.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not impose any costs on state or local government.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): This administrative regulation will not generate revenue.

Expenditures (+/-): This administrative regulation will not impose any costs.

Other Explanation:

KENTUCKY COMMUNITY AND TECHNICAL COLLEGE SYSTEM Kentucky Board of Emergency Medical Services

(Amended After Comments)

202 KAR 7:401. Paramedics.

RELATES TO: KRS 311A.025, KRS 311A.030, KRS 311A.080, KRS 311A.110, KRS 311A.135, KRS 311A.170

STATUTORY AUTHORITY: KRS 311A.020, KRS 311A.025, KRS 311A.030, KRS 311A.115, KRS 311A.125, KRS 311A.135, KRS 311A.170

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311A.025 requires the board to promulgate administrative regulations relating to requirements and procedures for licensure, relicensure and reciprocity for paramedics. This administrative regulation establishes those requirements and procedures.

Section 1. Paramedic Student Eligibility. (1) Individuals shall be eligible to enroll as a student in a paramedic education and training program if the applicant:

(a) [(1)] Is at least eighteen (18) years of age;

(b) [(2)] Holds a high school diploma, [or] GED, or home school

diploma;

(c) [(3) Understands, reads, speaks, and writes the English language with a comprehension and performance level equal to at least the ninth grade of education, otherwise known as Level 4, verified by testing as necessary;

(4)] Holds current unrestricted certification as an <u>Emergency</u> <u>Medical Technician [EMT]</u> in Kentucky or holds current unrestricted <u>certification</u> [registration] with the NREMT as an <u>Emergency</u> <u>Medical Technician [NREMT-B]</u>;

(d) [(5)] Is not currently subject to disciplinary action pursuant to KRS Chapter 311A that would prevent licensure; and[-]

(e) [(6)] Meets all additional requirements established by the EMS Training and Educational Institution (EMS-TEI). [EMS-TEI; and

(7) Holds a valid motor vehicle operator's license from a state or territory of the United States.]

Section 2. Licensure Requirements. (1) Individuals desiring initial licensure as a paramedic shall:

(a) <u>Successfully complete a board approved education and training program that conforms to the curriculum of the United States Department of Transportation, National Highway Traffic Safety Administration National Emergency Medical Services Educational Standards-Instructional Guidelines for the Paramedic;</u> [Meet all of the requirements contained in Section 1 of this administrative regulation;]

(b) Successfully complete[, within thirty (30) months of the beginning of the course,] all EMS-Training and Educational Institute (EMS-TEI) [TEI] requirements for the education or training program which:

1. <u>Meet or exceed the National Emergency Medical Services</u> <u>Educational Standards- Instructional Guidelines for the Paramedic</u> [Utilize the United States Department of Transportation, National Highway Traffic Safety Administration, 1998 National Standard Curriculum for Emergency Medical Technician-Paramedic], which shall not be satisfied by the completion of refresher or transition courses alone; [and]

2. <u>Meet all educational standards established in 202 KAR</u> <u>7:601:</u> [Shall not contain less than the median number of didactic, practical laboratory, and clinical and field internship hours for each subject and skill as contained in the "Field and Pilot Test Didactic and Practical Laboratory Hours Report" and "Field and Pilot Test Clinical Report" of the United States Department of Transportation, National Highway Traffic Administration, 1998 National Standard Curriculum for Emergency Medical Technician-Paramedic;]

(c) Present evidence of completion of education and training regarding determination of death and preservation of evidence as required by KRS 311A.185;

(d) Obtain <u>certification as a paramedic by the National Registry</u> of <u>Emergency Medical Technicians</u> [NREMT registration as a NRP NREMT-P];

(e) Submit a <u>completed Paramedic Initial Licensure Application</u> <u>in KEMSIS</u> [signed "Application for Paramedic Examination and Licensure"];

(f) [Present written evidence of completion of current HIV/AIDS education or training required by KRS 311A.110; and

(g) Pay the fee <u>pursuant to</u> [required by] 202 KAR 7:030:[-]

(g) Undergo a background check pursuant to KRS 311A.050 and 311A.100;

1. The background check shall be:

<u>a. National in scope for an applicant not currently certified at</u> any level in Kentucky;

<u>b. Statewide in scope for an applicant with current certification</u> in Kentucky;

c. Less than six (6) months old when the applicant submits to the board all requirements for licensure; and

d. Provided by a vendor that has been contracted through the board;

2. An applicant shall not directly submit a background check to meet the requirements of this section. The background check shall be submitted to the board by the company that conducts the background check; and

(h) Be a citizen of the United States, a permanent resident of

the United States, or otherwise lawfully present in the United States, as evidenced by submission to the board of:

A Social Security card;

Birth certificate;

<u>3. A United States Citizenship and Immigration Services</u> (U.S.C.IS) Permanent Resident Card (form I-551/Green Card); or

4. Other legal authorization to live and work in the United States;

(2) A Paramedic licensed pursuant to this section shall complete training regarding determination of death and preservation of evidence as required by KRS 311A.185 prior to beginning work for a licensed agency in Kentucky.

(a) Training in determination of death and preservation of evidence as required by KRS 311A.185 shall be provided during employee orientation, or by entities authorized to conduct continuing education pursuant to 202 KAR 7:601.[

(2) An applicant for licensure as a paramedic shall successfully complete all NREMT testing and become Kentucky licensed within two (2) years after fulfilling all of the requirements of their paramedic education or training program, including the completion of the field summative evaluation.]

Section 3. [Relicensure] Renewal of Licensure and Continuing Education Requirements. (1) To be eligible for renewal of licensure, a [A] paramedic shall submit to the board: [be eligible for relicensure if:]

(a) <u>A</u> [The applicant submits to the KBEMS office a signed,] completed <u>Paramedic License Renewal Application in KEMSIS</u> ["Universal Application for Recertification/Relicensure"];

(b) [The applicant maintains written evidence of completion of current education or training in CPR that:

1. Shall be taught by an individual who holds instructor certification at an appropriate level from:

a. The American Red Cross;

b. The AHA;

c. The National Safety Council;

d. The ASHI; or

e. Another board approved organization; and

2. Shall provide instruction and testing in:

a. One (1) rescuer CPR;

b. Two (2) rescuer CPR;

c. Techniques of changing from one (1) to two (2) rescuers during the performance of CPR;

d. Techniques of changing rescuers during the performance of two (2) rescuer CPR;

e. Techniques for relief of obstruction of the airway;

f. CPR of infants and small children;

g. Barrier-to-mouth, barrier-to-nose, or barrier-to-stoma resuscitation for adults, small children, and infants;

h. Use of oral and nasal airways;

i. Use of bag-valve-mask or other ventilation device;

j. Use of supplemental oxygen; and

k. Use and operation of an AED;

(c) The applicant maintains written evidence of completion of current HIV/AIDS training required by KRS 311A.110;

(d)] The [applicant pays the] fee pursuant to [established in] 202 KAR 7:030; and

(c) Written evidence of either [The applicant maintains evidence of any of the following]:

1. Current <u>certification</u> [registration] by the NREMT as a[n] <u>paramedic</u> [NREMT-P];

a. If this option is used the board may request, through a continuing education audit, proof of continuing education to verify compliance with the continuing education requirements of this section; or

2. NREMT Paramedic National Continued Competency Program for Continuing Education.

3. All applicants for renewal shall maintain written evidence of: a. Current training in a cardiopulmonary resuscitation (CPR) course that:

(i) Meets all guidelines established by the International Liaison Committee (ILCOR) on Resuscitation for CPR and Emergency Cardiovascular Care (ECC) [standards of the

American Heart Association Basic Life Support for Healthcare <u>Provider or Professional Rescuer course]</u>; and

(ii) Includes a psychomotor [examination component] and a cognitive assessment;

b. Current training in HIV/AIDS treatment and recognition required by KRS 311A.110;

c. Current training in Pediatric Abusive Head Trauma as required by KRS 311A.127;

d. Awareness of Sexual Violence Training required by KRS 311A.120; and

e. Training regarding determination of death and preservation of evidence as required by KRS 311A.185.[Successful completion of the University of Maryland Baltimore Campus Critical Care Emergency Medical Transport Program; or

3. Successful completion of sixty (60) hours of continuing education of which:

a. A maximum of sixteen (16) hours per course may be claimed for obtaining, maintaining, or instructing provider certification in:

(i) ACLS;

(iii) PALS;

(iiii) BTLS;

(iv) PHTLS; or

(v) PEPP; and

b. Thirty (30) of the required sixty (60) hours shall be obtained in the following areas:

(i) Two (2) in preparatory;

(ii) Four (4) in airway management;

(iii) Five (5) in cardiac management;

(iv) Four (4) in medical or behavioral emergencies;

(v) Five (5) in trauma;

(vi) Two (2) in obstetrics or gynecology;

(vii) Five (5) in pediatrics; and

(viii) Three (3) in operations.

(2) All applicants for relicensure shall complete a minimum of one (1) hour in disaster management or mass casualty incidents education or training.

(3) Each applicant shall provide evidence of current certification in ACLS through either the AHA or ASHI at the time of application.]

(2) [(4)] All continuing education shall be validated by <u>entities</u> authorized to conduct continuing education pursuant to 202 KAR <u>7:601.[</u>:

(a) The instructor, medical director, training officer, course coordinator, or provider of the continuing education offering; or

(b) A medical director, service director, or training officer of the ambulance service, first response agency, fire department, rescue squad or other medical employer.]

(3) [(5)] An application for renewal of licensure shall be denied if:

(a) Prior to the licensure expiration date, the paramedic applicant has not met the applicable requirements of this administrative regulation; or

(b) The applicant has been subjected to disciplinary action that prevents relicensure at the time of application.

(4) [(6)] A licensed paramedic, in good standing, who is a member of a National Guard or a military reserve unit who [and] is called to active duty by presidential order pursuant to 10 U.S.C. <u>SS</u> 121 and 673b <u>shall be renewed in accordance with KRS 12.355</u> upon submission of the Military Extension Application. [may be given a one (1) year extension following release from active duty to meet the applicable requirements for relicensure listed in this section. The paramedic shall submit a written request for this extension within sixty (60) days of release from active duty.]

(5) [(7)] The <u>board</u> [KBEMS] office may audit a paramedic's continuing education and continuing education records. <u>The paramedic shall submit the documentation requested within ten</u> (10) business days of receipt of the board's request.

(6) If documentation of continuing education hours consistent with this administrative regulation are not received by the office of the board within ten (10) business days of receipt of the board's request, the Paramedic license for the individual shall be summarily revoked and the individual shall reapply for licensure through Reinstatement if eligible.

(7) The ten (10) business days for submission shall not apply to investigations pursuant to KRS Chapter 311A.

(8) The paramedic shall maintain documentation of all continuing education for three (3) [four (4)] years from the date of completion.

Section 4. Paramedic Reciprocity. (1) <u>An individual who is</u> <u>certified or licensed [A person certified or licensed] in a contiguous</u> <u>state to the Commonwealth of Kentucky or</u> [another state or territory of the United States or registered] by the NREMT as a[n] <u>Paramedic [NREMT-P] or any member of the United States</u> <u>Armed Forces, or veteran who has transitioned within the past</u> <u>six (6) years from the United States Armed Forces, and has</u> <u>been registered by the National Registry as a Paramedic or</u> <u>has obtained National Registry as a Paramedic by</u> <u>successfully completing a board-approved bridge course to</u> <u>transition from the Army 68 Whiskey course to Paramedic that</u> <u>meets the National Emergency Medical Services Educations</u> <u>Standards for Paramedic</u> shall be eligible for [direct] reciprocity for [initial] Kentucky licensure as a paramedic if the <u>applicant</u> <u>submits [individual]</u>:

(a) <u>A completed Paramedic Reciprocity License Application in</u> <u>KEMSIS; and [Is at least eighteen (18) years of age;]</u>

(b) <u>Proof of the applicant's</u> [Holds current] unrestricted certification [registration] as an <u>NREMT Paramedic or Paramedic</u> certification or license in a contiguous state to the Commonwealth of Kentucky [NREMT-P];[

(c) Holds a high school diploma or GED; and

(d) Holds a valid motor vehicle operator's license from a state or territory of the United States.]

(2) An applicant shall pay the fee required for licensure through reciprocity pursuant to 202 KAR 7:030. [The individual shall:

(a) Understand, read, speak, and write the English language with a comprehension and performance level equal to at least the ninth grade of education, otherwise known as Level 4, verified by testing as necessary;

(b) Not have been found guilty of, entered a guilty plea or Alford plea to a felony offense or have completed a diversion program for a felony offense;

(c) Not have been subjected to discipline that would prevent reciprocity at the time of application;

(d) Submit an "Out-Of-State Paramedic Application" signed by the applicant;

(e) Submit written evidence of completion of current HIV/AIDS training required by KRS 311A.110;

(f) Present evidence of completion of training regarding the protocol governing the discontinuance of resuscitation, determination of death and preservation of evidence;

(g) Pay the fee required by 202 KAR 7:030; and

(h) Have successfully completed a training program, which utilized the United States Department of Transportation, National Highway Traffic Safety Administration, 1998 National Standard Curriculum, Emergency Medical Technician-Paramedic as the eurriculum for education if any individual initially certified or licensed after January 1, 1985. An earlier edition of the National Standard Curriculum which was in effect in at the time of initial certification or licensure shall be considered to meet this requirement.]

(3) An applicant for Paramedic reciprocity shall undergo a national background check and have the results submitted to the board. Background checks that are older than six (6) months shall not be considered current, and the applicant shall undergo another national background check prior to approval of licensure through reciprocity.

(4) An applicant shall not have been convicted of offenses described in KRS 311A.050.

(5) An applicant shall not have been subjected to discipline that would prevent reciprocity at the time of application.

(6) A Paramedic licensed pursuant to Section 4 of this administrative regulation shall not perform any procedures or skill on which the Paramedic has not been trained. A Paramedic who performs a skill for which the Paramedic does not have documented training shall have exceeded the scope of practice and shall be in violation of KRS 311A.050.

(7) A Paramedic licensed pursuant to this section shall complete training regarding determination of death and preservation of evidence as required by KRS 311A.185 prior to beginning work for a licensed agency in Kentucky.

(a) Training in determination of death and preservation of evidence as required by KRS 311A.185 shall be provided during employee orientation, or by entities authorized to conduct continuing education pursuant to 202 KAR 7:601.

Section 5. Exemptions from Paramedic Administrative Regulations. The Kentucky licensure requirements for a paramedic shall not apply to:

(1) United States military <u>members</u>, [personnel or state] National Guard <u>personnel</u>, or employees of the United States government <u>if the individual provides emergency medical services</u>:

(a) On land owned by the United States government;

(b) In facilities owned by the United States government;

(c) In the performance of official duties under federal law; or

(d) As part of assistance for a mass casualty or disaster incident pursuant to federal law or official state assistance request; or

(2) A paramedic licensed in another state or territory of the United States who:

(a) Enters Kentucky with a patient being transported to a medical facility or other final destination in Kentucky; or

(b) Travels through Kentucky during the course of a patient transport from an out-of-state location to a destination outside of Kentucky. [while providing services on a United States government-owned or operated facility, while engaged in the performance of their official duties under federal law, or while providing assistance in mass casualty or disaster type situation; or

(2) A paramedic licensed or certified in another state or territory of the United States who:

(a) Comes into Kentucky to transport a patient from another state into Kentucky; or

(b) Is transporting a patient through the state of Kentucky to an out-of-Kentucky location.]

Section 6. Reinstatement of License. (1) A paramedic whose <u>Kentucky</u> license has lapsed [for a period not exceeding five (5) years,] may reinstate their license <u>if the applicant submits</u> [by submitting]:

(a) A <u>completed Paramedic Reinstatement License Application</u> in KEMSIS"; [signed "Universal Reinstatement Application";]

(b) Evidence of previous licensure as a paramedic in the Commonwealth of Kentucky;

(c) Evidence of current training in:

1. HIV/AIDS training required by KRS 311A.110;

2. Pediatric Abusive Head Trauma as required by KRS 311A.127;

3. Awareness of Sexual Violence Training required by KRS 311A.120; and

4. A cardiopulmonary resuscitation (CPR) course that:

a. Meets all standards of the American Heart Association Basic Life Support for Healthcare Provider or Professional Rescuer

course; and

b. Includes a psychomotor examination component and a cognitive assessment;[

(b) Written evidence of current completion of training in CPR meeting the requirements as outlined in Section 3(1) (b) of this administrative regulation;

(c) Written evidence of completion of current HIV/AIDS training required by KRS 311A.110:]

(d) Payment of the fee <u>pursuant to</u> [established in] 202 KAR 7:030;

(e) The applicant for reinstatement of license shall undergo a national background check provided by a vendor that has been contracted through the board; and

1. An applicant shall not directly submit a background check to meet the requirements of this section. The background check shall be submitted to the board by the company that conducts the

background check;

2. Background checks that are older than six (6) months shall not be considered current, and the applicant shall undergo another national background check prior to approval of reinstatement of license;

(f) The applicant for reinstatement of licensure shall bear the burden of proof of previous licensure in Kentucky if the previous Paramedic license is in issue or dispute.[Evidence of previous certification or licensure as a paramedic in Kentucky; and

(f) Evidence of successful completion within twelve (12) months preceding their application for reinstatement of the National Standard Curriculum for [EMT] Paramedic Refresher Course or continuing education hours that meet the requirements of the curriculum.

(2) A paramedic, whose license has lapsed for a period that exceeds five (5) years, may reinstate their license by complying with Sections 1 and 2 of this administrative regulation.

(3) An application for reinstatement of licensure shall not be considered if:

(a) The applicant is subject to disciplinary action pursuant to KRS Chapter 311A;

(b) The applicant is an individual who has been convicted of, entered a guilty plea or Alford plea to a felony offense, or has completed a diversion program for a felony offense; or

(c) The applicant has been subjected to discipline that would prevent reinstatement at the time of application.]

(2) An applicant shall provide evidence of successful completion of the NREMT-Paramedic national continued competency program for continuing education within the twelve (12) months preceding application for reinstatement of the Paramedic license.

(3) An applicant shall provide evidence of current skills competency by completing and submitting validation of those skills on the Kentucky Paramedic Skills Verification Report. The verification report shall be completed by entities authorized to conduct continuing education pursuant to 202 KAR 7:601.

(4) An applicant ineligible for licensure pursuant to KRS 311A.050 through 311A.090 shall be ineligible for reinstatement.

Section 7. <u>Scope of Practice. (1) A Paramedic shall provide</u> emergency medical services consistent with the skills and procedures in the National EMS Scope of Practice Model and 202 <u>KAR 7:701.</u>

(2) If providing emergency medical services during a disaster or emergency that qualifies as part of the Emergency Management Assistance Compact pursuant to KRS 39A.050, or if acting pursuant to another agreement made pursuant to KRS Chapter 39, a Paramedic licensed in another state may perform the skills and procedures approved by the certifying state.[Demonstration of Competency. A paramedic applying for relicensing or reinstatement shall demonstrate continuing competency of skills by:

(1) Written verification of competency as evidenced by signature on the relicensure or reinstatement application of a medical director, ambulance service director or ambulance service training director; or

(2) Submission of evidence of current registration as a:

(a) NREMT-P; or

(b) Completion of:

1. ACLS;

2. PALS or PEPP; and

3. BTLS, PHTLS, or CCEMTP.]

Section 8. Critical Care Endorsement. (1) A paramedic licensed by the board may be granted a critical care endorsement [MTP] upon <u>completion</u> [presentation] of <u>the Paramedic Critical Care Endorsement [a board approved]</u> A[a]pplication, <u>payment of the fee pursuant to 202 KAR 7:030</u>, and completion of a training program that minimally meets the objectives of the University of Maryland Baltimore Campus CCEMTP Program. The ambulance service director and EMS medical director shall validate verification of the program having met the specified training standards;[-]

(2) The critical care endorsement shall be valid so long as the

paramedic maintains[:

(a)] current licensure as a paramedic by the board.[; and

(b) Current certification as a CCEMTP or verification of continued clinical competence by the paramedic's EMS medical director.]

(3) A paramedic with a critical care endorsement shall be authorized to perform the skills and procedures included in their education and training subject to authorization by the medical director through established protocols.[

(4) A licensed paramedic with a critical care endorsement shall be responsible for providing the KBEMS office with copies of their current CCEMTP credentials.]

Section 9. Public Notice of Negative Action. (1) The board [KBEMS] office shall cause to be published[$_{\tau}$] on the board Web site the name of a paramedic that:

(a) Is fined;

(b) Is placed on probationary status;

(c) Is placed on restricted status;

(d) Is suspended; or

(e) Has had their certification revoked.[in the KBEMS News or similar publication of the board, or otherwise disseminate the name of a paramedic that is fined, is placed on probationary status, is placed on a restricted status, is suspended, or has had their licensed revoked.]

Section 10. Expiration of Licensure. (1) Licensure periods and expiration dates shall be pursuant to KRS 311A.095.

(2) If a Paramedic license lapses or expires, the Paramedic shall cease provision of emergency medical services.

(3) A Paramedic who has allowed their license to lapse or expire shall be required to reinstate their licensure pursuant to Section 6 of this administrative regulation.[Temporary Certificate. (1) KBEMS staff may issue a temporary certificate to an individual who:

(a) Submits a completed "Application for Temporary Certificate";

(b) Is at least eighteen (18) years of age;

(c) Understands, reads, speaks, and writes the English language with a comprehension and performance level equal to at least the 9th grade of education, otherwise known as Level 4, verified by testing as necessary;

(d) Provides proof of being currently certified or licensed as a paramedic in another state or territory of the United States or is currently registered by the NREMT as a paramedic;

(e) Presents written evidence of completion of current HIV/AIDS training required by KRS 311A.110;

(f) Presents written evidence of completion of current training in CPR that meets the requirements of Section 2 of this administrative regulation;

(g) Pays the fee required by 202 KAR 7:030;

(h) Provides the board with a copy of a statewide criminal background check from their state of residence;

 (\bar{i}) Is not an individual who has been convicted of, entered a guilty plea or Alford plea to a felony offense, or has completed a diversion program for a felony offense; and

(j) Has not been disciplined by or has action pending against or had a certificate or license in the field of health care denied, limited, suspended, or probated by a certifying or licensing entity in Kentucky or other state or territory under the jurisdiction of the United States.

(2) A temporary certificate may be issued for a period which shall not exceed six (6) months and shall not be reissued or renewed.]

Section 11. Determination of Death Protocol. (1) The paramedic shall determine and document that the following signs of death are present:

(a) Unresponsiveness;

(b) Apnea;

(c) Absence of a palpable pulse at the carotid site;

(d) Bilaterally-fixed and dilated pupils; and

(e) Except in a case of trauma, asystole determined in two (2)

leads on an electrocardiograph.

(2) The paramedic shall determine that one (1) of the following factors or conditions exist:

(a) Lividity of any degree;

(b) Rigor mortis of any degree;

(c) Presence of venous pooling in the body;

(d) Damage or destruction of the body which is incompatible with life; or

(e) A copy of the EMS "Do Not Resuscitate (DNR) Form" or identification bracelet or other means of identification evidencing a patient's desire not to be resuscitated in accordance with KRS 311A.170; or

(f) A properly executed "Medical Orders for Scope of Treatment (MOST) form".

(3) If a paramedic has determined and documented that the conditions of subsections (1) and (2) of this section exist, the paramedic may, subject to the provisions of this administrative regulation, declare the patient dead.

(4) The paramedic may contact medical control or other licensed physician, if authorized in writing by the medical director, for advice and assistance in making a determination required by this administrative regulation.

(5) If a paramedic determines a patient to be dead, the paramedic shall remain on the scene unless their personal safety is jeopardized, until the arrival of the coroner, deputy coroner, or law enforcement officer from that jurisdiction.

Section 12. Discontinuance of Resuscitative Efforts. (1) A paramedic may discontinue resuscitation if:

(a) The patient has suffered cardiac arrest prior to arrival at the hospital;

(b) The paramedic has performed the resuscitative efforts required in the resuscitation protocol of the ambulance service medical director;

(c) The resuscitative efforts were unsuccessful; and

(d) The patient meets the criteria established in Section 11(1) of this administrative regulation.

(2) A paramedic may also discontinue resuscitation:

(a) If the safety of the paramedic is at risk; or

(b) At mass casualty incidents.

(3) A paramedic may discontinue resuscitation initiated by someone other than a paramedic if:

(a) The patient has suffered cardiac arrest;

(b) The resuscitative efforts required in the resuscitation protocol of the ambulance service medical director have been performed and documented;

(c) The resuscitative efforts were unsuccessful; and

(d) The patient meets the criteria established in Section 11(1) of this administrative regulation.

(4) If a paramedic discontinues resuscitation on a patient prior to transport of the patient to a medical facility, the paramedic shall make the notifications required by KRS 72.020 and at least one (1) member of the ambulance crew shall remain on the scene until the arrival of a coroner, deputy coroner or law enforcement officer.

(5) If a paramedic discontinues resuscitation on a patient during transport to a medical facility, the paramedic shall make the notifications required by KRS 72.020 to the officials of the county in which the paramedic discontinued resuscitation. Upon making the notification, the paramedic shall determine from the coroner whether to remain at that location, to return the deceased to a facility within the primary service area of the ambulance provider, or to continue on to the medical facility with the deceased.

(6) A paramedic shall discontinue resuscitation efforts if presented with a properly executed EMS DNR Form. or properly executed Medical Orders for Scope of Treatment (MOST) form.

Section 13. The paramedic shall document all items required by Sections 11 and 12 of this administrative regulation on the <u>Patient Care Report</u> [Ambulance Run Form] required by KRS 311A.190.

Section 14. Training of Paramedics in Determination of Death and Preservation of Evidence.

(1) The training program shall not be less than one (1) hour in length and, at a minimum, shall include:

(a) Information on and a copy of KRS 311A.170;

(b) Information on and a copy of this administrative regulation;

(c) Information on and a copy of KRS 72.020;

(d) Information on and a copy of KRS 446.400;

(e) Information on the duties of and role of the coroner and state medical examiner; and

(f) Information on preservation of evidence at the scene of a death.

(2) The training shall be:

(a) Provided as part of a paramedic training course conducted by an approved EMS-TEI via:

1. Classroom instruction;

2. Video conferencing or other distance learning media; or

3. Video [taped] presentation or computer based learning; and

(b) Conducted under the supervision of a medical director.

(3) The medical director of the ambulance service or EMS provider conducting the training shall request the coroner of the county in which the training is provided to attend and participate in the training.

(4) The EMS-TEI or the medical director providing the training shall maintain the following records:

(a) A copy of the course outline used in the training to verify that the training has been conducted in accordance with the requirements of this administrative regulation;

(b) A sign-in sheet with the printed and signed names and certification or license numbers and state of license of all paramedics who successfully completed the training, including the signature of the educator supervising the education program; and

(c) Curriculum vitae for each member of the course faculty.

(5) A certificate or letter of certification shall be provided to each participant in the program at the conclusion of the training.

(6) The <u>board</u> [KBEMS] office shall maintain an approved curriculum that may be used by entities providing training specified by this administrative regulation.

Section 15. Downgrading Licensure. (1) A paramedic currently licensed as a paramedic by the board shall be eligible for licensure downgrade if:

(a) The license is in good standing with no pending disciplinary action;

(b) The applicant submits a completed Paramedic License Downgrade Application in KEMSIS; and

(c) The applicant pays the fee pursuant to 202 KAR 7:030;

(2) A paramedic is only eligible to downgrade their license to an Advanced Emergency Medical Technician, Emergency Medical Technician, or Emergency Medical Responder certification.

(3) Certification periods and expiration dates shall be pursuant to KRS 311A.095.

(4) The applicant shall undergo a background check pursuant to KRS 311A.050 and 311A.100. The background check shall be:

(a) Statewide in scope for an applicant with current certification in Kentucky;

(b) Less than six (6) months old when the applicant submits to the board all requirements for certification; and

(c) Provided by a vendor that has been contracted through the board.

(5) The applicant shall provide proof of:

(a) Current certification by the NREMT as a Paramedic; or

(b) Successful completion of the NREMT Emergency Medical Technician National Continued Competency Program for Continuing Education which shall be validated by entities authorized to conduct continuing education pursuant to 202 KAR 7:601;

(c) Completion of a cardiopulmonary resuscitation (CPR) course that:

1. Meets all standards of the American Heart Association (AHA) Cardiopulmonary Resuscitation (CPR) and Emergency Cardiovascular Care (ECC); and

2. Includes a psychomotor and a cognitive assessment;

(d) Completion of current HIV/AIDS training required by KRS 311A.110; (e) Pediatric Abusive Head Trauma required by KRS 311A.127; and

(f) Awareness of Sexual Violence Training required by KRS 311A.120.

(6) Downgrade shall be denied if the applicant has not met the requirements of this section or has been subject to disciplinary action that prevents certification at the time of application.

(7) The applicant shall be responsible for meeting the renewal requirements of the downgraded certification level issued prior to expiration of that certification.

(8) To reinstate the certification or license that was previously held, the applicant shall meet the regulatory requirements for that level of certification or licensure.

(9) The applicant shall notify the board's licensed service director(s) with whom the applicant is affiliated immediately upon downgrading their license.

(10) Once the applicant has downgraded their certification or license, the applicant is no longer permitted to provide emergency medical services at the previous certification or license level held.

(11) An applicant applying for downgrade that does not comply with this section of this administrative regulation shall be subject to disciplinary action pursuant to KRS Chapter 311A.

(12) All endorsements, certifications, or licenses held at the previous certification or license level shall be void at the completion of the downgrade.

Section 16. Surrender of License. (1) A paramedic surrendering licensure shall:

(a) Submit a completed Paramedic License Surrender Application in KEMSIS; and

(b) Pay the fee pursuant to 202 KAR 7:030.

(2) The applicant shall notify the board's licensed service director(s) with whom the applicant is affiliated immediately upon surrendering their license.

Section 17. Reporting Requirements. (1) A paramedic shall maintain current demographic information in KEMSIS including:

<u>(a) Legal name;</u>

1. Any changes to your legal name shall be submitted using the Name Change application in KEMSIS; and

2. One of the following documents as verification of name change:

(i) Social Security card;

(ii) Driver's license; or

(iii) Passport;

(b) Mailing address;

(c) Email address; and (d) Phone number.

(2) A paramedic that does not comply with this section of this administrative regulation shall be subject to disciplinary action pursuant to KRS Chapter 311A.

Section <u>18[45]</u>. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) <u>"National Emergency Medical Services Education</u> Standards-Paramedic Instructional Guidelines", The United States Department of Transportation, National Highway Traffic Safety Administration, DOT HS 811 077E, January 2009;

(b) "Paramedic Initial License Application" in KEMSIS, July 2019;

(c) "Paramedic License Renewal Application" in KEMSIS, July 2019;

(d) "Paramedic Reciprocity License Application" in KEMSIS, July 2019;[The United States Department of Transportation, National Highway Traffic Administration, "1998 National Standard Curriculum, Emergency Medical Technician-Paramedic" (1998 Edition);

(b) Field and Pilot Test Didactic and Practical Laboratory Hours Report of the United States Department of Transportation, National Highway Traffic Administration, 1998 National Standard Curriculum for Emergency Medical Technician-Paramedic;

(c) Field and Pilot Test Clinical Report of the United States Department of Transportation, National Highway Traffic Administration, 1998 National Standard Curriculum for Emergency Medical Technician-Paramedic;

(d) "Application For Paramedic Examination and Licensure" (June 2003);

(e) "Out Of State Paramedic Application" (June 2003);

(f) "Application for Paramedic License Reinstatement" (June 2003);

(g)] (<u>e</u>) Kentucky Board of Emergency Medical Services, Pre-Hospital Determination of Death and Preservation of Evidence Training Curriculum (05-02)[; and]

(f) "Paramedic Reinstatement License Application" in KEMSIS, July 2019:

(g) [(h)] "Kentucky Emergency Medical Services Do Not Resuscitate (DNR) Order". July 2019:[-]

(h) "National EMS Scope of Practice Model", National Highway Traffic Safety Administration, DOT HS 810 657, February 2007;

(i) "National EMS Scope of Practice Model", National Highway Traffic Safety Administration, DOT HS 812 666, February 2019;

(j) "Kentucky Medical Orders for Scope of Treatment (MOST) Form", July 2019;

(k) "Paramedic Critical Care Endorsement Application" in KEMSIS, July 2019;

(I) "Paramedic Skills Verification Report", July 2019;

(m) "Paramedic License Downgrade Application" in KEMSIS, July 2019;

(n) "Paramedic License Surrender Application", in KEMSIS July 2019;

(o) "National Registry of Emergency Medical Technicians National Continued Competency Program Paramedic", October 2016;

(p) "American Heart Association Guidelines for CPR and Emergency Cardiovascular Care", November 2018;

(q) "National Registry of Emergency Medical Technicians Paramedic Psychomotor Examination Users Guide", September 2016;

(r) "Name Change Application" in KEMSIS, July 2019;

(s) "Military Extension Application" in KEMSIS, July 2019; and

(t) "United States Citizenship and Immigration Services (U.S.C.IS) Permanent Resident Card (form I-551/Green Card)", July 2019.

(2) This material may be inspected, obtained, or copied, subject to applicable copyright law, at the Office of the Kentucky Board of Emergency Medical Services, <u>118 James Court</u>, <u>Lexington, Kentucky 40505, by appointment</u> [2545 Lawrenceburg Road, Frankfort, Kentucky 40601], Monday through Friday, 8 a.m. to 4:30 p.m.

PHILIP DIETZ, Chairperson

APPROVED BY AGENCY: September 17, 2020

FILED WITH LRC: October 1, 2020 at noon

CONTACT PERSON: Jeffrey S. Walther, Legal Counsel, Kentucky Board of Emergency Medical Services, Walther, Gay & Mack, PLC; 163 East Main Street, Suite 200, Lexington, Kentucky 40588, phone (859) 225-4714, fax (859) 225-1493, email: administrativeregulations@wgmfirm.com.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Jeffrey S. Walther

(1) Provide a brief summary of:

(a) What this administrative regulation does: KRS 311A.025 requires the board to promulgate administrative regulations relating to requirements and procedures for licensure, relicensure and reciprocity for paramedics. This administrative regulation establishes those requirements and procedures.

(b) The necessity of this administrative regulation: KRS 311A.025 requires the board to promulgate administrative regulations relating to requirements and procedures for licensure, relicensure and reciprocity for paramedics. This administrative regulation establishes those requirements and procedures. These amendments are necessary to allow Kentucky Paramedics the opportunity to become licensed and maintain licensure to protect the citizens of the Commonwealth of Kentucky. Educational and

licensure processes are streamlined, and unnecessary or repetitive language across other administrative regulations have been removed.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 311A.025 by establishing the requirements and procedures for licensure, relicensure, and reciprocity for paramedics.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: KRS 311A.025 requires the board to promulgate administrative regulations relating to requirements and procedures for licensure, relicensure and reciprocity for paramedics. This administrative regulation requirements procedures. establishes those and This administrative regulation will assist Paramedics in becoming licensed utilizing more simplistic guidelines and processes and provides additional guidance on educational requirements and will allow the board to provide more effective customer service to applicants for licensure.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment streamlines licensure application processes for Paramedics and provides additional guidance on application processes and responsibilities of the Paramedic. Additionally, unnecessary and dated requirements and terminology have been removed.

(b) The necessity of the amendment to this administrative regulation: These amendments are necessary to allow Paramedics the opportunity to become licensed and maintain licensure to protect the citizens of the Commonwealth of Kentucky. Educational and licensure processes are streamlined, and unnecessary or repetitive language across other administrative regulations have been removed.

(c) How the amendment conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 311A.025 by establishing the requirements and procedures for licensure, relicensure, and reciprocity for paramedics.

(d) How the amendment will assist in the effective administration of the statutes: KRS 311A.025 requires the board to promulgate administrative regulations relating to requirements and procedures for licensure, relicensure and reciprocity for paramedics. This administrative regulation establishes those requirements and procedures.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The Kentucky Board of Emergency Medical Services, its members, and staff, local governments, emergency medical services providers, and paramedics will be affected by this administrative regulation.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The Kentucky Board of Emergency Medical Services, its members, staff, and licensed agencies shall implement the standards relating to Emergency Medical Technicians pursuant to this administrative regulation and shall execute their duties consistent with this amendment.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost to any entity identified in question (3).

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Applicants seeking licensure as a Paramedic will benefit from decreased licensure requirements and processing time.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation: There will be no cost to the administrative body to implement this

administrative regulation.

(a) Initially: There will be no cost to the administrative body to implement this administrative regulation.

(b) On a continuing basis: There will be no cost to the administrative body to implement this administrative regulation.

(6) What is the source of funding to be used for the implementation and enforcement of this administrative regulation: No funding source is necessary to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This regulation did not establish any fees.

(9) TIERING: Is tiering applied? Tiering is not applied to this administrative regulation because this amendment applies equally to all licensed agencies.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Emergency Medical Services, its members, and staff, local governments, emergency medical services providers, and paramedics will be affected by this administrative regulation.

2. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 311A.025 requires the board to promulgate administrative regulations relating to requirements and procedures for licensure, relicensure and reciprocity for paramedics. This administrative regulation establishes those requirements and procedures.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will generate no revenue for the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will generate no revenue for subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not impose any costs on state or local government.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not impose any costs on state or local government.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): This administrative regulation will not generate revenue.

Expenditures (+/-): This administrative regulation will not impose any costs.

Other Explanation:

KENTUCKY COMMUNITY AND TECHNICAL COLLEGE SYSTEM

Kentucky Board of Emergency Medical Services (Amended After Comments)

202 KAR 7:601. Training, education, and continuing education

RELATES TO: KRS Chapter 271, KRS 311A.050, KRS

311A.110, KRS 311A.115, KRS 311A.120, KRS 311A.130, KRS Chapter 362, and KRS Chapter 365.

STATUTORY AUTHORITY: KRS 311A.020, KRS 311A.025, KRS 311A.030, KRS 311A.060, KRS 311A.110, KRS 311A.115, KRS 311A.120, KRS 311A.125, and KRS 311A.130.

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311A.110, KRS 311A.115, KRS 311A.120, and KRS 311A.125 require the board to promulgate administrative regulations establishing standards related to the training and education of emergency medical services personnel. KRS 311A.130 requires proper in-service and in-house in-service training and education. KRS 311A.025 requires the board to establish levels of certification. This administrative regulation establishes requirements for an organization to be approved by the board as an Emergency Medical Service Training and Education Institute (EMS-TEI) and also establishes standards for the certification and recertification of emergency medical services[EMS] educators and providers.

Section 1. Education Committee.

(1) The board shall create and recognize a standing committee on EMS Education.

(2) The Education Committee shall consist of seven (7) voting members representative of EMS Educators in the <u>Commonwealth</u> [state] of Kentucky. <u>The Education Committee shall consist of:</u>

(a) One (1) voting member of the board;

(b) One (1) director, coordinator or lead instructor affiliated with a board certified EMS-TEL4.

(c) One (1) director, coordinator, or lead instructor affiliated with a board certified EMS-TEL3.

(d) One (1) director, coordinator, or lead instructor affiliated with a board certified EMS-TEI 2.

(e) One (1) director, coordinator, or lead instructor affiliated with a board certified EMS-TELCE.

(f) Two (2) EMS educators at large affiliated with a board certified EMS-TEI.[. At least one (1) voting member of the Education Committee shall also be a member of the Kentucky Board of Emergency Medical Services.]

(3) The Education Committee shall schedule on an annual basis at least six (6) regular meetings of the committee.

(4) The purpose and charge of the Education Committee shall be to:

 (a) Assist the board in developing a strategic plan for EMS education in the [state of Kentucky] Commonwealth of Kentucky;

(b) Act as a resource for EMS educators and EMS-TEIs in the Commonwealth of Kentucky; and

(c) Assume the lead role in formulating, drafting, and sending to the board for approval and subsequent promulgation of all administrative regulations that set the standards and requirements for EMS education <u>and EMS provider certification</u> in <u>the Commonwealth of Kentucky</u>.

Section 2. EMS-TEI Certification.

(1) Only an entity certified by the board as an EMS-TEI shall be authorized to conduct training and education programs in the <u>Commonwealth of Kentucky</u> that lead to certification or licensure by the <u>board [Kentucky Board of Emergency Medical Services (KBEMS)]. Training shall include:</u>

(a) In person;

(b) Online or hybrid; and

(c) Laboratory, clinical, or field internship.

(2) An applicant for certification as an EMS-TEI in the <u>Commonwealth of</u> Kentucky may be certified at the following levels:

(a) EMS-TEI 1, which includes EMR <u>and continuing education;</u> (b) EMS-TEI 2, which includes EMR. [and] EMT, <u>and</u>

continuing education; (c) EMS-TEI 3, which includes EMR, EMT, [and] AEMT. and continuing education;

(d) EMS-TEI 4, which <u>includes[include]</u> EMR, EMT, AEMT, [and EMT – P,] Paramedic, and continuing education; or

(e) EMS-TEI CE, which includes continuing education only.

(3) An applicant may seek one (1) level[or multiple levels] of

certification during the [two (2)] <u>one (1)</u> year certification term. <u>A</u> <u>single applicant, agency, or business shall not hold more than one</u> (1) TEI certification simultaneously.

(4) An applicant for a level of EMS-TEI certification shall meet all requirements [ef] for that level.

(5) <u>An applicant for certification as an EMS-TEI shall</u> electronically submit a completed Training and Educational Institution (TEI) Application, the appropriate EMS-TEI preinspection worksheet (Level 1-4 or CE Only), and upload all required documentation listed in the EMS-TEI pre-inspection worksheet to the EMS-TEI KEMSIS account. [An applicant for certification at a level of EMS-TEI shall submit a completed Training and Educational Institution (TEI), KBEMS-E14, with the Kentucky Board of Emergency Medical Services (KBEMS).]

(6) <u>An applicant shall submit a nonrefundable fee pursuant to</u> 202 KAR 7:030 with the Training and Education Institution (TEI) <u>Application [An applicant shall submit fees as required by 202 KAR</u> 7:030 with the Training and Education Institution (TEI), KBEMS-E14.]

(7) An applicant applying for an EMS-TEI certification shall meet all requirements for that level within sixty (60) days of submitting the Training and Education Institution (TEI) Application for certification. An applicant that exceeds the sixty (60) day requirement shall reapply and resubmit all required fees.

(8) An Emergency Medical Services (EMS) training and educational entity not residing in the Commonwealth of Kentucky, but seeking to do business in Kentucky as an EMS-TEI, shall obtain EMS-TEI certification with the board before teaching any EMS courses that lead to certification or licensure by the board. Such courses include:

(a) Initial EMS certification courses; and

(b) EMS continuing education courses.

1. This does not include continuing education courses covered in Section 13(1) of this administrative regulation.

(9) An EMS-TEI that had its certification revoked shall be eligible to apply for certification as an EMS-TEI two (2) years after the date of revocation. This will be enforced by name of entity holding the EMS-TEI certification and name of owner or operator listed on the TEI Application and official business license(s) filed by the entity, owner or operator with local, county and state officials.

(10) An EMS-TEI may surrender its certification prior to the end of a certification period by notifying the board in writing of the intent to do so thirty (30) days prior to the intended effective date of the surrender.

(a) An EMS-TEI surrendering its certification while classes are underway shall notify the students impacted by the closure in writing at least thirty (30) days prior to the intended effective date of closure.

(b) An EMS-TEI surrendering its certification while courses are underway shall complete the courses underway before surrendering its EMS-TEI certification or fully refund all tuition and fees paid by the students in the courses underway that are impacted by the EMS-TEI closure.

(11) An EMS-TEI that does not comply with Section 2(10) of this administrative regulation shall not be eligible to reapply for EMS-TEI certification for a period of five (5) years from the date of closure. This administrative regulation shall not preclude civil action against the TEI Owner, Director, or business.

Section 3. [Initial] Certification Requirements for EMS-TEIs.

(1) If an applicant [is organized as a business entity and] is required [pursuant to KRS Chapters 271, 362, and 365] to file <u>as a business entity</u> with Kentucky's Secretary of State, the applicant for EMS-TEI certification shall provide proof of registration with the Kentucky Secretary of State <u>to the board</u> that the EMS-TEI is legally able to conduct business in the <u>Commonwealth of</u> [state] Kentucky. The applicant shall provide documentation of exemption status if not registration with the Kentucky Secretary of State and proof of registration with local, county or state officials as an individual operator or a Doing Business As (DBA).

(2) If an applicant is required to notify, obtain permission, or obtain license from another regulatory entity in the Commonwealth of Kentucky to operate as an educational entity, it shall be the

responsibility of the applicant to make the appropriate notifications. obtain permission, or obtain license to legally operate in the Commonwealth of Kentucky.

(a) An EMS-TEI that fails to comply with Section 3(1) or (2) of this administrative regulation shall be subject to disciplinary action by the board pursuant to KRS Chapter 311A.

(3) Facilities.

(a) Facilities where EMS-TEI courses are conducted shall be maintained and operated in compliance with the safety and health requirements pursuant to local, city, and county ordinances and federal and state laws; and

1. Sponsored or approved by a sponsoring agency;

2. Enrollment shall not exceed the design characteristics of the facilities;

3. Controlled environment, including:

(a) Temperature;

(b) Humidity;

(c) Lighting; and

<u>4. Adequate and appropriate for instruction in classrooms and</u> laboratories:

(a) Provide appropriate space for students to participate in classroom activities, kinematic learning and practice activities;

(b) Provide appropriate space for instructor preparation; and

(c) Adequate and secure storage for instructional materials.

(4) [(2)] An applicant shall provide the board with an organizational chart indicating, at a minimum:

(a) The names, <u>contact information</u>, and addresses of the owner, operator, chief administrative officer, and other personnel necessary for operation of the entity as an EMS-TEI;

(b) The <u>name[names]</u> and [addresses] <u>contact information</u> of the <u>EMS-TEIs</u> [EMS-TEI's designated agent for receiving service] <u>director;</u>

(c) The name and [address] contact information of the EMS-TEIs [EMS-TEI's] medical director; proof that the medical director is qualified pursuant to 202 KAR 7:801; and a [document] memorandum of understanding or contract executed between the owner of the EMS-TEI and the medical director outlining the relationship, duties, and requirements of a medical director for an EMS- TEI. The memorandum of understanding or contract shall include at a minimum that:

<u>1. The medical director shall be responsible for medical oversight of the program;</u>

2. The medical director shall review and approve the educational content of the program curriculum;

3. The medical director shall review and approve the instruments and processes used to evaluate students in didactic, laboratory, clinical, and field internship;

4. The medical director shall review the progress of each student throughout the program, and assist in the determination of appropriate corrective measures, when necessary;

5. The medical director shall engage in cooperative involvement with the program director; and

<u>6. The medical director's interaction shall be in a variety of settings, such as lecture, laboratory, clinical, field internship.</u> Interaction may be by synchronous electronic methods.[; and]

(d) The name and [address] <u>contact information</u> of the <u>EMS-TEIs</u> [EMS-TEI's] program coordinator[-]; and

(e) The names and contact information of all EMS-TEI Instructors.

(5) EMS training courses that require accreditation by the National Registry of EMT's (NREMT) shall submit current accreditation to the board upon request. [(3) Beginning January 1, 2013, if the EMS-TEI will be offering courses leading to certification or licensure for EMS personnel in Kentucky that is dependent on EMS-TEI accreditation, the applicant for EMS-TEI shall submit proof of accreditation.]

(a) An accreditation letter of review is acceptable in the interim for newly formed EMS-TEIs that are required by the NREMT to obtain accreditation for testing purposes. This does not apply to out of state applicants. Out-of-state applicants that are required by the NREMT to obtain accreditation for testing purposes must provide documentation of full accreditation prior to receiving EMS-TEI certification by the board. (b) Continuous accreditation status must be maintained by the EMS-TEI as required by this administrative regulation. Failure to maintain continuous accreditation status by the TEI shall be grounds for summary revocation of the TEI certification.

(6) EMS-TEIs shall obtain and maintain professional liability malpractice insurance of a minimum of \$1 million. The EMS-TEI shall provide proof of professional liability malpractice insurance upon initial certification, certification renewal, and upon application for certification upgrade.

Section 4. Certification Periods and Inspections. (1) An EMS-TEI shall display the current certificate issued through the <u>board</u>: [Kentucky Board of Emergency Medical Services]

(a) In a prominent place in the <u>EMS-TEIs</u> [EMS-TEI's] business; [and.]

(b) In the classroom if classes are being conducted away from the primary business location; and

(c) Provided electronically to the student if the classes are being conducted online.

(2) Certification of an EMS-TEI shall be valid for a period of one (1) year [two (2) years] unless limited by disciplinary action.

(3) Prior to expiration of the <u>one (1) year</u> [two (2) years] certification period, an EMS-TEI may apply for recertification for a subsequent <u>one (1)</u> [two (2)] year period.

(4) Upon application for recertification, an applicant shall <u>electronically submit</u> [resubmit an] <u>a</u> Training and Educational Institution (TEI), [KBEMS-E14] <u>Certification Renewal Application through the EMS-TEI KEMSIS account with the board[-]</u>

(a) The appropriate EMS-TEI pre-inspection worksheet (Level 1-4 or CE Only) and upload all required documentation listed in the EMS-TEI pre-inspection worksheet (Level 1-4 or CE Only) to the EMS-TEI KEMSIS account;

(b) An EMS-TEI level 1 thru 4 shall provide documentation that the EMS-TEI has instructed or initiated at least one (1) initial certification course at one of the levels in which the EMS-TEI is certified within the preceding **twenty-four (24)[twelve (12)]** months of the current expiration date;

(c) An EMS-TEI CE shall provide documentation that the EMS-TEI has instructed or initiated at least one (1) continuing education provider course that meets the continuing education requirements established by 202 KAR 7:201, 202 KAR 7:301, 202 KAR 7:330, or 202 KAR 7:401 within the preceding twelve (12) months of the current expiration date; and

(5) An EMS-TEI seeking <u>certification renewal</u> [recertification] shall pay all applicable <u>nonrefundable</u> fees upon application. Failure to pay fees or subsequent rejection of a payment method shall result in denial of the Training and Educational Institution (TEI) <u>Application</u> [, KBEMS-E14].

(6) An applicant for EMS-TEI renewal shall meet all renewal requirements prior to the expiration date of the TEI certification.

(a) A TEI that does not comply with all renewal requirements prior to the certification expiration date shall expire.

(b) A TEI that allows the TEI certification to expire shall be required to apply as an initial EMS TEI.

(7) [(6)] <u>An</u> [A newly certified] EMS-TEI <u>applying for initial or</u> <u>certification upgrade</u> shall undergo an inspection prior to offering <u>classes</u> [the EMS-TEI's first class. Failure to submit to the inspection shall result in immediate revocation of the certification]. The type of inspection, on-site or virtual, shall be determined by the office of the board and the EMS-TEI shall be responsible for establishing the virtual connection at their facility if necessary.

(8) [(7)] Each inspection shall ensure that the EMS-TEI has met all applicable requirements [in Section 5] of this administrative regulation. If the board's inspection finds that the EMS-TEI has failed to meet a requirement, the EMS-TEI shall correct all deficiencies prior to offering a class <u>and receiving subsequent</u> certification as an EMS-TEI. [

(8) The board shall inspect an EMS-TEI upon submission of the EMS-TEI's notice of intent to upgrade the level of courses offered.]

(9) <u>The board may conduct inspections of EMS-TEIs for initial</u>, renewal, certification upgrade, or to monitor compliance with statutory and regulatory requirements for TEIs. Inspections may be

schedule or unscheduled. [The board may inspect an EMS-TEI upon submission of the Training and Educational Institution (TEI), KBEMS-E14, to renew certification as an EMS-TEI.]

(10) <u>The office of the board shall conduct an application review</u> of required documentation and inspection of the EMS-TEI applicant no later than sixty (60) days following the submission of the <u>Training and Educational Institution (TEI) Application by the EMS-TEI applicant for initial certification and upgrades.</u> [The board shall conduct the inspection of an EMS-TEI no more than ninety (90) days following KBEMS' receipt of notice of intent to upgrade.]

(11) Approval of notice of intent to upgrade shall not extend the one (1) year [two (2) year] EMS-TEI certification period.

(12) An EMS-TEI requesting a name change or change in ownership shall:

(a) Notify the board in KEMSIS no later than thirty (30) days prior to the name change or change in ownership by completing:

<u>1. A new Training and Educational Institution (TEI) Application</u> electronically through the EMS-TEI KEMSIS account;

2. Legal documentation reflecting the legal name or ownership change or registration with the Kentucky Secretary of State Office reflecting the change which shall be uploaded with the TEI application in KEMSIS; and

<u>3. Payment of the application fee pursuant to 202 KAR 7:030 in KEMSIS.</u>

Section 5. EMS-TEI Operating Requirements.

(1) Each EMS-TEI shall maintain files for a period of <u>three (3)</u> [seven (7)] years beyond the end date of each EMS Course program that contain the following documentation:

(a) For courses requiring accreditation, all documents necessary for the EMS-TEI to have met the accrediting agency's standards, policies, and guidelines;

(b) A copy of the last accreditation self-study and letter of accreditation

(c) [(b)] The student attendance sign-in sheets for each course taught, including:

1. Lectures;

2. Practical skills lessons; and

3. Clinical and field rotations;

(d) [(c)] A master copy of each set of [written] examinations administered and answer keys for the exams;

(e) [(d)] A master copy of practical skills examination forms;

(f) [(e)] A master copy of each course syllabus;

(g) [(f)] Current, written affiliation agreements executed between hospitals or EMS agencies and the EMS-TEI;

(h) [(g)] Health records for students as may be required by the EMS-TEI or as expressly required in written affiliation agreements and determined necessary for students to complete clinical assignments, field -internships, or summative field evaluations;

(i) [(h)] Records of all disciplinary actions taken against a student, if applicable. Records shall include notification to students of the complaint; responses, if applicable, made by or on behalf of the student; and actions taken as a result of a complaint or other documented incident, grievance, or deficiency;

(j) [(i)] For students requiring remediation, documentation of specific activities or procedures requiring remediation and actions taken in response to deficiencies, including how the specific remediation was accomplished and [if] the success or failure of remediation;

(k) (ij) A master file of the objectives and competencies to be achieved by students during each educational program; and

(I) [(k)] Documentation of <u>other</u> [another] requirements that the EMS-TEI has established as part of the offered courses.

(2) Failure of an EMS-TEI to maintain records required by the board shall result in disciplinary action against an EMS-TEI.

(3) <u>The board [KBEMS]</u> shall require an EMS-TEI to submit a copy of the EMS-TEI[']s annual accreditation report <u>electronically</u> <u>through the EMS-TEIs KEMSIS account</u> if accreditation is necessary for licensure or certification of the students taking the EMS-TEI[']s offered course.

(4) EMS-TEIs shall conduct an annual review and revision of all courses and programs to ensure the EMS-TEI has complied with necessary updates to courses, programs, and accepted educational standards. <u>The participants involved with the annual</u> review shall include:

(a) The program director;

(b) Program coordinator;

(c) Medical director;

(d) An instructor or a faculty member that was actively involved in teaching courses during the preceding twelve (12) months of the annual review; and

(e) A student that successfully completed a course offered through the EMS-TEI during the preceding twelve (12) months of the annual review.

(5) An EMS-TEI shall document in writing the required annual review and updates resulting from the annual assessment.

(6) Documentation of the annual review shall be in writing, signed by the <u>program director</u>, [owner or] program coordinator, and <u>medical director</u>. The annual review shall be maintained in the course or <u>TEI</u> program files and submitted to the board electronically with the annual TEI renewal application.

(7) An EMS-TEI shall assure that all physical resources required by the curriculum, including classrooms, skill practice areas, notices of where to purchase or access textbooks, instructional aides, equipment, and supplies shall be:

(a) Available at each class session where skills are taught or practiced;

(b) Adequate in number to allow for practice by students enrolled; and

(c) In good working order and well-maintained.

(8) An EMS-TEI shall maintain and protect the privacy of all records pertaining to the health and safety of patients, students, and faculty members that are obtained or developed through or as a result of participation in training and educational activities with the EMS-TEIs.

(9) The EMS-TEI shall be responsible for knowing and following all federal and state laws [and requirements established in 202 KAR Chapter 7] relevant to safeguarding privacy of records, including educational and health records.

(10) The EMS-TEI shall develop and make available to all prospective students a clearly defined admissions policy [and procedure].

(11) An <u>EMS-TEIs</u> [EMS-TEI's] admission policy shall include specific requirements for students to gain admission, maintain enrollment, and all academic requirements necessary to successfully complete the offered course or program. <u>The</u> admission policy shall be provided to the student at the start of the course and a verified receipt by signature shall be kept in the student's file including any changes to the admission policy while the student is enrolled in the course. Admissions policies [and procedures] shall include at a minimum:

(a) Tuition rates and fees associated with the training and education program;

(b) Fees and other costs associated with remediation;

(c) A descriptive synopsis of the curriculum for each type of course taught;

(d) Course educational objectives;

(e) Classroom lecture and skills practice schedules;

(f) Clinical or field rotation locations with [tentative] beginning and ending dates;

(g) Participation requirements for each clinical or field rotation site:

(h) Continued course competency and course completion requirements; and

(i) [(h)] Citations to and language of prohibited actions pursuant to KRS [Chapter] 311A.050 that provide grounds for sanctions against or denial of individuals making application for certification or licensure by the board.

(12) EMS-TEIs shall establish written policies that provide for:

(a) The creation and use of course or program advertising that accurately portrays the course or program content as offered by the EMS-TEI;

(b) A uniform process for filing, investigating, and resolving complaints or grievances by applicants, students, preceptor sites, patients, members of the general public, or faculty members;

(c) A procedure for a student to withdraw from a course and a

clear statement of refund policies and the steps necessary for a student to obtain a refund of tuition or fees already paid;

(d) Faculty to <u>acquire or</u> develop examinations for each course offered;

(e) The establishment of and adherence to examination procedures and policies;

(f) The requirements for a student to take and pass examinations in courses the EMS-TEI offers <u>including</u> requirements that shall be met during the course for the student to be eligible to take the National Registry of EMTs certification exam; and

(g) <u>Public disclosure, both in print and web-based materials,</u> concerning the EMS-TEI student cumulative pass rate on the <u>NREMT certification exam for the calendar year. The disclosure</u> shall be updated by January 31 of each year and shall include at a <u>minimum</u>:

1. All provider levels tested;

2. Date range for which the report was calculated;

3. EMS-TEI name, number, and physical address;

4. Number of students that took the exam; and

5. Cumulative pass rate calculated by percentage.[Notification to all students and prospective students of their right to ask for and obtain the pass — fail rates of past students who have taken the National Registry Exam or other board approved certification test. The pass — fail rate shall be calculated for courses given within the last two (2) years.]

(13) An EMS-TEI shall assure <u>that</u> each student, while participating in a clinical or field rotation, is clearly identified as a student [and by first and last name]. Identification shall be accomplished by use of:

(a) [A] Nameplate;

(b) A uniform; or

(c) Other publicly apparent means.

(14) A student or a faculty member shall maintain proper personal and professional conduct during classroom, clinical, and field internship activities.

(15) [(14)] EMS-TEIs shall <u>have</u> [include] a <u>program director</u> [chief administrative officer (CAO) or designee] who shall <u>be</u> responsible for:

(a) <u>All aspects of the program, including administration,</u> organization, and supervision of the educational program [Administer and oversee the EMS-TEI];

(b) <u>Assuring[Assure]</u> the quality and credentials of the program coordinator, EMS educators, EMS educator adjuncts, and students accepted into the <u>EMS-TEIs[EMS-TEI's]</u> programs or courses;

(c) <u>Assuring[Assure]</u> the security of examination results and materials;

(d) <u>Monitoring[Monitor]</u> the activities of the <u>EMS-TEIs[EMS-</u> TEI's] faculty and students; [and]

(e) <u>Maintaining</u>[Maintain] records and documents and submit reports[-];

(f) Continuously reviewing the quality and improvement of the educational program;

(g) Long range planning and ongoing development of the program;

(h) The orientation, training, and supervision of clinical and field internship preceptors; and

(i) The effectiveness and quality of fulfillment of responsibilities delegated to another qualified individual.

(16) [(15)] EMS-TEIs shall include faculty and instructional staff who shall be responsible for:

(a) Didactic, clinical instruction, or supervised practice in each location where students are assigned; and

(b) Coordination, supervision, and frequent assessment of the students' progress in achieving acceptable program requirements.[If applicable, an EMS-TEI shall have a Paramedic Course Coordinator for paramedic training and education courses. The Paramedic Course Coordinator shall maintain a Level III EMS Educator status in the Commonwealth of Kentucky.]

(<u>17)</u> [(16)] A certified EMS-TEI shall maintain an ongoing level of competence, evidenced by a minimum <u>annual</u> pass rate <u>for each</u> <u>level of instruction</u> of <u>seventy (70)</u> [fifty (50)] percent <u>calculated</u> [based] upon a <u>third attempt cumulative</u> [measurement] <u>pass rate</u> of students who have taken the <u>National Registry of EMTs and</u> other board-approved <u>exam(s)</u> [exam for the first time] within the twelve (12) [twenty-four (24)] months immediately preceding the EMS-TEI[¹]s renewal date. <u>The minimum annual pass rate shall be</u> calculated, and compliance determined by, the office of the board.

(a) EMS-TEIs that fail to maintain a seventy (70) percent pass rate for each level of instruction as required by Section 5(17) of this administrative regulation shall notify all students enrolled in courses offered by the EMS-TEI that the EMS-TEI is not in compliance with testing standards.[

(17) An EMS-TEI's competency shall also be demonstrated by compliance with KRS Chapter 311A and 202 KAR Chapter 7 and the EMS-TEI's process for remediating students who take but fail to pass the board -approved test.]

(18) If an EMS-TEI fails to meet an ongoing level of competence determined according to this <u>administrative regulation</u> and demonstrated by compliance with KRS Chapter 311A and 202 KAR Chapter 7 [section], the EMS-TEI shall be subject to a plan of correction mediated through the office of the board. An EMS-TEI that cannot maintain an ongoing level of competence may be subject to discipline pursuant to KRS <u>Chapter</u> 311A.

(19) If requested by the office of the board, the EMS-TEI shall submit graduate data to the Kentucky Center for Education and Workforce Statistics including:

(a) Student's name;

(b) Date of birth;

(c) Social Security number;

(d) Gender;

(e) Ethnicity;

(f) Residency at point of graduation; and

(g) The Classification of Instructional Programs (CIP) code, if applicable.

(20) The EMS-TEI director shall keep the EMS-TEI KEMSIS account information updated, including:

(a) The EMS-TEI demographics;

(b) The EMS-TEI personnel roster; and

(c) The EMS-TEI policy and procedures required by this administrative regulation.

(21) The program director of EMS-TEIs offering initial certification courses shall create and maintain, with current information, a National Registry of EMTs educational program account.

(a) The EMS education program name, director name, address, and contact information listed with NREMT shall match the EMS-TEI program information listed in KEMSIS.

Section 6. Disciplinary Action. (1) As certified entities under the board's jurisdiction, all EMS-TEIs shall be subject to the disciplinary procedures and sanctions established in KRS <u>Chapter</u> 311A.

(2) Discipline of an EMS-TEI as a certified entity shall not prevent the board from taking disciplinary action against a certified or licensed individual associated with the EMS-TEI at any level of certification or licensure applicable.

Section 7. Reporting Requirements for EMS-TEI. (1) An EMS-TEI shall submit <u>electronically</u> to <u>the board</u> [KBEMS] the documents <u>as</u> required by [subsection (2) of] this section for all EMS courses <u>or psychomotor testing</u> that lead to <u>certification by</u> <u>The National Registry of EMTs</u> [licensure] or certification <u>or</u> licensure by the board.

(2) An EMS-TEI shall submit the following documents to the board office:

(a) Course N]otification <u>Application</u> [form] <u>submitted no less</u> than fourteen (14) days prior to the course start date; [and]

<u>1. An EMS-TEI shall notify the board within seven (7) days of any changes to a board approved class or psychomotor testing start and end date using Course Change Notification Application.</u>

2. The start and end date shall only be changed once and cannot exceed thirty (30) days from the original start and end date.

3. A course or psychomotor test shall have a start date in the same calendar year in which the course or psychomotor testing number is issued.

(b) Initial Educational [Institution] Course Roster[Rosters]

submitted no less than fourteen (14) days prior to the course start date listed on the Course Notification Application;

(c) If applicable, the Comprehensive Skills Evaluation Report within thirty (30) days of the course completion date listed on the Course Notification Application:

(d) Final Educational Course Roster within thirty (30) days of course completion date listed on the Course Notification Application:

(e) Psychomotor Exam Application submitted no less than fourteen (14) days prior to the psychomotor exam start date.

<u>1. Psychomotor examinations leading to board certification or licensure shall be conducted using board approved psychomotor examination procedures.</u>

(3) Upon submission of all documents required by [subsection (2) of] this section for courses <u>or psychomotor testing</u> that lead to <u>certification by The National Registry of EMTs and</u> licensure or certification <u>by [,the office of]</u> the board, the TEI shall <u>be</u> assigned a <u>course or psychomotor testing</u> number or other identifier [to the course].

(4) <u>An EMS-TEI that fails to provide documents as required by</u> subsection (2) of this section shall be subject to disciplinary action pursuant to KRS Chapter 311A up to and including revocation of the TEI. [An EMS-TEI shall notify the board office thirty (30) days prior to the start of a course. Failure to notify KBEMS shall violate this section of this administrative regulation and may subject the EMS-TEI to disciplinary action under KRS 311A.]

(5) A <u>course</u> [elass] <u>or psychomotor testing</u> shall not commence until the EMS-TEI has obtained an identification code and notified the board as required in this section.

(6) A course <u>or psychomotor testing</u> that does not meet all requirements of this administrative regulation <u>may</u> [shall] not lead to certification or licensure for the EMS students enrolled in the course <u>or psychomotor testing</u>.

(7) An EMS-TEI shall notify the board within seven (7) days of any changes to the lead instructor of an initial course that leads to certification or licensure by the board.

(8) An EMS-TEI shall notify the board within seven (7) days of cancelation of an initial certification or licensure course.

(a) An EMS-TEI that cancels an initial certification or licensure course that is underway or planned shall fully refund all tuition and fees paid by the students in the course that are impacted by the course cancellation.

Section 8. Requirements for All Training and Education Courses. (1) <u>All EMS educational programs in Kentucky that lead</u> to EMS Provider certification by The National Registry of Emergency Medical Technicians (NREMT) and certification or licensure by the board shall: [All EMS training and education courses that lead to certification or licensure by KBEMS shall:]

(a) Comply with this administrative regulation;

(b) Not <u>begin</u> [commence] until the EMS-TEI has filed all documents required pursuant to Section 7 [(2)] of this administrative regulation;

(c) Not begin until the EMS-TEI has paid all fees required pursuant to 202 KAR 7:030;

(d) Use the National Emergency Medical Services Education Standards [<u>Instructional Guidelines</u>] that are appropriate for the level of EMS provider course being offered;

(e) Teach students the <u>Kentucky and National</u> EMS Scope of Practice Models;

(f) Meet the course administrative and faculty requirements in this administrative regulation, <u>if applicable</u>, <u>[and]</u> as established by the <u>NREMT</u> [beard] approved accrediting agency; and

(g) Use <u>educators</u> [lead instructors] certified by <u>the board</u> [KBEMS] as EMS educators who are minimally certified or licensed at the level of the offered course.

(h) An EMS-TEI shall ensure that all student course work including lectures, practical skills lessons, and clinical or field rotations for courses that lead to certification by the National Registry of EMTs and certification and licensure by the board be completed within thirty (30) days of the course completion date listed on the Course Notification Application. The board shall not accept any changes made to course completion documents listed in Section 7 of this administrative regulation if submitted less than thirty (30) days of the course completion date as listed on the Course Notification Application.

<u>1. In exceptional circumstances, the EMS-TEI may submit a</u> <u>Final Course Roster of students approved by the EMS-TEI</u> <u>program director and medical director for course work extension</u> <u>required in Section 5 of this administrative regulation.</u>

(i) The EMS-TEI director shall approve all students to test with the National Registry of EMTs within seven (7) days of successful completion of an initial certification course and completion of all necessary documents and applications by the student.

(2) The EMS-TEI may use <u>an assistant instructor who is not a</u> <u>board certified educator</u> to instruct no more than twenty-five (25) <u>percent of the classroom education time</u> [adjunct faculty] for initial certification or licensure courses. [if the adjunct faculty:

(a) Meets one (1) of the requirements established in Section 13 of this administrative regulation; and

(b) Teach for no more than five (5) percent of the classroom education time for each EMS course without the supervision of the program coordinator or certified instructor present and available in the classroom.]

(3) The EMS-TEI <u>shall maintain an instructor to student ratio of</u> <u>no more than 1:15 for</u> [shall have additional skills educators for] classroom sessions where skills are practiced. These sessions shall not proceed without the presence of:

(a) A certified educator for the first <u>fifteen (15)</u> [ten (10)] students; and

(b) An additional educator or adjunct faculty for each one (1) to <u>fifteen (15)</u> [ten (10)] additional students. Additional adjunct faculty used shall:

<u>1.</u> Not be required to be certified as an EMS educator but shall be certified by the board as an EMS provider at or above the level for the course being taught; or

2. Be a Registered Nurse (RN), Advanced Practice Registered Nurse (APRN), Physician (DO or MD), or Physician Assistant (PA); and

(4) The EMS-TEI program director and medical director shall approve any assistant instructor or adjunct faculty before the individual may assist in instruction. [and shall meet at least one (1) requirement established in Section 13 of this administrative regulation.]

(5)[(4)] The EMS-TEI shall have a medical director qualified pursuant to 202 KAR 7:801, who shall:

(a) Be employed by or under <u>memorandum of understanding</u> or <u>a</u> written contract with the EMS-TEI to serve as the medical director of the program;

(b) Be routinely available to the EMS-TEI to provide consultation regarding issues related to the training and education program;

(c) Participate in the approval of the didactic clinical and evaluation material and student progress review;

(d) Meets the <u>applicable</u> accrediting agency standards, policies, and guidelines;

(e) Provide medical consultation and guidance to the course faculty; and

(f) Certify[ies] the skills of all [of the] EMS-TEI['s] students who are enrolled in courses leading to EMS Provider certification by The National Registry of Emergency Medical Technicians (NREMT) or certification or licensure by the board.

(6) [(5)] An EMS-TEI shall maintain a written contractual affiliation agreement or memorandum of <u>understanding</u> [agreement] with each clinical rotation site that outlines, at a minimum, the responsibilities of each entity and reporting requirements for students involved in clinical and field training and education.

(7) [(6)] An EMS-TEI shall provide faculty from the EMS-TEI training and education program, clinical coordinators, or designees under contract with the EMS-TEI to oversee student activity while in the clinical <u>or field internship</u> setting.

(8) The EMS-TEI shall provide clinical or field preceptor training to all clinical or field preceptors overseeing students during clinical or field internship rotations.

Section 9. Emergency Medical Responder Training and Education Course Requirements. [Each Emergency Medical Responder (EMR) training and education course shall follow]:

(1) Each Emergency Medical Responder (EMR) training and education course shall:

(a) Include all training and education requirements established in KRS Chapter 311A, 202 KAR 7:201, and 202 KAR 7:701;

(b) Use the National Emergency Medical Services Education Standards – Emergency Medical Responder Instructional Guidelines for the duration of course including individual class segments; and

(c) Ensure student competency throughout the course by a nationally recognized independent validated examination measuring process.

(2) To be eligible for certification as an EMR, a student shall also receive instruction covering the National and Kentucky EMS Scope of Practice for an EMR.

(3) EMR candidates shall meet all student eligibility requirements pursuant to 202 KAR 7:201.[All training and education requirements established in KRS Chapter 311A and 202 KAR 7:201; and

(2) The National Emergency Medical Services Education Standards – Instructional Guidelines for duration of course and individual class segments.]

Section 10. Emergency Medical Technician Training and Education Course Requirements. (1) Each Emergency Medical Technician (EMT) training and education course shall:

(a) Include all training and education requirements established in KRS Chapter 311A, [and] 202 KAR 7:301, and 202 KAR 7:701; [and]

(b) <u>Use</u> the National Emergency Medical Services Education Standards – <u>Emergency Medical Technician</u> Instructional Guidelines for duration of course and individual class segments: and

(c) Ensure student competency throughout the course by a nationally recognized independent validated examination measuring process.

(2) To be eligible for certification as <u>an EMT[EMTs]</u>, <u>a student</u> shall receive instruction covering the National and Kentucky EMS Scope of Practice for an EMT.

(3) Each student shall complete [a] clinical [er] and field rotation that meets the requirements for EMT education as determined by this administrative regulation, [and] including the National and Kentucky EMS Scope of Practice for an EMT student as approved by the applicable accrediting agency's minimum requirements.

(4) [(3)] The minimum requirements of clinical or field rotations for EMTs shall include [minimally]:

(a) [A] Clinical [er] and field rotations [consisting of at least twenty-four (24) hours] conducted at a [in a hospital emergency department, public health department, urgent treatment center, physician's office,] licensed ambulance service or other licensed health care facility_selected by the EMS-TEI director and medical director that, if applicable, meets nationally accepted accreditation standards;

(b) Interviews and assessments [of] on a minimum of ten (10) patients with at least five (5) interviews and assessments conducted in a pre-hospital ambulance service setting; and

(c) Recording <u>the</u> patient history and [completing] assessment on a [prehospital] care report form for each of the ten (10) patients required in paragraph (b) of this subsection.

(5) [(4)] If a student fails to achieve the [a] goals established by [for] the <u>EMS-TEI for the EMT</u> education program, the EMS-TEI [<u>CAO Officer or</u>] program director <u>and medical director</u> shall require the student to repeat the failed portion of <u>the EMT</u> education program. [a clinical or field rotation experience.]

(6) [(5)] If a student is required to repeat a portion of the EMT education program, [a clinical or field rotation experience,] the [CAO or] program director and medical director shall have a written procedure for remediation that ensures the student shall be provided with adequate due process protections that include at a minimum: (a) Notification of allegations or academic issues;

(b) A right for the student to be heard on the subject of the allegations or academic issues; [and]

(c) A right for the student to appeal the decision of the EMS-TEI to the director and medical director about the allegations or academic issues[-]; and

(d) The notification to the student shall be in writing and signed and dated by all witnesses.[

(6) If additional time is required, the notification to the student shall be signed and dated by the student.]

(7) EMT candidates shall meet all student eligibility requirements pursuant to 202 KAR 7:301.

(8) EMT students shall meet health and immunization standards as required through established TEI policy, or policies established by contracted TEI clinical sites.

Section 11. Advanced-Emergency Medical Technician Training and Education Programs.

(1) Advanced-Emergency Medical Technician (A[-]EMT) training and education course requirements. Each AEMT training and education course shall:

(a) Include all training and education [as required] pursuant to KRS Chapter 311A, 202 KAR 7:330, and 202 KAR 7:701; [and]

(b) Use the National Emergency Medical Services Education Standards – Advanced Emergency Medical Technician Instructional Guidelines for duration of course and individual class segments; and [Follow the National Emergency Medical Services Education Standards – Instructional Guidelines.]

(c) Ensure student competency throughout the course by a nationally recognized independent validated examination measuring process.

(2) To be eligible for certification as an A[-]EMT[s], a student shall:

(a) Complete a clinical and [er] field rotation that meets the requirements for A[-]EMT education as determined by this administrative regulation [and] including the National and Kentucky EMS Scope of Practice for an A[-]EMT student as approved by the applicable accrediting agency's minimum requirements.

(3) The minimum requirements of clinical and field rotations for A[-]EMTs shall include:

(a) Clinicals or field rotations [that occur] conducted at a licensed [in a hospital emergency department, public health department, urgent treatment center, physician's office, advanced life support] ambulance service, or other licensed [advanced] health care facility[;] selected by the EMS-TEI director and medical director that, if applicable, meets nationally accepted accreditation standards;

(b) Interviews and assessments <u>on</u> [ef] a minimum of <u>twenty</u> (20) [thirty-five (35)] patients, including at least <u>ten (10)</u> [fifteen (15)] interviews and assessments while the student is actively in the role of team leader with a licensed ambulance service; and

(c) Record of patient history and assessment on a [prehospital] care report form for each of the twenty (20) [thirty-five (35)] patients required in paragraph (b) of this subsection.

(4) If a student fails to achieve <u>the goal</u> [a goals] established <u>by</u> <u>the EMS-TEI</u> for the A[-]EMT education program, the EMS-TEI [chief administrative officer or] program director <u>and medical</u> <u>director</u> shall require the student to repeat the failed portion of <u>the</u> <u>AEMT education program.</u> [a clinical or field rotation experience.]

(5) If a student is required to repeat a portion of <u>the AEMT</u> education program, [a clinical or field rotation experience,] the [CAO or] program director and medical director shall have a written procedure for remediation that ensures the student shall be provided with adequate due process protections that include at a minimum:

(a) Notification of allegations or academic issues;

(b) A right for the student to be heard on the subject of the allegations or academic issues; [and]

(c) A right for the student to appeal the decision of the EMS-TEI to the director and medical director about the allegations or academic issues[-]; and

(d) The notification to the student shall be in writing and signed and dated by the:

1. Student;

TEI Administrator;

3. Medical Director; and

Course Coordinator.

(6)_AEMT candidates shall meet all student eligibility requirements pursuant to 202 KAR 7:330. [If the EMS-TEI requires the student to complete additional ride-time, the EMS-TEI shall give the student written notification for the student to sign and date.]

(7) AEMT students shall meet health and immunization standards as required through established TEI policy, or policies established by contracted TEI clinical sites.

Section 12. Paramedic Training and Education Programs. Paramedic training and education course requirements.

(1) Each Paramedic training and education course shall:

(a) Include all training and education as required by this administrative regulation, KRS Chapter 311A, <u>202 KAR 7:401, 202 KAR 7:701</u>, and any other Kentucky statutes <u>or administrative regulations</u> that place mandates upon paramedic students; [and]

(b) <u>Use</u> the National Emergency Medical Services Education Standards – <u>Paramedic</u> Instructional Guidelines <u>for duration of</u> <u>course and individual class segments; and</u>

(c) Ensure student competency throughout the course by a nationally recognized independent validated examination measuring process.

(2) To be eligible for licensure as a paramedic, a student shall complete a clinical or field rotation that meets the requirements for paramedic education as determined by this administrative regulation [and] including the National and Kentucky EMS Scope of Practice for a Paramedic student as approved by the applicable accrediting agency's minimum requirements.

(3) The minimum requirements of clinical or field rotations for paramedics shall include:

(a) Clinicals or field rotations [that shall be] conducted at [in] a [hospital emergency department, public health department, urgent treatment center, physician's office,] licensed [advanced life support] ambulance service[,] or other licensed [advanced] health care facility selected by the EMS-TEI director and medical director that, if applicable, meets nationally accepted accreditation standards;

(b) [Interviews and assessments of a minimum of seventy-five (75) patients, including at least fifty (50) interviews and assessments while the student is actively in the role of team leader with a licensed ambulance service; and

(c)] Record of patient history and assessment on a prehospital care report form for each of the [seventy-five (75)] patients required in [subsection (3)(b) of] this section.

(4) If a student fails to achieve the [a] goals established by [fer] the <u>EMS-TEI for the EMS</u> education program, the EMS-TEI [chief administrative officer or] program director and medical director shall require the student to repeat the failed portion of the paramedic education program. [a clinical or field rotation experience.]

(5) If a student is required to repeat a portion of <u>the paramedic</u> education program [a clinical or field rotation experience], the [CAO er] program director <u>and medical director</u> shall have a written procedure for remediation that ensures the student shall be provided with adequate due process protections that include at a minimum:

(a) Notification of allegations or academic issues;

(b) A right for the student to be heard on the subject of the allegations or academic issues; [and]

(c) A right for the student to appeal the decision of the EMS-TEI to the director and medical director about the allegations or academic issues[-]; and

(d) The notification to the student shall be in writing and signed and dated by the:

1. Student;

2. TEI Administrator;

3. Medical Director; and

4. Course Coordinator.

(6) Paramedic candidates shall meet all student eligibility

requirements pursuant to 202 KAR 7:401. [If additional time is required to be completed for remediation, the EMS-TEI shall provide written notification of the additional time required and shall obtain a dated signature from the student.]

(7) Paramedic students shall meet health and immunization standards as required through established TEI policy, or policies established by contracted TEI clinical sites.

Section 13. Continuing Education. (1) Training and education courses provided to individuals [outside the roster of a licensed service and] that fulfill the continuing education requirements necessary to receive [recertify or renew] a certification or licensure from the board shall be provided by:

(a) An entity certified by the board [KBEMS] as an EMS-TEI;

1. An EMS-TEI CE which includes continuing education only shall pay an annual certification fee that shall not exceed fifty (50) dollars per certification period.

(b) An agency or department having contractual agreements with a <u>board [KBEMS]</u> certified EMS-TEI that is in good standing and not subject to disciplinary action;

(c) A <u>board</u> [KBEMS] approved symposia, state, national, or international school;

(d) A <u>board</u> [KBEMS] approved or nationally accredited <u>online</u> [on-line] or distance education provider, but which shall not provide more than <u>ninety (90)</u> [fiffy (50)] percent of the total continuing education hours to fulfill the <u>continuing</u> education [CE] requirements for renewal pursuant to KRS Chapter 311A or 202 KAR Chapter 7; or

(e) [A course that has been accredited by the board approved accrediting agency for continuing education.] <u>One or more of the approved continuing education entities listed below:</u>

<u>1. The Commission on Accreditation for Pre-Hospital</u> Continuing Education (CAPCE);

2. Kentucky Board of Nursing;

3. Kentucky Board of Medical Licensure;

4. Kentucky Board of Respiratory Care;

5. Department of Homeland Security and all department components:

6. U.S. Fire Administration and all department components;

7. Kentucky Department of Criminal Justice (DOCJT);

8. Kentucky Cabinet for Health and Family Services; or

9. Courses approved by any State EMS Office that are offered and or completed outside the Commonwealth of Kentucky.

(2) Continuing education courses shall:

(a) Contain material relevant to the job specifications and professional development of EMS personnel; and

(b) Be conducted at an EMS level appropriate for the discipline of the participants.

(3) EMS-TEIs that provide continuing education shall provide course completion documentation by hardcopy or electronically to all participants that successfully complete the continuing education course. The course completion documentation shall contain at a minimum the following items:

(a) Official name of the EMS-TEI as listed in the EMS-TEI KEMSIS account and certification number of the EMS-TEI issued by the board:

(b) Name of primary instructor and state EMS office EMS provider number;

(c) Name of course;

(d) Breakdown of completed hours and subject categories instructed that meet the continuing education requirements established by 202 KAR 7:201, 202 KAR 7:301, 202 KAR 7:330, and 202 KAR 7:401; and

(e) Signature of one of the following EMS-TEI representatives:

1. Director;

Course coordinator; or

3. Course instructor.

Section 14. Continuing Education Instructor Requirements. (1) The following persons shall be qualified to conduct continuing education courses for persons certified or licensed by <u>the board</u> [KBEMS]:

(a) An EMS provider [paramedic licensed by the board or]

licensed or certified by the board that holds a continuing education educator credential [in another state];

(b) A physician (DO or MD) or Physician Assistant (PA) licensed in Kentucky or another state, who has specific expertise in an area of a prehospital discipline;

(c) A registered nurse <u>(RN) or Advanced Practice Registered</u> <u>Nurse (APRN)</u> licensed in Kentucky or another state, who has specific expertise in an area of a prehospital discipline;

(d) An EMS Educator certified in Kentucky; or

(e) An individual who is at least one (1) of the following and who shall be limited to teaching the specific subject approved by the EMS-TEI director and medical director:

1. Certified by a state or federal agency to teach or perform subject matter relevant to the National Emergency Medical Services Education Standards [- Instructional Guidelines] and <u>National and Kentucky</u> EMS Scope of Practice for a prehospital discipline;

2. Certified by a nationally recognized entity to provide EMS related training and education;

3. A presenter at a National or State Symposium accredited by an agency or other <u>board [KBEMS]</u> approved entity; or

4. A presenter approved by an EMS medical director who has specific expertise in an area of a prehospital discipline. [as uniquely qualified by experience or education; or

5. A presenter approved as being uniquely qualified by an emergency response agency's chief administrative officer.]

(2) The EMS-TEI or other approved contractual department or agency providing continuing education shall be required to:

(a) Maintain a roster, objectives, and outline for every continuing education course taught on file for a period of <u>three (3)</u> [seven (7)] years beyond the end date of each EMS Course; [and]

(b) Maintain all documentation to have met the <u>applicable</u> accreditation agency standards, policies, and guidelines established in this administrative regulation; and [-]

(c) Meet the requirements of this administrative regulation.

(3) If requested by the board, the EMS-TEI shall submit to <u>the</u> <u>board</u> [KBEMS] the required documents for EMS continuing education courses taught within the preceding <u>three (3)</u> [seven (7)] years that lead to re-certification or re-licensure by the <u>board</u> [KBEMS], including:

(a) Contractual agreements;

(b) The continuing education <u>instructor</u> [educator's] curriculum vitae <u>or resume that includes at a minimum the educator's name,</u> <u>address, phone number, email address, education history, and</u> <u>employment history documenting the qualifications listed in Section</u> <u>14(1) have been met;</u>

(c) A completed <u>Continuing</u> Education[al Institution] Course <u>Student</u> Roster. The course roster shall include the participants name, signature, participant KEMSIS number, and board EMS credential held. If rosters are created or stored electronically, there shall be a verification of attendance component that can be verified by the board if requested; and

(d) Objectives, <u>syllabi</u> [and], outline, and a list of instructor resources used for each continuing education course.

Section 15. Pilot Programs. (1) <u>A board certified TEI that is in</u> <u>good standing may apply for an Educational Pilot Program. [A</u> <u>licensed EMS provider agency may apply to KBEMS for</u> authorization to perform a pilot program.

(2) A pilot program shall involve specialized training and education, as well as associated procedures not otherwise provided for in 202 KAR Chapter 7.

(3) Educational Pilot Programs shall be subject to the provisions of 202 KAR 7: 565. [A licensed EMS provider agency seeking authorization for a pilot program shall submit a written request to the board.

(4) An authorized entity approved by the board to conduct a pilot program shall agree in writing:

(a) To submit periodic reports related to the progress of the pilot program; and

(b) To abide by the board -established requirements for the pilot program.

(5) An individual otherwise certified or licensed by the board

who successfully completes an approved pilot program shall perform the procedures relevant to the training and education received in the pilot program subject to protocols established by the medical director for the pilot program.

(6) The board may establish pilot program limitations on:

(a) The geographic area or service location where the procedure may be performed; and

(b) The performance of the procedure subject to a:

1. Specific and defined event;

2. Disaster; or

3. Designated directive.

(7) The board may authorize the use of physicians or other medical professionals to supervise and monitor the training and education of students involved in a pilot program.

(8) The board may restrict or limit actions that involve the performance of an invasive procedure or the administration of medication subject to:

(a) Required physician or medical director oversight; or

(b) The use of protocols that have been submitted to the board for review and approved by the state medical advisor and the board.]

Section 16. EMS Educators. (1) An EMS Educator may be certified at the following levels:

(a) <u>EMR Educator, which certifies the individual to teach EMR</u> initial certification and continuing education courses [Level I – EMR Educator, which certifies the individual to teach EMR courses or EMR continuing education];

(b) <u>EMT Educator, which certifies the individual to teach EMR</u> and <u>EMT initial certification and continuing education courses;</u> [Level II – <u>EMT Educator, which certifies the individual to teach</u> <u>EMT and EMR courses or EMT and EMR continuing education; or</u>]

(c) <u>AEMT Educator, which certifies the individual to teach</u> <u>EMR, EMT, and AEMT initial certification and continuing education</u> <u>courses:</u> [Level III — Advanced Educator, which certifies the individual to teach EMR, EMT, A-EMT, and paramedic courses or continuing education.]

(d) <u>Paramedic Educator, which certifies the individual to teach</u> EMR, EMT, AEMT, and Paramedic initial certification and <u>continuing education courses; and</u> [Level IIIR - Registered nurses and physicians who are not currently certified as an EMT, A-EMT, or paramedic shall only be certified as Level III instructors who teach A-EMTs or paramedics.]

(e) CE Educator, which certifies the individual to teach continuing education courses at or below the level of EMS provider certification or license issued by the board.

(2) Depending on the level of certification sought, an applicant for certification as a Kentucky EMS educator shall:

(a) Already hold a certificate or license in Kentucky as an Emergency Medical Responder (EMR), an Emergency Medical Technician (EMT), an Advanced Emergency Medical Technician (AEMT), or a P[p]aramedic;

<u>1. Hold a license in Kentucky or another state as a Registered</u> <u>Nurse (RN), Advanced Practice Registered Nurse (APRN),</u> <u>Physician (DO or MD), or Physician Assistant (PA);</u>

(a) A Registered Nurse (RN), Advanced Practice Registered Nurse (APRN), Physician (DO or MD), or Physician Assistant (PA); shall be considered an advanced EMS provider at the paramedic level only for the purpose of credentialing the individual as an EMS educator.

(b) Not be issued a certificate as an EMS educator for a level of instruction higher than their EMS provider certification or license;[-]

(c) Have successfully completed:

1. The National Association of EMS Educators Emergency Medical Services Education Standards [- Instructional Guidelines] for Educating EMS Instructors [educators] course; or

2. An [KBEMS-] approved EMS educator course that meets the objectives of the [National Highway Traffic Safety Administration (NHTSA)] National Highway Traffic Safety Administration National Guidelines for Educating EMS Instructors and The National Emergency Medical Services Education Standards which [and] is designed to represent a common core for teaching knowledge and skills to assist $\underline{\text{in}}$ the education of adult learners; or

3. <u>Has completed one of the EMS educator courses listed</u> <u>below:</u> [A Bachelor's Degree or higher in education;]

(a) International Fire Service Training Association (IFSTA) Fire Instructor Course:

(b) Eastern Kentucky University's EMC 440 EMS Instruction Course; or

(c) An instructor course accepted by one of the below entities that is equivalent to the EMS educator course objectives found in the U.S. Department of Transportation / National Highway Traffic Safety; or

4. Holds an unrestricted and current license or certification as a teacher or educator through a state board of education in the U.S.

(d) [Have been certified or licensed for a minimum of four (4) years as an EMS provider at the same level or at a higher level for which the applicant seeks to become an EMS educator;

(c) Provide documentation that two (2) years of the four (4) years' experience required in this section is experience providing care with an EMS organization that complies with the requirements of KRS Chapter 311A or 202 KAR Chapter 7.

(f)] Provide documentation <u>using the KBEMS Lecture and Skill</u> <u>Verification Form that</u> the applicant has assisted with a course that meets the following requirements:

1. The board has approved the course as leading to certification or licensure;

2. Assistance with the course has been under the supervision of a <u>board</u>-certified EMS educator <u>through a board-certified EMS-</u><u>TEI</u> with the approval of the program director and medical director [who attests using the board -approved Certified Educator form that the educator has served as a course coordinator or lead educator for at least three (3) separate courses and who has not been subject to disciplinary action or reprimand by the board pursuant to KRS Chapter 311A within the past thirty-six (36) months]; and

3. The <u>courses[course]</u> in which the applicant <u>can [will]</u> assist to meet the requirements of Section 16(3) of this administrative regulation shall be in a board-approved initial course at or below the level of educator the applicant is seeking. [is at the same level of EMS educator the applicant is seeking;]

a. Continuing education courses shall not be accepted to meet the requirements in this section of this administrative regulation;

(g) Provide evidence of completion of a board sponsored orientation program;]

(e) [(h)] Submit a completed: [EMS Responder Application and pay all established fees]

1. CE Educator Initial Application;

2. EMR Educator Initial Application;

EMT Educator Initial Application;

4. AEMT Educator Initial Application; or

5. Paramedic Educator Initial Application;

(f) Pay all fees pursuant to 202 KAR 7:030; and

(g) An applicant shall undergo a background check pursuant to KRS 311A.050 and 311A.100. The background check shall be:

1. National in scope for an applicant not currently certified or licensed at any level in Kentucky;

2. Statewide in scope for an applicant with current certification or licensure in Kentucky;

3. Less than six (6) months old when the applicant submits to the board all requirements for Educator certification; and

4. Provided by a vendor that has been contracted through the board.

(h) An applicant shall not directly submit a background check to meet the requirements of this section. The background check shall be submitted to the board by the company that conducts the background check.

(3) [If applying to become a Level I or II] Applicants applying for EMR, EMT, AEMT or Paramedic Educator certification shall:

(a) [Be certified minimally as an EMT to teach EMTs or EMRs and minimally certified as an EMR to teach only EMRs;

(b)] Submit documented proof on the Lecture and Skills Verification Form that the applicant:

1. Completed a minimum of five (5) presentations meeting the

objectives of the National Emergency Medical Services Education Standards for Educating EMS Instructors [-Instructional Guidelines and EMS Scope of Practice Model National education [for EMT or EMR] as applicable for level of certification]; and

2. Demonstrated skills from at least five (5) subjects meeting the objectives of the National Emergency Medical Services Education Standards for Educating EMS Instructors. [-Instructional Guidelines and EMS Scope of Practice Model National education for EMT EMT or EMR as applicable for level of certification;

3. Completed all presentations and all skills demonstrations on different topics for a total of ten (10) separate topics; and

4. Attended a minimum of fifty (50) percent of clock hours of the course; and]

(4) <u>Applicants applying for CE [If applying to become a Level</u> III] Educator shall:

(a) [Be certified as a paramedic or higher; and

(b)] Present documented proof of <u>completing a nationally</u> recognized or <u>EMS-TEI</u> instructor <u>course</u>. [instruction in [a minimum of fifty (50) classroom clock hours in a minimum of five (5) different subject areas that shall include instruction in pharmacology, cardiac emergencies, and traumatic injuries,] meeting the objectives of the National Emergency Medical Services Education Standards Instructional Guidelines and EMS Scope of Practice Model for paramedic education.]

(5) The expiration date of an EMS educator certification shall correspond to those established in KRS Chapter 311A and 202 KAR Chapter 7. [

(6) Documented proof of the educator's experience shall be submitted on the Educator Practical Requirements form.]

Section 17. Renewal of EMS Educator Certification. (1) An EMS educator shall be eligible to renew the EMS educator certification if the applicant for renewal:

(a) Has maintained state certification or licensure as a<u>n EMS</u> provider <u>or as a Registered Nurse (RN)</u>, <u>Advanced Practice</u> <u>Registered Nurse (APRN)</u>, <u>Physician (DO or MD)</u>, <u>or Physician</u> <u>Assistant (PA)</u>; at a level equal to or greater than the level at which they are certified as an EMS educator;

(b) Has submitted to the board [written] evidence of completion of all training and education <u>pursuant to</u> [as required by] KRS Chapter 311A;

(c) During the preceding two (2) years, has been actively engaged in instruction and obtained [a minimum of fifty -two (52) contact hours that include] at least four (4) [eight (8)] hours [contact hours] on topics related to methods of instruction (MOI):[. The eight (8) relevant to MOI:

1. May include a board -approved and required educator update; and

2. The chief administrative officer of the EMS-TEI employing the instructor shall provide proof of the courses or contact hours if requested to do so in an audit by the board;]

(d) Is not subject to discipline pursuant to KRS Chapter 311A;

(e) Has paid fees $\underline{pursuant \ to} \ [required \ by] \ 202 \ KAR \ 7:030; and$

(f) Has submitted to the board a completed and signed Educator Renewal [EMS Responder] Application.

(2) The EMS educator shall maintain all training and education documentation outlined in this administrative regulation for two (2) [four (4)] years from the date of completion.

(3) The <u>board [KBEMS]</u> office may audit an EMS educator's continuing education and <u>EMS provider</u> continuing education records.

Section 18. EMS Educator reinstatement. (1) An EMS Educator whose certification has lapsed [for a period not exceeding five (5) years] may reinstate [his certificate]. To reinstate a certificate, the EMS educator shall submit:

(a) A completed: [EMS Responder Application;]

1. CE Educator Reinstatement Application;

2. EMR Educator Reinstatement Application;

3. EMT Educator Reinstatement Application;

4. AEMT Educator Reinstatement Application; or

5. Paramedic Educator Reinstatement Application;

(b) Evidence of at least <u>four (4)</u> [sixteen (16)] hours of training in methodology of instruction (MOI); <u>and</u>

(c) [Written evidence of completion of a board -sponsored EMS Educator orientation course; and

(d)] Payment of the reinstatement fee <u>pursuant to</u> [as established in] 202 KAR 7:030;[-]

(d) Evidence of previous certification as an EMS Educator in Kentucky; and

(e) An applicant shall undergo a background check pursuant to KRS 311A.050 and 311A.100. The background check shall be:

1. National in scope for an applicant not currently certified or licensed at any level in Kentucky;

2. Statewide in scope for an applicant with current certification or licensure in Kentucky;

<u>3. Less than six (6) months old when the applicant submits to</u> the board all requirements for Educator certification; and

4. Provided by a vendor that has been contracted through the board.

(h) An applicant shall not directly submit a background check to meet the requirements of this section. The background check shall be submitted to the board by the company that conducts the background check.[

(2) An EMS Educator whose certification has lapsed for a period exceeding five (5) years shall seek certification as an initial applicant.]

Section 19. Transition for Currently Certified Educators. (1) An educator certified prior to the effective date of this administrative regulation [after October 2012] shall be transitioned as follows:

(a) [(1)]Level I Educator shall be certified as an EMR Educator [EMS instructors shall be certified as Level I educators];

(b) [(2)] Level II Educator shall be certified as an EMT Educator [Instructors shall be certified as Level II Educators];

(c) [(3)] Level III Educator shall be certified as a Paramedic Educator [Currently certified Level III Instructors shall be certified as Level III educators]:

(d) [(4) Level I and Level II shall be certified as Level I and Level II educators]; and[

(5) Level III instructors currently licensed as paramedics shall be certified as Level I, Level II, and Level III educators; and

(6)] Level IIIR Educator shall be certified as Level III Educator. [III instructors currently licensed as RNs or physicians shall be certified as Level IIIR educators.]

Section 20. EMS Educator Reciprocity. (<u>1</u>) A person certified as an EMS <u>Educator</u> [instructor] in another state or US territory shall be eligible for Kentucky EMS <u>Educator</u> [instructor] certification upon [demonstrating]:[

(1) Evidence of certification or licensure as an EMS provider for a minimum of four (4) years at the same level or at a higher level for which they are applying to be a Kentucky EMS educator;

(2) Proof of four (4) years' educational experience in another state or territory;

(3)] (a) Submission of a completed: [EMS Responder Application;]

1. CE Educator Reciprocity Application;

2. EMR Educator Reciprocity Application;

3. EMT Educator Reciprocity Application;

4. AEMT Educator Reciprocity Application; or

5. Paramedic Educator Reciprocity Application;[

(4) Evidence of at least sixteen (16) board -approved hours of training in methodology of instruction (MOI);

(5) Written evidence of completion of a board -sponsored EMS Educator orientation course;] and

(b) [(6)] Payment of the educator fee <u>pursuant to</u> [as established in] 202 KAR 7:030;

(c) Submission of proof that the applicant is certified as an EMS educator in another state or US territory;

<u>1. The applicant may only apply for educator certification at the same level of Educator certification currently held in another state or U.S. territory.</u>

(d) Submission of certification or license by the board as an EMS provider or license as a Registered Nurse (RN), Advanced

Practice Registered Nurse (APRN), Physician (DO or MD), or Physician Assistant (PA); and

(e) Submission to a background check pursuant to KRS 311A.050 and 311A.100. The background check shall be:

1. National in scope for an applicant not currently certified or licensed at any level in Kentucky;

2. Statewide in scope for an applicant with current certification or licensure in Kentucky;

3. Less than six (6) months old when the applicant submits to the board all requirements for Educator certification; and

4. Provided by a vendor that has been contracted through the board.

5. An applicant shall not directly submit a background check to meet the requirements of this section. The background check shall be submitted to the board by the company that conducts the background check.

Section 21. EMS Educator Temporary Certification.

(1) An EMS educator applicant holding EMS educator certification or licensure from another state or US territory may be granted a temporary certification in Kentucky upon submission of the EMS Responder Application.

(2) A temporary card shall not be valid for more than one (1) year.

(3) At the end of one (1) year, an applicant for reciprocity who has not completed the requirements established in Section 18 of this administrative regulation shall not be eligible for an extension or renewal of the temporary certification period.

(4) An Applicant failing to meet the time limit for obtaining certification through reciprocity shall seek certification as a Kentucky EMS Educator by completing all requirements for initial certification.

Section 22. EMS Evaluator.

(1) An applicant for certification as an EMS evaluator shall:

(a) 1. Be currently certified as a Level I, Level II, or Level III EMS educator; or

2. Hold current unrestricted licensure in a state as a physician; (b) Have completed a board -approved evaluator training

program; (c) Have a minimum of two (2) years' patient care experience prior to serving as an evaluator;

(d) Submit a completed EMS Responder Application; and

(e) Have paid all fees required by 202 KAR 7:030.

(c) Have paid all rees required by 202 KAR 7:030

(2) The certification period of an EMS evaluator shall be contemporaneous with the expiration date of a certificate or license issued by the board, the KBN or KBML, or the state that issues his or her license.

(3) An EMS evaluator shall be certified as:

(a) Level I, which qualifies the evaluator to assess EMR candidates for certification;

(b) Level II, which certifies the evaluator to assess EMT and EMR candidates for certification; or

(c) Level III, which certifies the individual to evaluate paramedic, EMT, AEMT, and EMR candidates for certification or licensure. A licensed physician or registered nurse who is not also a licensed or certified EMS provider shall evaluate paramedics only. A person certified as an A-EMT may evaluate A-EMTs, EMTs, and EMRs.

(4) An Individual shall not be endorsed as an EMS evaluator at a level greater than the level at which certified or licensed as an EMS educator.

Section 23. Renewal of EMS Evaluator Endorsement. A person who holds an endorsement as an EMS evaluator shall be eligible to renew the EMS evaluator endorsement if the individual:

(1) Maintains current state certification or licensure as a provider:

(2) During the certification period, participates in a minimum of two (2) separate evaluations [on two (2) separate dates] or attends a board -sponsored evaluator class;

(3) Is not subject to discipline pursuant to KRS Chapter 311A;

(4) Submits to the board a completed EMS Responder

Application; and

(5) Pays all fees required by 202 KAR 7:030.]

Section <u>21</u> [24]. Educator [and Evaluator] Oversight. <u>The board</u> [KBEMS] may conduct <u>unscheduled</u> [scheduled or, if part of an official investigation, unscheduled] visits to an EMS educator's classroom or to an EMS <u>psychomotor examination</u> [evaluation] site to verify compliance with KRS Chapter 311A and 202 KAR Chapter 7, instructional quality, and evaluative standards required by this administrative regulation.

Section <u>22</u> [25]. Incorporation by reference. (1) The following material is incorporated by reference:

(a) "Training and Educational Institution (TEI) <u>Application in</u> <u>KEMSIS</u>", <u>2019</u> [KBEMS-E14,] July [2012];

(b) "Course Notification <u>Application in KEMSIS</u>", <u>July 2019</u> [KBEMS-E22, September 2012];

(c) "<u>Initial</u> Educational [Institution] Course Roster", <u>July 2019</u> [KBEMS-E23, September 2012];

(d) "National Emergency Medical Services Education Standards[<u>- Instructional Guidelines</u>]", National Highway Traffic <u>Safety Administration</u> [Association], DOT HS 811 077A, January 2009;

<u>1. "National Emergency Medical Services Education</u> Standards-Emergency Medical Responder Instructional Guidelines", National Highway Traffic Safety Administration, DOT HS 811 077B, January 2009;

2. "National Emergency Medical Services Education Standards-Emergency Medical Technician Instructional Guidelines", National Highway Traffic Safety Administration, DOT HS 811 077C, January 2009;

<u>3. "National Emergency Medical Services Education</u> <u>Standards-Advanced Emergency Medical Technician Instructional</u> <u>Guidelines", National Highway Traffic Safety Administration, DOT</u> <u>HS 811 077D, January 2009;</u>

4. "National Emergency Medical Services Education Standards-Paramedic Instructional Guidelines", National Highway Traffic Safety Administration, DOT HS 811 077E, January 2009.

(e) "<u>National EMS Scope of Practice Model</u>", National Highway Traffic <u>Safety Administration</u> [Association], DOT HS 810 657, February 2007;

(f) <u>"National EMS Scope of Practice Model"</u>, National Highway <u>Traffic Safety Administration</u>, DOT HS 812 666, February 2019 ["EMS Responder Application", KBEMS-E1, September 2012];

(g) <u>"National Guidelines for Educating EMS Instructors"</u>, <u>National Highway Traffic Safety Administration</u>, <u>August 2002</u> ["Certified Educator", KBEMS-E24, September 2012]; [and]

(h) <u>CoAEMSP Interpretations of theStandards and Guidelines</u>", <u>February 2019</u> ["Educator Practical Requirements", KBEMS-E20, July 2012];

(i) "Lecture and Skills Verification Form", July 2019;

(j) "Final Educational Course Roster", July 2019;

(k) "Continuing Education Course Student Roster", July 2019;

(I) "Course Change Notification Application" in KEMSIS, July 2019:

(m) "Psychomotor Exam Application" in KEMSIS, July 2019;

(n) "Comprehensive Skill Evaluation Report", July 2019;

(o) "CE Educator Initial Application" in KEMSIS, July 2019;

(p) "EMR Educator Initial Application" in KEMSIS, July 2019;

(q) "EMT Educator Initial Application" in KEMSIS, July 2019;

(r) "AEMT Educator Initial Application" in KEMSIS, July 2019; (s) "Paramedic Educator Initial Application" in KEMSIS, July

(t) "CE Educator Reciprocity Application" in KEMSIS, July 2019;

(u) "EMR Educator Reciprocity Application" in KEMSIS, July 2019;

(v) "EMT Educator Reciprocity Application" in KEMSIS, July 2019;

(w) "AEMT Educator Reciprocity Application" in KEMSIS, July 2019;

(x) "Paramedic Educator Reciprocity Application" in KEMSIS, July 2019;

2019:

(y) "CE Educator Reinstatement Application" in KEMSIS, July 2019;

(z) "EMR Educator Reinstatement Application" in KEMSIS, July 2019:

(aa) "EMT Educator Reinstatement Application" in KEMSIS, July 2019;

(bb) "AEMT Educator Reinstatement Application" in KEMSIS, July 2019;

(cc) "Paramedic Educator Reinstatement Application" in KEMSIS, July 2019; and

(dd) "Educator Renewal Application" in KEMSIS, July 2019.

(2) This material may be inspected, [copies, or] obtained, or copied, subject to applicable copyright law, at the [Kentucky Community and Technical College,] Office of[for] the Kentucky Board of Emergency Medical Services, <u>118 James Court</u>, Lexington, Kentucky 40505, by appointment [300 north Main Street, Versailles, Kentucky 40383], Monday through Friday, <u>8[8:30]</u> a.m. to 4:30 p.m.

PHILIP DIETZ, Chairperson

APPROVED BY AGENCY: September 17, 2020 FILED WITH LRC: October 1, 2020 at noon

CONTACT PERSON: Jeffrey S. Walther, Legal Counsel, Kentucky Board of Emergency Medical Services, Walther, Gay & Mack, PLC; 163 East Main Street, Suite 200, Lexington, Kentucky 40588, phone (859) 225-4714, fax (859) 225-1493, email: administrativeregulations@wgmfirm.com.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Jeffrey S. Walther

(1) Provide a brief summary of: (a) What this administrative regulation does: KRS 311A.110, KRS 311A.115, KRS 311A.120, and KRS 311A.125 require the board to promulgate administrative regulations establishing standards related to the training and education of emergency medical services personnel. KRS 311A.130 requires proper inservice and in-house in-service training and education. KRS 311A.025 requires the board to establish levels of certification. This administrative regulation establishes requirements for an organization to be approved by the board as an Emergency Medical Service Training and Education Institute (EMS-TEI) and also establishes standards for the certification of emergency medical services educators and providers.

(b) The necessity of this administrative regulation: KRS 311A.110, KRS 311A.115, KRS 311A.120, and KRS 311A.125 require the board to promulgate administrative regulations establishing standards related to the training and education of emergency medical services personnel. KRS 311A.130 requires proper in-service and in-house in-service training and education. KRS 311A.025 requires the board to establish levels of certification. This administrative regulation is necessary to establish requirements for an organization to be approved by the board as an Emergency Medical Service Training and Education Institute (EMS-TEI) and establish standards for the certification and recertification of emergency medical services educators and providers.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 311A.110, KRS 311A.115, KRS 311A.120, and KRS 311A.125 require the board to promulgate administrative regulations establishing standards related to the training and education of emergency medical services personnel. KRS 311A.130 requires proper in-service and in-house in-service training and education. KRS 311A.025 requires the board to establish levels of certification. This administrative regulation conforms to the content of these statutes by establishing requirements for an organization to be approved by the board as an Emergency Medical Service Training and Education Institute (EMS-TEI) and establishing standards for the certification and recertification of emergency medical services educators and providers.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: KRS

311A.110, KRS 311A.115, KRS 311A.120, and KRS 311A.125 require the board to promulgate administrative regulations establishing standards related to the training and education of emergency medical services personnel. KRS 311A.130 requires proper in-service and in-house in-service training and education. KRS 311A.025 requires the board to establish levels of certification. This administrative regulation will assist in the effective administration of these statutes by establishing requirements for an organization to be approved by the board as an Emergency Medical Service Training and Education Institute (EMS-TEI) and establishing standards for the certification and providers.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment will modify and update educational mandates for all levels of EMS professionals entering the field, as well as regulatory requirements for EMS training and educational institutions, educators, and renewal requirements for educators and training and educational institutions.

(b) The necessity of the amendment to this administrative regulation: Educational standards for the EMS professions have been updated across the nation over the last few years. The amendments to this administrative regulation align with nationally accepted educational standards and training center requirements.

(c) How the amendment conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 311A.025, KRS 311A.110, KRS 311A.115, KRS 311A.120, KRS 311A.125, KRS 311A.130 by establishing requirements for an organization to be approved by the board as an Emergency Medical Service Training and Education Institute (EMS-TEI) and establishing standards for the certification and recertification of emergency medical services educators and providers.

(d) How the amendment will assist in the effective administration of the statutes: KRS 311A.020 requires the board to establish procedures and processes for committees and subcommittees. This administrative regulation will assist in the effective administration of KRS 311A.025, KRS 311A.110, KRS 311A.115, KRS 311A.120, KRS 311A.125, KRS 311A.130 by establishing requirements for an organization to be approved by the board as an Emergency Medical Service Training and Education Institute (EMS-TEI) and establishing standards for the certification and recertification of emergency medical services educators and providers.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The Kentucky Board of Emergency Medical Services, its members, and staff, local governments, emergency medical services providers, emergency medical services providers, emergency medical services personnel will be affected by this administrative regulation.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The Kentucky Board of Emergency Medical Services, its members, staff, and licensed agencies shall conform to the procedures and standards established by this administrative regulation regarding approval as an Emergency Medical Service Training and Education Institute (EMS-TEI) and certification and recertification as emergency medical services educators and providers.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost to any entity identified in question (3).

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): All entities will benefit from enhanced educational delivery guidance.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation: There will be no cost to the administrative body to implement this administrative regulation.

(a) Initially: There will be no cost to the administrative body to implement this administrative regulation.

(b) On a continuing basis: There will be no cost to the administrative body to implement this administrative regulation.

(6) What is the source of funding to be used for the implementation and enforcement of this administrative regulation: No funding source is necessary to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This regulation did not establish any fees.

(9) TIERING: Is tiering applied? Tiering is not applied to this administrative regulation because this amendment applies equally to all licensed agencies.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Emergency Medical Services, its members, and staff, local governments, emergency medical services providers, emergency medical services educators, and emergency medical services personnel will be affected by this administrative regulation.

2. Identify each state or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 311A.110, KRS 311A.115, KRS 311A.120, and KRS 311A.125 require the board to promulgate administrative regulations establishing standards related to the training and education of emergency medical services personnel. KRS 311A.130 requires proper in-service and in-house in-service training and education. KRS 311A.025 requires the board to establish levels of certification. This administrative regulation establishes requirements for an organization to be approved by the board as an Emergency Medical Service Training and Education Institute (EMS-TEI) and also establishes standards for the certification and recertification of emergency medical services educators and providers.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will generate no revenue for the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will generate no revenue for subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not impose any costs on state or local government.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not impose any costs on state or local government.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): This administrative regulation will not generate revenue.

Expenditures (+/-): This administrative regulation will not impose any costs.

Other Explanation:

PUBLIC PROTECTION CABINET Department of Alcoholic Beverage Control (Amended After Comments)

804 KAR 4:415. Direct shipper license.

RELATES TO: KRS 243.027, 243.028, 243.029, 243.030(33), 244.050, 244.440, 244.585; 804 KAR 4:015, 804 KAR 4:100, 804 KAR 4:410.

STATUTORY AUTHORITY: KRS 241.060, KRS 243.027

NECESSITY, FUNCTION, AND CONFORMITY: KRS 243.027 authorizes the Department of Alcoholic Beverage Control to set forth the requirements and the form for a direct shipper license application. KRS 243.027(3)(c) authorizes the Department to establish through regulation what information the Department determines to be necessary to implement and administer the direct shipper license. KRS 243.027(6)(a) authorizes the department to reduce unlicensed deliveries and shipments of alcoholic beverages in the state. KRS 241.060(1) authorizes the Department to promulgate reasonable administrative regulations governing procedures relative to application for licenses as well as the supervision and control of the trafficking of alcoholic beverages. To protect the public health and safety of Kentucky citizens, this administrative regulation establishes requirements for the direct shipper license and the privileges and responsibilities of a direct shipper license.

Section 1. Qualifications. To qualify for a direct shipper license, the applicant shall:

(1) Hold either a current license, permit, or other authorization to manufacture alcoholic beverages in the state where it is located or a current license in this state under KRS 243.212 or 243.215 to supply alcoholic beverages;

(2) Hold a current permit or authorization under the Federal Alcohol Administration Act as follows:

(a) If a manufacturer other than a brewery, a basic permit to produce or manufacture beverage alcohol;

(b) If a manufacturer that is a brewery, a brewer's notice to produce or manufacture malt beverages; or

(c) If an importer, wholesaler, or distributor licensed as a supplier under KRS 243.212 or 243.215, a basic importer's[importers] permit for the purpose of directly shipping only those products for which the applicant is designated the primary source of supply under the applicant's supplier license[to import beverage alcohol];

(3) Complete the online direct shipper license application via the department's licensing portal at https://abc-portal.ky.gov/s/kyabcnewlicensetype;

(4) Provide the address and a description of the premises from which the applicant will ship alcoholic beverages to consumers, and documentation showing ownership or possession of the premises under a written agreement;

(5) Pay the annual license fee established in KRS 243.030(33);

(6) Disclose all of the applicant's current alcohol-related licenses, permits, and authorizations granted by this state, the federal government, and, if applicable, the state in which the applicant manufactures alcoholic beverages;

(7) Disclose all convictions for violations of alcoholic beverage laws, or misdemeanors directly or indirectly attributable to the use of alcoholic beverages or the use or trafficking in controlled substances, in the last two (2) years in any state, by the applicant or the applicant's officers, directors, or members or managers as defined in KRS 275.015;

(8) Disclose all convictions or sentences served for felonies of any kind by the applicant or the applicant's officers, directors, or members or managers as defined in KRS 275.015, in the last five (5) years;

(9) Complete all registration requirements with respect to payment of any applicable excise tax, state or local sales or use tax, local regulatory license fee, or other tax owed in this state to

directly ship alcoholic beverages to consumers in this state; and

(10) Consent to the jurisdiction of the Commonwealth of Kentucky for purposes of enforcement of KRS Chapters 241 to 244.

Section 2. Prohibited substantial interests. A direct shipper license applicant and direct shipper licensee shall comply with 804 KAR 4:015 and for that purpose shall be considered a "manufacturer" as defined in 804 KAR 4:015.

Section 3. Licensed Premises.

(1) The licensed premises described in a direct shipper license application may be different from the premises where the applicant is licensed, permitted, or otherwise authorized to manufacture or supply alcoholic beverages.

(2) If the direct shipper licensee will use the licensed premises described in the direct shipper license application for storage of alcoholic beverages incidental to shipment, such premises shall also comply with the laws of the jurisdiction in which it is located in order to store[be licensed or otherwise authorized for storage of] the alcoholic beverages to be shipped.

(3) <u>Direct shipper licensees may engage in transportation</u> of their products as permitted by their[If, as described in subsection (1), the licensed premises described in the direct shipper license application is different from a direct shipper licensee's manufacturing or supplying premises, the direct shipper licensee may transport alcoholic beverages between the licensed premises described in the direct shipper license application and the licensee's manufacturing premises, subject to the constraints of the direct shipper's] license, permit, or authorization to manufacture or supply alcoholic beverages.

Section 4. Minimum Production. A manufacturer that is either a direct shipper license applicant or a direct shipper licensee, and who intends to ship wine or distilled spirits, shall meet the minimum quantities of production set forth in KRS 243.155(2) and KRS 243.120(2)(a) as applicable.

Section 5. Brand Registration. In accordance with 804 KAR 4:410, a direct shipper licensee shall register with the department all brands the licensee intends to ship <u>to consumers</u> in[-or into] this state[<u>-that the licensee has not already registered under another license issued by the department</u>].

Section 6. Independent Contractors. A direct shipper licensee shall not contract with an independent contractor or agent who has, or would have, a substantial interest prohibited under 804 KAR 4:015 if the independent contractor or agent is treated as a "manufacturer" as defined in 804 KAR 4:015.

Section 7. Records. A direct shipper licensee shall comply with the record retention and audit requirements set forth in 804 KAR 4:100, except a licensee shall maintain such records for a minimum of three (3) years. The licensee shall make available for inspection all records regarding direct shipment to Kentucky consumers at the request of the department.

Section 8. Minimum Price. A direct shipper licensee shall sell alcoholic beverages at a price no less than <u>the cost of production[current wholesale price, if a current wholesale price is available,]</u> in accordance with KRS 244.050.

ALLYSON C TAYLOR, Commissioner

KERRY B. HARVEY, Secretary

APPROVED BY AGENCY: October 15, 2020

FILED WITH LRC: October 14, 2020 at 11:14 a.m.

CONTACT PERSON: Joshua Newton, General Counsel, Department of Alcoholic Beverage Control, 500 Mero Street, 2 NE #226, Frankfort, Kentucky 40601, phone (502) 782-0770, fax (502) 564-4850, email Joshua.Newton@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Joshua Newton

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements and process to apply for the license to ship alcoholic beverages direct to consumers created by House Bill 415, Ky Acts ch. 80, passed in April 2020, and places restrictions upon licensees that follow from that act and other Alcoholic Beverage Control laws under KRS chapters 241 to 244.

(b) The necessity of this administrative regulation: KRS 243.027 requires that the department promulgate a regulation to set forth the requirements for a direct shipper license application and to describe any other information the department determines to be necessary to implement and administer the direct shipper licensing program.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation provides detailed requirements to file an application for a direct shipper license as well as other information necessary to implement and administer the program. Additional restrictions included in the regulation bring the requirements for direct shipper licensees into conformity with the requirements of other licenses issued by the Department, per the KRS 243.027(5)(f) direction that licenses are held contingent on obeying all laws and administrative regulations of the origin state and destination state, and the KRS 243.027(4) requirement that the Department use the same standards relating to causes for license denial as those it uses for similarly situated in-state applicants.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation is required for the issuance of direct shipper licenses, as it describes the requirements for the successful application for a direct shipper license and provides additional restrictions and requirements that will assist in reducing unlicensed shipments and promulgating reasonable administrative regulations relative to applications for licenses and governing the supervision and control of traffic in alcoholic beverages as required by KRS 243.027(6)(a) and KRS 241.060(1).

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: NA

(b) The necessity of the amendment to this administrative regulation: NA

(c) How the amendment conforms to the content of the authorizing statutes: NA

(d) How the amendment will assist in the effective administration of the statutes: NA

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The direct shipper license affects an unknown number of individuals, businesses, and organizations. Forty-four (44) states including Kentucky now permit some form of direct shipping of alcoholic beverages, and the direct shipper license may affect them all, along with an unknown number of local governments. The administrative regulation potentially affects all of the Department's approximately 1,300 licensed alcoholic beverage manufacturers and suppliers as well as any of thousands of licensed alcoholic beverage manufacturers or suppliers outside of Kentucky by providing them with the means to apply for a license and requirements they must meet under the license to ship direct to consumers alcoholic beverages under brands they own or for which they have exclusive license. It also affects all alcoholic beverage consumers in Kentucky and in other states that permit direct-to-consumer shipping by creating licensure and other requirements by which alcoholic beverage manufacturers and suppliers in and out of Kentucky may become licensed to ship alcoholic beverages directly to them. Additionally, it affects the Department of Alcoholic Beverage Control, and local alcoholic beverage control boards.

(4) Provide an analysis of how the entities identified in the

previous question will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions each of the regulated entities have to take to comply with this regulation or amendment: Regulated entities will not be required to undertake any action to comply with this regulation unless they apply for a direct shipper license. Regulated entities who wish to ship alcoholic beverages direct to consumers will have to complete an online application, pay an annual license fee, disclose a number of documents, including proof of ownership or possessory interest in the premises to be licensed under a written agreement, their criminal background checks, their alcoholic beverage licenses issued by Kentucky, the federal government, and their home state if not Kentucky, provide an address and description of the premises to be licensed, and register with all states and localities to which they intend to ship to pay appropriate taxes and fees to ship to them. Regulated entities who wish to ship will also need to register the brands they intend to ship to consumers in [and into]Kentucky with the Department, and out-of-state regulated entities will need to meet minimum production requirements that in-state regulated entities must meet, as well as other restrictions that prohibit interlocking substantial interests, contracting with independent contractors with prohibited interlocking substantial interests, and pricing alcoholic beverages for shipment at less than the price at which the alcoholic beverage costs to produce[sells at wholesale]. Additionally, the regulation puts requirements on the duration regulated entities must retain records and clarifies potential ambiguity regarding the location of a regulated entity's licensed premises.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: Compliance with this administrative regulation will cost each entity at least the amount of the application fee under KRS 243.030(33), but additional costs are unknown at this time.

(c) As a result of compliance, what benefits will accrue to the entities: If the regulated entities comply with the regulation, they will have submitted a complete application for a direct shipper license, which, if granted, will result in the issuance of a license to ship limited quantities of alcoholic beverages directly to consumers in Kentucky. Further, by complying with the regulation, regulated entities who are granted direct shipper licenses may avoid enforcement actions by the Department that may affect their direct shipper license.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There has been no additional cost for the Department to implement this regulation initially, as the work to gather requirements, develop, and test the implementation of the online application was performed by existing employees and contractors.

(b) On a continuing basis: The Department does not know at this time how much it will cost to implement this regulation on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Enforcement of this administrative regulation will be funded by the statutory licensing fees paid by applicants under this regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: At this time, no increase in fees or funding will be necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation did not establish any fees, and did not directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Explain why or why not. Tiering is not applied because this will affect all regulated entities equally.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government

(including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department of Alcoholic Beverage Control and local Alcoholic Beverage Control administrators.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 243.027, 243.028, 243.029, 241.060(1).

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The specific dollar estimate of revenue this administrative regulation will generate cannot yet be determined. However, potentially thousands of producers in Kentucky and across the country may seek to engage in direct shipment and if so must each pay the current \$100 fee for a direct shipper license.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The specific dollar estimate of revenue this administrative regulation will generate cannot yet be determined. However, the current \$100 fee for a direct shipper license must be paid annually and thus will continue to generate revenue.

(c) How much will it cost to administer this program for the first year? Costs to administer this program are currently unknown. The Department will have costs associated with modification and maintenance of the online direct shipper application and database for accepting applications. The Department will also have unknown costs to develop enforcement protocols and procedures and enforce the regulation. The Department does not know if these costs will exceed current budgetary estimates.

(d) How much will it cost to administer this program for subsequent years? Costs to administer this program in the future are currently unknown.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

PUBLIC PROTECTION CABINET Department of Charitable Gaming (Amended After Comments)

820 KAR 1:050. Raffles.

RELATES TO: KRS 238.545, 238.550 STATUTORY AUTHORITY: KRS 238.515

NECESSITY, FUNCTION, AND CONFORMITY: KRS 238.515 authorizes the Department of Charitable Gaming to establish and enforce reasonable standards for the conduct of charitable gaming and to promulgate administrative regulations necessary to implement KRS Chapter 238. This administrative regulation establishes standards for the conduct of raffles.

Section 1. Raffle Ticket Construction. (1) Raffle tickets shall have a detachable section or duplicate ticket and shall be consecutively numbered. If raffle tickets are sold electronically, the charitable organization selling the tickets shall provide all purchasers with a physical ticket or electronic communication that contains the information required by subsection (2).

(2) The detachable section or duplicate of the ticket shall bear a duplicate number corresponding to the number on the ticket and shall provide space for the purchaser's name, complete address, and telephone number. (3) The following information shall be on each ticket:

(a) The date and time for each drawing;

(b) The location of each drawing;

(c) The name of the charitable organization conducting the raffle;(d) The charitable organization's license number or exemption number;

(e) The price of the ticket; and

(f) Each prize to be awarded with a fair market value over \$500.

(4) The requirements of subsections (2) and (3) of this section shall be waived if:

(a) The raffle tickets sell for five (5) dollars or less, or

(b) The raffle sales are initiated and concluded and all winners are selected at a licensed charity fundraising event or a licensed special limited charity fundraising event.

Section 2. Raffle Prizes. (1) A charitable organization conducting a raffle in which real or personal property prizes are to be awarded shall be responsible for the transfer and delivery of the prize without lien or interest of others.

(2) All raffle prizes shall be awarded as indicated on the raffle ticket unless the event at which the raffle was to be conducted is postponed. If the raffle is postponed, all reasonable efforts shall be made to notify ticket holders of the new drawing date.

(3) If the prize to be awarded is the jackpot of a progressive raffle board, the charitable organization's charitable gaming session records shall report in the gross receipts total all startup cash, monies derived from raffle ticket sales, and any other contribution to the jackpot.

Section 3. Conduct of Raffles. (1) Any person holding a raffle ticket shall be permitted to observe the raffle drawing. <u>A charitable organization may broadcast a raffle drawing via a verifiable online live streaming service to provide ticket holders an opportunity to view the drawing if the charitable organization provides purchasers instructions for viewing the drawing at the time tickets are purchased.</u>

(2) A person shall not be required to be present at a raffle drawing in order to be eligible for the prize drawing.

(3) For raffles using paper tickets, each [Each] ticket seller shall return to the charitable organization the stubs or other detachable sections or duplicates of all tickets sold prior to the drawing.

(4) For raffles using paper tickets, before [Before] drawing, the charitable organization shall place the seller's portion of each ticket sold into a receptacle from which the winning tickets are to be drawn. The receptacle shall be designed so that each ticket placed in it has an equal chance to be drawn.

(5) If a charitable organization uses electronic raffle software to conduct a raffle, the charitable organization shall ensure that the electronic raffle software has been:

(a) Purchased, leased, or otherwise obtained from a distributor licensed by the department;

(b) Manufactured by a manufacturer licensed by the department;

(c) Certified by an independent testing lab; and

(d) Approved by the department for use in the Commonwealth.

(6) A charitable organization shall conduct a raffle entirely with **traditional** paper tickets or entirely with **an** electronic **or online raffle system [tickets]**: a charitable organization shall not use both paper and electronic tickets in the same raffle, except for paper receipts or bearer tickets generated by an electronic or online raffle system in compliance with this regulation.

Section 4. Claiming Raffle Prizes. (1) If the winner is not present at the drawing, the charitable organization shall notify the winner within seven (7) days of the drawing that the winner shall claim the prize within thirty (30) days.

(2) If a winner does not wish to claim the prize but wishes to donate it to the charitable organization, the charitable organization shall obtain a written statement of the winner's intention within the thirty (30) day period. A charitable organization shall not accept the donation to the charitable organization of a prize won if doing so

would violate KRS 238.540.

(3) If a raffle winner does not claim the prize or donate it to the charitable organization within thirty (30) days after having been contacted by certified mail, or if the raffle winner is ineligible by law to claim the prize, the charitable organization shall notify the department and draw another ticket in the presence of department personnel.

(4) The requirements of subsections (1), (2), and (3) of this section shall be waived, and the charitable organization shall be allowed to draw tickets until a winner is present if:

(a) The raffle tickets sell for five (5) dollars or less;

(b) The raffle sales are initiated and concluded and all winners are selected at a licensed charity fundraising event; or

(c) The raffle sales are initiated and concluded and all winners are selected at a licensed special limited charity fundraising event.

Section 5. Electronic Raffle Definitions. (1) "Bearer ticket" means an electronic or paper ticket that contains one or more draw numbers purchased.

(2) "Counterfoil" means an electronic record or paper ticket stub, also known as a barrel ticket, which will be drawn to determine a winner and contains a single draw number matching the player's purchased bearer ticket and may, depending on the type of raffle, contain the name, address, or telephone number of the player.

(3) "Draw number" means a uniquely identifiable number that is provided to the purchaser for each chance purchased and may be selected as the winning number for the raffle.

(4) "Electronic raffle system" means computer software and related equipment used by raffle licensees to sell tickets, account for sales, and facilitate the drawing of tickets to determine the winners.

(5) "Raffle sales unit" (or "RSU") means a portable and/or wireless device, a remote hardwired connected device or a standalone cashier station that is used as a point of sale for bearer tickets.

(6) "Validation number" means a unique number which may represent one or more draw numbers that will be used to validate the winning number for the raffle.

Section 6. Electronic Raffle System Standards. (1) Each electronic raffle system shall have a device or facility that provides for the sale of bearer tickets and the collection and accounting tools needed to track all sales initiated through the raffle system. The system shall have the ability to support all RSUs, whether they are hard-wired or connected wirelessly, to ensure that each RSU sends or transmits all ticket sales to the system. The system shall have the ability to facilitate winner selection by either manual or electronic means.

(2) Time Limits: The electronic raffle system software must be capable of setting time limits for when tickets may be purchased for a raffle drawing.

(3) Configuration Changes: After the commencement of a raffle, the electronic raffle system software shall not allow changes to parameters which may affect the integrity of the raffle.

(4) Bearer Tickets: After the payment of a fee, participants shall receive a bearer ticket for one or more chances to win a raffle drawing. The bearer ticket shall be printed with the information required by Section 1(2) of this administrative regulation and:

(a) The date and time (in twenty-four (24) hour format showing hours and minutes) that the ticket was purchased;

(b) All unique draw numbers purchased for the raffle;

(c) The RSU identifier from which the ticket was generated; and

(d) A unique validation number or barcode.

(5) Validation Numbers: The algorithm or method used by the electronic raffle system to generate the bearer ticket validation number must be unpredictable and ensure against duplicate validation numbers for the raffle currently in progress.

(6) Voiding a Ticket: The electronic raffle system shall be designed to flag or otherwise identify a voided bearer ticket and its corresponding draw number. The system shall record at a minimum the draw numbers and the validation number from the

voided bearer ticket. Voided draw numbers shall not be able to be resold or reissued for that raffle.

(7) Counterfoils: Where a manual draw is used to determine a winner, all counterfoils used in a raffle drawing must be the same size, shape, and weight. A counterfoil shall be printed or stored electronically for each purchased draw number. If an electronic random number generator is used to determine the winner of the raffle drawing, a printed counterfoil is not required. A counterfoil must only contain one draw number and shall contain the following information, which matches the bearer ticket issued to the player:

(a) Event Identifier or Location;

(b) The draw number;

(c) Issued date and time (in twenty-four (24) hour format showing hours and minutes);

(d) Value or cost of the bearer ticket; and

(e) Unique validation number or barcode.

(8) Reprinting of Counterfoils: Where the system supports the reprinting of counterfoil tickets, this facility shall require additional supervised access controls, and the draw numbers for all reprinted counterfoils shall be flagged in the system as reprints.

(9) Raffle Prize Displays: An electronic raffle system may include a raffle prize display that can be viewed by participants of the raffle that displays the raffle prize and the current progression of the prize. The electronic raffle system may have multiple raffle awards displayed in an alternating fashion.

(10) Electronic Raffle Drawing Requirements: A raffle drawing shall be held at a date, time, place stated on the charitable organization's license or certificate of exemption. The drawing shall be administered by an officer or chairperson of the charitable organization. A raffle drawing shall only be conducted after:

(a) The close of the raffle; and

(b) All sales and voided sales for the particular raffle purchase period have been reconciled.

(11) Closing the Raffle Purchase Period: The system must be capable of closing off the sale of bearer tickets at a time determined by the operator. No sales of tickets may occur after the raffle purchase period has been closed. The system must be capable of displaying to the operator by way of the RSU device display that all sales from a particular device have been uploaded, transferred or otherwise communicated to the electronic raffle system.

(a) On verification of the sales data transfer, the RSU device must be capable of being reset or closed; and

(b) The RSU must not be enabled for any further sales for the current raffle.

(12) Voided Tickets: Voided tickets shall not be qualified toward any prize. The system shall be capable of reconciling voided sales for the raffle purchase to identify all voided tickets that may be committed to the draw. The system shall record an acknowledgement from the event manager that voided tickets have been reconciled before permitting a winning number to be entered into the system for validation.

(13) Winner Determination: The operator shall conduct an electronic or other approved draw procedure which ensures a randomly selected draw number as a winner from all tickets sold. Each drawn counterfoil shall be verified as a sold and valid ticket. This process shall be repeated for each advertised prize.

(14) Official Drawing Results: Results of the drawing become official and final after the drawn number is verified as a winning bearer ticket for the respective drawing, and is presented to the participants of the raffle. The system shall display the winning draw on all capable display devices that are intended to be viewed by participants.

(15) Winner Verification: Winning tickets shall be verified prior to payout. Participants must present the bearer ticket to an authorized agent for validation with the system. The system shall be capable of verifying the winning draw numbers and shall allow for the validation of draw numbers either manually or through the use of a bar code scanner or equivalent.

(16) System Reporting Requirements: The system shall be capable of producing general accounting reports to include the following information for each draw conducted:

(a) Raffle Drawing Report. A report which includes the

following for each raffle drawing:

Date and time of the event;

2. Organization running the event;

3. Sales information;

4. Prize value awarded to participant;

5. Prize distribution (total raffle sales vs. prize value awarded to participant)

6. Refund totals by event;

7. Draw numbers-in-play count;

8. Winning number(s) drawn (including draw order, call time, and claim status); and

9. All other information required by 820 KAR 1:057.

(b) Exception Report: A report which includes system exception information, including, but not limited to, changes to system parameters, corrections, overrides, and voids;

(c) Bearer Tickets Report: A report which includes a list of all bearer tickets sold including all associated draw numbers, selling price, and RSU identifier;

(d) Sales by RSU: A report which includes a breakdown of each RSU's total sales (including draw numbers sold) and any voided and misprinted tickets;

(e) Voided Draw Number Report: A report which includes a list of all draw numbers that have been voided including corresponding validation numbers;

(f) Raffle Sales Unit Event Log: A report which lists all events recorded for each RSU, including the date and time and a brief text description of the event or identifying code.

(g) Raffle Sales Unit Corruption Log: A report which lists all RSUs unable to be reconciled to the system, including the RSU identifier, RSU operator, and the money collected;

(h) All information required by 820 KAR 1:057.

Section 7. Raffle Sales Unit Standards. (1) After the payment of a fee, participants shall receive a chance to win a raffle drawing. A chance to win a raffle drawing shall be purchased from an attendant-operated Raffle Sales Unit ("RSU").

(a) Attendant-Operated Raffle Sales Unit: A participant may purchase a bearer ticket from an attendant-operated RSU by providing payment for the ticket(s) to the attendant. Upon receiving payment, the attendant will provide the participant the bearer ticket(s) purchased by the participant.

(b) Player-Operated Raffle Sales Unit: A participant may purchase a bearer ticket from a player-operated RSU by following the instructions appearing on the screen of the RSU and providing payment for the ticket(s). Upon payment for the ticket(s), the RSU will issue the corresponding bearer ticket(s) purchased by the participant.

(2) An RSU must be capable of generating and printing a bearer ticket with one or more uniquely identifiable draw numbers.

(a) The system must not generate duplicate draw numbers within the same event.

(b) For each draw number generated, there must be one and only one corresponding counterfoil with the same draw number.

(c) The RSU must be capable of providing a transaction receipt in the form of a bearer ticket to a purchaser.

(3) Access Controls: Access to raffle sales software shall be controlled by a secure logon procedure. It shall not be possible to modify the configuration settings of an RSU without an authorized secure logon.

(4) Touch Screens: Touch screens shall be accurate once calibrated and shall maintain that accuracy for at least the manufacturer's recommended maintenance period.

(5) RSU Interface: The functions of all buttons, touch or click points represented on the RSU interface shall be clearly indicated within the area of the button, or touch/click point and/or within the help menu. There shall be no functionality available through any buttons or touch/click points on the RSU that are undocumented.

(6) Communications: A Raffle Sales Unit must be designed or programmed such that it may only communicate with authorized electronic raffle systems components. The electronic raffle system must have the capability to uniquely identify and authorize each RSU used to sell tickets for a raffle.

(7) Wireless Raffle Sales Units: Communication must only

occur between the RSU and the electronic raffle system via authorized access points.

(8) Printing Bearer Tickets: If the RSU connects to a printer that is used to produce bearer tickets, the bearer ticket shall include information as indicated in Section 1(2). It may be permissible for some of this information to be contained on the ticket stock itself.

(a) The RSU must control the transfer of ticket data sent to the printer, and only transfer ticket data to the printer when sufficient space is available in the printer memory to receive the ticket information.

(b) If a barcode forms part of the validation number printed on the bearer ticket, the printer must support the barcode format and print with sufficient resolution to permit validation by a barcode reader.

(9) Printer Error Conditions: The bearer ticket printer shall be able to detect and indicate to the operator the following error conditions:

(a) Low battery;

(b) Out of paper or paper low;

(c) Printer disconnected -It is permissible for the system to detect this error condition when it tries to print.

(d) If the unit is capable of reprinting a ticket, the reprinted ticket shall clearly indicate that it is a reprint of the original ticket.

(10) Critical Memory Requirements: Critical memory means memory that is used to store all data that is considered vital to the continued operation of the RSU. Critical memory shall be maintained for the purpose of storing and preserving critical data. This includes, but is not limited to:

(a) When not communicating with the system, recall of all tickets sold including, at minimum, draw numbers and validation numbers; and

(b) RSU configuration data.

(11) Maintenance of Critical Memory: Critical memory storage shall be maintained by a methodology that enables errors to be identified. This methodology may involve signatures, checksums, partial checksums, multiple copies, time stamps and/or effective use of validity codes.

(12) Comprehensive Checks: Comprehensive checks of critical memory shall be made on startup and shall detect failures with an extremely high level of accuracy.

(13) Unrecoverable Critical Memory. An unrecoverable corruption of critical memory shall result in an error. Upon detection, the raffle sales unit shall cease to function.

(14) Backup Requirements. The RSU must have a backup or archive capability, which allows the recovery of critical data should a failure occur.

(15) RSU Program Identification: All programs shall contain sufficient information to identify the software and revision level of the information stored on the RSU, which may be displayed via a display screen.

(16) Detection of Program Corruption: RSU programs shall be capable of detecting program corruption and cause the RSU to cease operations until corrected.

(17) Verification of Program Updates: Prior to execution of the updated software, the software must be successfully authenticated on the RSU.

(18) Independent Control Program Verification: The RSU shall have the ability to allow for an independent integrity check of the RSU's software from an outside source and is required for all software that may affect the integrity of the raffle. This must be accomplished by being authenticated by a third-party device or by allowing for removal of the media such that it can be verified externally. This integrity check will provide a means for field verification of the software to identify and validate the program. The test laboratory, prior to device approval, shall evaluate the integrity check method.

Section 8. Random Number Generator Requirements. (1) A random number generator shall reside on a program storage device secured in the logic board of the system. The numbers selected by the random number generator for each drawing shall be stored in the system's memory and be capable of being output

to produce a winning number. The use of an RNG results in the selection of raffle outcomes in which the selection shall:

(a) Be statistically independent;

(b) Conform to the desired random distribution;

(c) Pass industry-standard recognized statistical tests, as chosen by the independent testing laboratory; and

(d) Be unpredictable.

(2) Applied Tests. The test laboratory may employ the use of various recognized tests to determine whether or not the random values produced by the random number generator pass the desired confidence level of 99%. The independent test lab shall choose the appropriate tests on a case by case basis depending on the RNG under review. These tests may include, but are not limited to:

(a) Chi-square test;

(b) Equi-distribution (frequency) test;

(c) Gap test;

(d) Overlaps test;

(e) Poker test;

(f) Coupon collector's test;

(g) Permutation test;

(h) Kolmogorov-Smimov test;

(i) Adjacency criterion tests;

(j) Order statistic test;

(k) Runs tests (patterns of occurrences should not be recurrent);

(1) Interplay correlation test;

(m) Serial correlation test potency and degree of serial correlation (outcomes should be independent of the previous game);

(n) Tests on subsequences; and

(o) Poisson distribution.

(3) Period: The period of the RNG, in conjunction with the methods of implementing the RNG outcomes, must be sufficiently large to ensure that all valid, sold numbers are available for random selection.

(4) Range: The range of raw values produced by the RNG must be sufficiently large to provide adequate precision and flexibility when scaling and mapping.

(5) Background RNG Cycling or Activity Requirement: In order to ensure that RNG outcomes cannot be predicted, adequate background cycling or activity must be implemented between each drawing at a speed that cannot be timed. The rate of background cycling or activity must be sufficiently random in and of itself to prevent prediction.

(6) RNG Seeding or Re-Seeding: The methods of seeding or re-seeding implemented in the RNG must ensure that all seed values are determined securely and that the resultant sequence of outcomes is not predictable.

(a) The first seed shall be randomly determined by an uncontrolled event. After every bearer ticket draw, there shall be a random change in the RNG process (new seed, random timer, delay, etc.). This will verify the RNG does not start at the same value, every time. It is permissible not to use a random seed; however, the manufacturer must ensure that the selection process will not synchronize.

(b) Unless proven to have no adverse effect on the randomness of the RNG outcomes or actually improve the randomness of the RNG outcomes, seeding and re-seeding must be kept to an absolute minimum. If for any reason the background cycling or activity of the RNG is interrupted, the next seed value for the RNG must be a function of the value produced by the RNG immediately prior to the interruption.

(7) Scaling Algorithms. The methods of scaling (i.e. converting raw RNG outcomes of a greater range into scaled RNG outcomes of a lesser range) shall be linear, and shall not introduce any bias, pattern or predictability. The scaled RNG outcomes must be proven to pass various recognized statistical tests as chosen by the independent testing laboratory.

(a) If a random number with a range shorter than that provided by the RNG is required for some purpose within the raffle system, the method of re-scaling, (i.e., converting the number to the lower range), is to be designed in such a way that all numbers within the lower range are equally probable.

(b) If a particular random number selected is outside the range of equal distribution of rescaling values, it is permissible to discard that random number and select the next in sequence for the purpose of re-scaling.

(8) Winning Number Draw: The winning number selection shall only be produced from sold bearer ticket numbers from the current drawing to be available for selection.

(a) Each valid, sold raffle number shall be available for random selection at the initiation of each drawing; and

(b) For raffles which offer multiple awards or drawings with separate buy-ins for each, the winning number selection shall only be produced from sold bearer ticket numbers corresponding with each applicable award or drawing. As winning numbers are drawn, they shall be immediately used as governed by the rules of the raffle (i.e. the bearer tickets are not to be discarded due to adaptive behavior).

(9) No Corruption from Associated Equipment: An electronic raffle system shall use appropriate protocols to protect the random number generator and random selection process from influence by associated equipment, which may be communicating with the electronic raffle system.

Section 9. Electronic Raffle System Server Requirements (1) The Electronic Raffle System Server(s) may be located locally, within a single facility or may be remotely located outside of the facility through a Wide Area Network (WAN).

(2) Physical Security: The servers shall be housed in a secure location that has sufficient physical protection against alteration, tampering or unauthorized access.

(3) Logical Access Control: The electronic raffle system shall be logically secured through the use of passwords, biometrics, or other means certified as secure by the independent testing lab. The storage of passwords, PINs, biometrics, and other authentication credentials shall be secure. The system must have multiple security access levels to control and restrict different classes of access to the electronic raffle system.

(4) Security from Alteration, Tampering or Unauthorized Access: The electronic raffle system shall provide a logical means for securing the raffle data against alteration, tampering, or unauthorized access. The following rules also apply to the raffle data within the Electronic Raffle System:

(a) No equipment shall have a mechanism whereby an error will cause the raffle data to automatically clear. Data shall be maintained at all times regardless of whether the server is being supplied with power.

(b) Data shall be stored in such a way as to prevent the loss of the data when replacing parts or modules during normal maintenance.

(5) Data Alteration: The electronic raffle system shall not permit the alteration of any accounting, reporting, or significant event data without supervised access controls. In the event any data is changed, the following information shall be documented or logged:

(a) Data element altered;

(b) Data element value prior to alteration;

(c) Data element value after alteration;

(d) Time and date of alteration; and

(e) User login to identify the personnel that performed the alteration.

(6) Server Programming: There shall be no means available for an operator to conduct programming on the server in any configuration (e.g. the operator should not be able to perform SQL statements to modify the database). However, network administrators may perform authorized network infrastructure maintenance with sufficient access rights, which include the use of SQL statements that were already resident on the system.

(7) Copy Protection: Copy protection to prevent unauthorized duplication or modification of software, for servers or RSUs, may be implemented provided that:

(a) The method of copy protection is fully documented and provided to the Test Laboratory, who will verify that the protection works as described; or

(b) The program or component involved in enforcing the copy

protection can be individually verified by the methodology described in subsection (17).

(8) Uninterruptible Power Supply Support: Where the server is a stand-alone application, it must have an uninterruptible power supply ("UPS") connected and of sufficient capacity to permit a graceful shut-down and that retains all electronic raffle system data during a power loss. The electronic raffle system server may be a component of a network that is supported by a network-wide UPS provided that the server is included as a device protected by the UPS.

(9) System Clock Requirements: An Electronic Raffle System must maintain an internal clock that reflects the current date and time (in twenty-four (24) hour format showing hours and minutes) that shall be used to provide for the following:

(a) Time stamping of significant events;

(b) Reference clock for reporting; and

(c) Time stamping of all sales and draw events.

(10) System Clock Synchronization Feature: If multiple clocks are supported the system shall have a facility to synchronize clocks within all system components.

(11) RSU Management Functionality: An electronic raffle system must have a master list of each authorized RSU in operation, including at minimum the following information for each entry:

(a) A unique RSU identification number or corresponding hardware identifier (i.e. MAC);

(b) Operator identification; and

(c) Tickets issued for sale, if applicable.

(12) RSU Validation: It is recommended that RSUs be validated at least once per year with at least one method of authentication. The system shall have the ability to remotely disable the RSU after the threshold of unsuccessful validation attempts has been reached.

(13) Counterfoil Printers: Where printed counterfoils are in use, the printer mechanism shall be able to detect and indicate the following error conditions:

(a) Out of paper:

(b) Paper low;;

- (c) Memory Error;
- (d) Printer failure; and
- (e) Printer disconnected.

(14) Printer Disable. At any time during an active draw, the operator shall have the ability to manually disable a printer and remove the printer from the configuration without affecting the remaining printers or any outstanding print requests.

(15) Significant Event Logging. Significant events shall be communicated and logged on the electronic raffle system, which shall include:

(a) Connection/Disconnection of an RSU or any component of the system;

(b) Critical memory corruption of any component of the system. (c) Counterfoil Printer errors:

1. Out of paper/paper low;

2. Printer disconnect/failure; and

3. Printer memory error.

(d) Establishment and failure of communications between sensitive electronic raffle system components.

(e) Significant event buffer full;

(f) Program error or authentication mismatch;

(g) Firewall audit log full, where supported; and

(h) Remote access, where supported.

(16) Significant Event Surveillance or Security Functionality. Each significant event conveyed to the electronic raffle system shall be stored. An electronic raffle system shall provide an interrogation program that enables on-line comprehensive searching of the significant events through recorded data. The interrogation program shall have the ability to perform a search based at least on the following:

(a) Date and time range;

(b) Unique component identification number; and

(c) Significant event identifier.

(17) Storage Medium Backup: The electronic raffle system shall have sufficient redundancy and modularity so that if any single component or part of a component fails, the raffle can continue. Redundant copies of critical data shall be kept on the electronic raffle system with open support for backups and restoration.

(a) All storage shall be through an error checking, nonvolatile physical medium, or an equivalent architectural implementation, so that should the primary storage medium fail, the functions of the electronic raffle system and the process of auditing those functions can continue with no critical data loss.

(b) The database shall be stored on redundant media so that no single failure of any portion of the system would cause the loss or corruption of data.

(18) Recovery Requirements. In the event of a catastrophic failure when the electronic raffle system cannot be restarted in any other way, it shall be possible to reload the electronic raffle system from the last viable backup point and fully recover the contents of that backup, including, but not limited to:

(a) Significant Events;

(b) Accounting information;

(c) Reporting information; and

(d) Specific site information such as employee files, raffle setup, etc.

(19) Verification of System Software. System software components and modules shall be verifiable by a secure means at the system level denoting the program identification and version. The system shall have the ability to allow for an independent integrity check of the components and modules from an outside source and is required for all software that may affect the integrity of the system. This must be accomplished by being authenticated by a third-party device, or by allowing for removal of the media such that it can be verified externally. This integrity check shall provide a means for field verification of the system components and modules to identify and validate the programs or files. The independent testing laboratory, prior to system approval, shall approve the integrity check method.

Section 10. Electronic Raffle System Communication Requirements. (1) Communication Protocol: Each component of an electronic raffle system must function as indicated by the communication protocol implemented. An electronic raffle system must provide for the following:

(a) Communication between all system components must provide mutual authentication between the component and the server.

(b) All protocols must use communication techniques that have proper error detection and recovery mechanisms, which are designed to prevent eavesdropping and tampering. Any alternative implementations will be reviewed on a case-by-case basis, with regulatory approval; and

(c) All data communications critical to the raffle shall employ encryption. The encryption algorithm shall employ variable keys, or similar methodology to preserve secure communication.

(2) Connectivity: Only authorized devices shall be permitted to establish communications between any system components. Electronic raffle systems shall provide a method to:

(a) Verify that the system component is being operated by an authorized user:

(b) Enroll and un-enroll system components;

(c) Enable and disable specific system components.

(d) Ensure that only enrolled and enabled system components participate in the raffle; and

(e) Ensure that the default condition for components shall be un-enrolled and disabled.

(3) Loss of Communications: Raffle sales units (RSUs) may continue to sell tickets when not in communication with the system. Sales taking place on the RSU during a loss of communication with the system shall be logged on the device. The RSU shall deactivate upon detecting the limit of its buffer overflow. Upon the re-establishment of communication, the system shall require the RSU to re-authenticate with the server(s). All tickets sold during communication loss shall be transmitted to the system. Loss of communications shall not affect the integrity of critical memory.

(4) System Security: All communications, including remote

access, must pass through at least one approved application-level firewall and must not have a facility that allows for an alternate network path. Any alternate network path existing for redundancy purposes must also pass through at least one application-level firewall.

(5) Firewall Audit Logs. The firewall application must maintain an audit log and must disable all communications and generate a significant event which meets the requirements as specified in Section 9(13) if the audit log becomes full. The audit log shall contain:

(a) All changes to configuration of the firewall;

(b) All successful and unsuccessful connection attempts through the firewall; and

(c) The source and destination IP Addresses, Port Numbers and MAC Addresses.

(6) Remote Access. "Remote access" means any access from outside the system or system network including any access from other networks within the same establishment. The electronic raffle system shall have the option to disable remote access. Remote access shall accept only the remote connections permissible by the firewall application and electronic raffle system settings. In addition, there shall be:

(a) No unauthorized remote user administration functionality, such as adding users, or changing permissions;

(b) No unauthorized access to any database other than information retrieval using existing functions:

(c) No unauthorized access to the operating system; and

(d) For systems using an electronic random number generator, the electronic raffle system must immediately detect remote access.

(7) The system manufacturer may, as needed, remotely access the electronic raffle system and its associated components for the purpose of product and user support..

(8) Remote Access Auditing. The electronic raffle system must maintain an activity log which updates automatically depicting all remote access information, to include:

<u>(a) Log on name;</u>

(b) Time and date the connection was made;

(c) Duration of connection; and

(d) Activity while logged in, including the specific areas accessed and changes that were made.

(9) Wide Area Network Communications. Wide Area Network ("WAN") communications are permitted as allowed by the regulatory body and shall meet the following requirements:

(a) The communications over the WAN are secured from intrusion, interference and eavesdropping via techniques such as use of a Virtual Private Network (VPN) or encryption; and

(b) Only functions documented in the communications protocol shall be used over the WAN. The protocol specification shall be provided to the Testing Laboratory. (10) Wireless Network Communications. If a wireless

(10) Wireless Network Communications. If a wireless communication solution is utilized, it shall adhere to the following requirements:

(a) Segregation of Networks. Networks used by the electronic raffle systems should be separate and not include other devices that are not part of the electronic raffle system.

(b) Service Set Identifier (SSID). The wireless network name (SSID) used to identify the wireless network should be hidden and not broadcast.

(c) Media Access Control (MAC) Address Filtering. The wireless network should use MAC address filtering as means to validate whether or not a device may connect to the wireless network.

(d) Device Registration. The electronic raffle system should use a device registration method as means to validate whether or not a device is an authorized device on the electronic raffle system.

Section 11. Online Raffle Ticket Sales. (1) All systems used for the sale of raffle tickets through the Internet must meet the requirements contained within this document and the terms and conditions set forth by these regulations for the sale of raffle tickets through the Internet.

(2) Definitions:

(a) "Access control" means the restriction of access to a place or other resource. Locks and login credentials are two mechanisms of access control.

(b) "Address Resolution Protocol ('ARP')" is the protocol used to translate IP addresses into MAC addresses to support communication on a LAN ("Local Area Network"). The Address Resolution Protocol is a request and reply protocol and it is communicated within the boundaries of a single network, never routed across internetwork nodes (connection points, either a redistribution point or an end point for data transmissions).

(c) "Algorithm" means a finite set of unambiguous instructions performed in a prescribed sequence to achieve a goal, especially a mathematical rule or procedure used to compute a desired result. Algorithms are the basis for most computer programming.

(d) "Authentication" means a security measure designed to protect a communications system against acceptance of a fraudulent transmission or simulation by establishing the validity of a transmission, message or originator.

(e) "Bi-Directional" means the ability to move, transfer or transmit in both directions.

(f) "Counterfoil" means an electronic record or paper ticket stub, also known as a barrel ticket, which will be drawn to determine a winner and contains a player's draw number matching the bearer ticket purchased and may, depending on the type of raffle, contain the name, address, or telephone number of the player.

(g) "Crypto-analytic" means an attack against the encryption key (refer to definition of encryption key).

(h) "Cryptographic" means anything written in a secret code, cipher, or the like.

(i) "Distributed Denial of Service ('DDoS')" means a type of Denial of Service ("DoS") attack where multiple compromised systems, usually infected with a destructive software program, are used to target a single system causing a Denial of Service (DoS) attack. Victims of a DDoS attack consist of both the end targeted system and all systems maliciously used and controlled by the hacker in the distributed attack.

(j) "Domain" is a term used to identify one or more IP addresses. A domain name is used in a Uniform Resource Locator ("URL") to identify particular Web pages.

(k) "Encryption" means the reversible transformation of data from the original (the plaintext) to a difficult-to-interpret format (the ciphertext) as a mechanism for protecting its confidentiality, integrity and sometimes its authenticity.

(I) "Encryption key" means a sequence of numbers used to encrypt or decrypt (to decode/decipher) data.

(m) "Firewall" means any number of security schemes that prevent unauthorized users from gaining access to a computer network or that monitor transfers of information to and from the network.

(n) "Geolocation" means identifying the real-world geographic location of an Internet connected computer, mobile device, or website visitor.

(o) "Host" means a computer system that is accessed by a user working at a remote location. Typically, the term is used when there are two computer systems connected by modems and telephone lines. The system that contains the data is called the host, while the computer at which the user sits is called the remote terminal. A computer that is connected to a TCP/IP network, including the Internet. Each host has a unique IP address.

(p) "Hypertext Transfer Protocol ('HTTP')" means the underlying protocol used by the World Wide Web. HTTP defines how messages are formatted and transmitted, and what actions Web servers and browsers should take in response to various commands.

(q) "Internet" means an interconnected system of networks that connects computers around the world via the TCP/IP protocol. TCP/IP protocol is short for Transmission Control Protocol/Internet Protocol, the suite of communications protocols used to connect hosts on the Internet.

(r) "Intrusion Detection System ('IDS')" or "Intrusion Prevention System ('IPS')" means a system that inspects all inbound and outbound network activity and identifies suspicious patterns that may indicate a network or system attack from someone attempting to break into or compromise a system. Used in computer security, intrusion detection refers to the process of monitoring computer and network activities and analyzing those events to look for signs of intrusion in a system.

(s) "Internet Protocol ('IP')" means an identifier for a computer or device on a TCP/IP network.

(t) "Media Access Control ('MAC')" means hardware address that uniquely identifies each node, such as computer or printer, of a network.

(u) "Man-in-the-Middle ('MITM')" means an active Internet attack where the person attacking attempts to intercept, read or alter information moving between two computers.

(v) "Message authentication" means a security measure designed to establish the authenticity of a message by means of an authenticator within the transmission derived from certain predetermined elements of the message itself.

(w) "Online" means being connected to the Internet.

(x) "Online Purchasing Platform" means the raffle system hardware and software which drives the features common to all raffles offered, and which forms the primary interface to the Raffle System for both the patron and the operator. The online purchasing platform provides the patron with the means to register an account, log in to/out of their account, modify their account information, make ticket purchases, request account activity statement/reports, and close their account. In addition, any web pages displayed to the patron that relate to ticket purchasing offered on the raffle system. The online purchasing platform provides the operator with the means to review patron accounts, enable or disable raffles, generate various financial transaction and account reports, input raffle outcomes, enable or disable patron accounts, and set any configurable parameters.

(y) "Protocol" means a set of formal rules describing how to transmit or exchange data, especially across a network. TCP/IP is the standard communications protocol of the Internet and most internal networks.

(z) "Shellcode" means a small piece of code used as the payload (cargo of data transmission) in the exploitation of computer security. Shellcode exploits a vulnerability and allows an attacker the ability to reduce a computer system's information assurance.

(aa) "Security certificate" means information, often stored as a text file, which is used by the Secure Socket Layers ("SSL") protocol to establish a secure connection. A security certificate contains information about whom it belongs to, who it was issued by, valid dates, a unique serial number or other unique identification that can be used to verify the contents of the certificate. In order for an SSL connection to be created, both sides must have a valid security certificate, which is also called a digital ID.

(ab) "Stateful firewall" means a firewall that keeps track of the state of network connections traveling across it. The firewall is programmed to distinguish legitimate packets for different types of connections. Only packets matching a known active connection will be allowed by the firewall; others will be rejected. Stateful inspection, also referred to as Dynamic Packet Filtering, is a security feature often included in business networks,

(ac) "Stateless" means a communications protocol that treats each request as an independent transaction that is unrelated to any previous request so that the communication consists of independent pairs of requests and responses. A stateless protocol does not require the server to retain session information or status about each communications partner for the duration of multiple requests. In contrast, a protocol which requires the keeping of internal state is known as a stateful protocol. Examples of stateless protocols include Internet Protocol (IP) and the Hypertext Transfer Protocol (HTTP).

(2) All online raffle ticket sales systems, software and database requirements must be tested and certified by an independent testing laboratory to meet the applicable requirements set forth in this document and approved by the department.

(3) Operation manuals and service manuals must be expressed in broad terms that are directly relevant to the system

used to sell raffle ticket(s) through the Internet and must be provided at the request of the Department.

(4) Geolocation: The raffle system, online purchasing platform or the patron device must be able to reasonably detect the physical location of an authorized patron attempting to access the service. Third parties may be used to verify the location of patrons.

(5) Inventory: When issued a charitable gaming license to conduct a raffle, the charitable organization shall provide the number of raffle tickets available for sale through the Internet. The raffle system software shall have the ability to set time limits for which tickets may be purchased. Upon completion of the sale of the final raffle ticket for a charitable organization raffle, the raffle must close.

(6) Systems used by the purchaser to obtain raffle ticket(s) through the Internet must be designed to be reasonably impervious to communication errors. Personally identifiable information, sensitive account data and financial information shall be protected over a public network.

(7) Asset Management: All assets housing, processing of communication controlled information, including those comprising the operating environment of the Raffle system and/or its components, should be accounted for and have a designated "owner" responsible for ensuring that information and assets are appropriately classified, and defining and periodically reviewing access restrictions and classifications.

(8) Raffle Equipment Security: Raffle system servers must be located in server rooms which restrict unauthorized access. Raffle system servers shall be housed in racks located within a secure area

(9) Network Security Management: To ensure Purchasers are not exposed to unnecessary security risks by choosing to participate in raffles, these security requirements must apply to the following critical components of the raffle system:

(a) Raffle system components which record, store, process, share, transmit or retrieve sensitive Purchaser information, e.g. credit card/debit card details, authentication information, patron account balances;

(b) Raffle system components which store results of the current state of a Purchaser's purchase order;

(c) Points of entry to and exit from the above systems (other systems which are able to communicate directly with the core critical systems); and

(d) Communication networks which transmit sensitive patron information.

(10) Networks should be logically separated such that there should be no network traffic on a network link which cannot be serviced by hosts on that link.

(a) The failure of any single item should not result in denial of service:

(b) An Intrusion Detection System/Intrusion Prevention System must be installed on the network which can:

1. Listen to both internal and external communications;

2. Detect or prevent Distributed Denial of Services ("DDoS") attacks;

3. Detect or prevent shellcode from traversing the network;

4. Detect or prevent Address Resolution Protocol ("ARP") spoofing; and

5. Detect other Man-in-the-Middle indicators and server communications immediately if detected.

(c) Stateless protocols should not be used for sensitive data without stateful transport (HTTP is allowed if it runs on TCP).

(d) All changes to network infrastructure must be logged;

(e) Virus scanners or detection programs should be installed on all pertinent information systems. These programs shall be updated regularly to scan for new strains of viruses;

(f) Network security shall be tested by a qualified and experienced individual at least once per year; and

(g) Testing shall include testing of the external (public) interfaces and the internal network.

(h) Testing of each security domain on the internal network shall be undertaken separately.

(11) Communication Protocol: Online raffle tickets offered for sale by a charitable organization shall support a defined

communication protocol that ensures purchasers are not exposed to unnecessary security risks when using the Internet for this purpose. Each component of a raffle system must function as indicated by the communication protocol implemented. The system must provide for the following:

(a) All critical data communication shall be protocol based or incorporate an error detection and correction scheme to ensure accuracy of messages received;

(b) All critical data communication shall employ encryption. The <u>encryption algorithm shall employ variable keys or similar</u> methodology to preserve secure communication;

(c) Communication between all system components must provide mutual authentication between the component and the server:

(d) All protocols shall use communication techniques that have proper error detection and recovery mechanisms, which are designed to prevent eavesdropping and tampering.

(e) All data communications critical to raffle ticket sales through the Internet shall employ encryption. The encryption algorithm shall employ variable keys, or similar methodology to preserve secure communication.

(12) Remote Access: Remote access means any access from outside the system or system network including any access from other networks within the same establishment. Remote access shall only be allowed with prior written approval of the department and shall have the option to be disabled. Where allowed, remote access shall accept only the remote connections permissible by the firewall application and online raffle ticket sales settings. In addition, there shall be:

(a) No authorized remote user administration functionality;

(b) No authorized access to any database other than information retrieval using existing functions;

(c) No authorized access to the operating system; and

(d) The raffle system must maintain an activity log which updates automatically depicting all remote access information.

(13) Error Recovery: The system used by a licensed charitable organization to offer the sale of raffle ticket(s) through the Internet must be able to recover messages when they are received in error. This would include inaccurately inputting personal/banking information which would result in the Purchaser being notified that the information is invalid and must require review and corrective measures. In the event of a catastrophic failure when the system cannot be restarted in any other way, it shall be possible to reload the system information from the last viable backup point and fully recover the contents of that backup, including, but not limited to:

(a) Significant events;

(b) Accounting information;

(c) Reporting information; and

(d) Specific site information, including but not limited to employees file and the raffle set-up.

(14) Bi-Directional Requirements: Any system used to sell raffle ticket(s) through the Internet shall be tested by an independent testing laboratory, who shall certify that:

(a) The physical network is designed to provide exceptional stability and limited communication errors;

(b) The system is stable and capable of overcoming and adjusting for communication errors in a thorough, secure and precise manner; and

(c) Information is duly protected with the most secure forms of protection via encryption, segregation of information, firewalls, passwords and personal identification numbers.

(15) Encryption: Security messages that traverse data communications lines must be encrypted using an encryption key or keys to ensure that communications are demonstrably secure against crypto-analytic attacks. The encryption keys or keys used to provide security to the system that provide for the sale of raffle tickets through the Internet must be monitored and maintained. Additionally, there must be a documented process for:

(a) Obtaining or generating encryption keys;

(b) Managing the expiry of encryption keys if encryption keys; (c) Revoking encryption keys;

(d) Securely changing the current encryption keyset; (e) The storage of any encryption keys; and

(f) To recover data encrypted with a revoked or expired encryption key for a defined period of time after the encryption key becomes valid.

(16) Cryptographic Controls: Cryptographic controls shall be implemented for the protection of the following information:

(a) Any sensitive or personally identifiable information shall be encrypted if it traverses a network with a lower level of trust;

(b) Data that is not required to be hidden but must be authenticated shall use some form of message authentication technique;

(c) Authentication must use a security certificate [from an organization] approved by the independent testing laboratory;

(d) The grade of encryption used should be appropriate to the sensitivity of the data;

(e) The use of encryption algorithms shall be reviewed periodically by qualified Management staff to verify that the current encryption algorithms are secure:

(f) Changes to encryption algorithms to correct weaknesses shall be implemented as soon as practical. If no such changes are available, the algorithm shall be replaced; and

(g) Encryption keys must not be stored without being encrypted themselves through a different encryption method and/or by using a different encryption key.

(17) Firewalls. All online raffle systems shall utilize firewalls that comply with the following provisions:

(a) A firewall shall be located at the boundary of any two dissimilar security domains.

(b) All connections to hosts used for the sale of raffle tickets through the Internet shall be housed in a secure data center and must pass through at least one application-level firewall. This includes connections to and from any non-related hosts used by the operator.

(c) The firewall shall be a separate hardware device with the following characteristics:

1. Only firewall-related applications may reside on the firewall; and

2. Only a limited number of accounts may be present on the firewall.

(d) The firewall shall reject all connections except those that have been specifically approved.

(e) The firewall shall reject all connections from destinations which cannot reside on the network from which the message originated.

(f) The firewall shall maintain an audit log of all changes to parameters which control the connections permitted through the firewall.

(g) The firewall shall maintain an audit log of all successful and unsuccessful connection attempts. Logs should be kept for 90 days and a sample reviewed monthly for unexpected traffic.

(h) The firewall shall disable all communication if the audit log becomes full.

(18) Firewall Audit Logs: The audit log shall contain:

(a) All changes to configuration of the firewall;

(b) All successful and unsuccessful attempts through the firewall; and

(c) The source and destination IP addresses, port numbers and MAC addresses.

(19) System Clock: The system used for the sale of raffle tickets through the Internet shall maintain an internal clock that reflects the current date and time that shall be used for the following:

(a) Time stamping of significant events;

(b) Reference clock for reporting; and

(c) Time stamping of all sales.

(20) Purchase Session: A purchase session consists of all activities and communications performed by a purchaser during the time the purchaser accesses the raffle system or online purchasing platform. Tickets sold online shall only be purchased during a purchase session.

(21) Purchasing Tickets: A participant may purchase a raffle ticket from the website by following the instructions appearing on the screen and providing payment for the tickets. Each raffle ticket must be sold individually for the price indicated. Multiple discounted prices will only be allowed if a way of ensuring financial accountability is possible by the online purchasing platform or raffle system:

(a) A ticket purchase via a credit card transaction or other methods which can produce a sufficient audit trail must not be processed until such time as the funds are received from the issuer or the issuer provides an authorization number indicating that the purchase has been authorized;

(b) There must be a clear notification that the purchase has been accepted by the system and the details of the actual purchase accepted must be provided to the patron once the purchase is accepted; and

(c) Purchase confirmation shall include the amount of the purchase accepted by the raffle system or online purchasing platform.

(22) Disputes: The raffle system or online purchasing platform must conspicuously provide a mechanism to advise the patron of the right to make a complaint against the operator and to enable the patron to notify the department of such a complaint.

(23) Bearer Ticket Issuance: After the payment of a fee, the Purchaser shall receive a receipt through the Internet that the purchase of a raffle ticket or tickets is complete. Upon receiving the receipt acknowledging the purchase through the Internet, the purchaser may receive the raffle ticket via e-mail. The receipt acknowledging purchase and the issuance of the raffle tickets through the Internet must be processed as two (2) separate transactions.

(24) Validation Numbers: The method used by the raffle system to generate the bearer ticket validation number must be unpredictable and ensure against duplicate validation numbers for the raffle currently in progress.

(25) Voiding a Ticket: If a ticket is voided, the appropriate information shall be recorded, which includes the draw numbers and the validation number pertaining to the voided ticket. Voided draw numbers shall not be able to be resold or reissued.

(26) Raffle Drawing Requirements

(a) A raffle drawing shall be held the date, time, and place stated on the organization's license or certificate of exemption.

(b) The operator shall conduct a manual or electronic draw procedure which ensures a randomly selected draw number as a winner from all the tickets sold. Each drawn counterfoil shall be verified as a sold and valid ticket. Voided tickets shall not be gualified toward any prize. This process shall be repeated for each advertised prize.

(c) Results of the drawing become official and final after the drawn number is verified as a winning raffle ticket for the respective drawing and is presented to the participants for the raffle. The winning draw number shall be made available on the raffle website for the participants to review. Operators may utilize any additional methods in presenting the winning draw number(s) to the participants.

(27) Accounting Requirements: Any system used for the sale of raffle tickets through the Internet must have the capability to log sales and to print reports detailing sales and accounting information for specific dates and time periods must be available. This information shall include, but is not limited to, the price of each raffle ticket, number of raffle tickets sold, and total sales. The system or other equipment shall be capable of producing accounting reports to include the following information:

(a) Data required to be maintained for each raffle drawing, including:

1. Date and time of event;

2. Organization running the event;

3. Sales information;

4. Value of prize(s) awarded;

5. Prize distribution;

6. Refund totals of event

7. Draw numbers-in-play;

8. Winning number(s) drawn (including draw order, call time and claim status); and

9. Any other information required by 820 KAR 1:057.

(b) Exception Report: A report which includes system exception information, including, but not limited to, changes to system parameters, corrections, overrides and voids.

(c) Bearer Tickets Reports: A report which includes a list of all bearer tickets sold including all associated draw numbers and selling price.

(d) Sales Report: A report which includes a breakdown of sales of raffle ticket(s) through the Internet, including draw numbers sold and any voided and misprinted tickets.

(e) Voided Draw Number Report: A report which includes a list of all draw numbers that have been voided including corresponding validation numbers.

(f) Event Log: A report which lists all events recorded specific to the sales of raffle ticket(s) through the Internet. This will include the date and time of the transaction and a brief description of the transaction and/or identifying code.

(g) Corruption Log: A report which lists all Internet transactions that were unable to be reconciled to the system.

(28) Sales and Accounting Report Requirements: Any raffle ticket sold must be included in the sales and accounting reports and be detailed in all financial transactions on the system. In addition, a log relating to accounting and raffle ticket sales must be maintained on the system. The charitable organization conducting the raffle shall be given the option of printing this log on demand.

(29) Backup Requirements: Any system used for the sale of raffle ticket(s) through the Internet must have a backup and archive utility to allow the licensed charitable organization, conducting the raffle, the ability to save critical data should a system failure occur. This backup can be automatically run by the charitable organization.

(30) Data Alteration: The alteration of any accounting, reporting or significant event data related to the sale of raffle tickets through the Internet shall include supervised access controls. In the event any data is changed, the following information shall be logged, documented, stored and available upon request for review:

(a) Data element altered;

(b) Data element value prior to alteration;

(c) Data element value after alteration;

(d) Time and date of alteration; and

(e) User login of the personnel that performed the alteration.

(31) Access Controls: The allocation of access privileges shall be restricted and controlled on business requirements and the principle of least privilege.

(a) A formal user registration and de-registration procedure must be in place for granting and revoking access to all information systems and services.

(b) All users shall have a unique identifier (user ID) for their personal use only, and a suitable authentication technique shall be chosen to substantiate the claimed identity of a user.

(c) The use of generic accounts shall be limited, and where used for reasons for their use shall be formally documented.

(d) Password provision must be controlled through a formal management process.

(e) Passwords must meet business requirements for length, complexity and lifespan.

(f) Access to system applications shall be controlled by a secure log-on procedure.

(g) Appropriate authentication methods, in addition to passwords, shall be used to control access by remote users

(h) Any physical access to areas housing components used for the sale of raffle ticket(s) through the Internet application and any logical access to these applications must be recorded.

(i) The use of automated equipment identification to authenticate connections from specific locations and equipment shall be formally documented and must be included in the regular review of access by Management.

(j) Restrictions on connection times shall be used to provide additional security for high-risk applications.

(k) The use of utility programs that might be capable of overriding system application controls shall be restricted and tightly controlled.

(I) A formal policy shall be in place and appropriate security measures shall be adopted to protect against the risks of using mobile computing and communication facilities.

(32) Purchaser Account Registration: The raffle system or

online purchasing platform must employ a mechanism to collect purchaser information prior to registration of a purchaser account. The purchaser must be fully registered, and the purchaser's account must be activated prior to permitting ticket purchases. Once the identity verification is successfully complete, and the purchaser has acknowledged all of the necessary privacy policies and the terms and conditions, the purchaser account registration is complete and the patron account can become active.

(33) Third Party Services: Any third-party service providers contracted to provide service involving accessing, processing, communicating or managing the sale of raffle tickets through the Internet must adhere to information contained in this document. The security roles and responsibilities of third party service providers should be defined and documented as it relates to the security of information.

(a) Agreements with third party service providers involving accessing, processing, communicating or managing the purchase of on-line raffle tickets through the Internet/or its components, or adding products or services to the system used/or its components shall cover all relevant security requirements.

(b) The services, reports and records provided by the third party shall be monitored and reviewed by the Department upon request.

(c) Changes to the provision of services, including maintaining and improving existing information security policies, procedures and controls, shall be managed, taking account of the criticality of business systems and processes involved and re-assessment of risks.

(d) The access rights of third party service providers to the system and/or its components shall be removed upon termination of their contract or agreement, or adjusted upon change.

This is to certify that this administrative regulation was distributed for review and comment to the Charitable Gaming Advisory Commission prior to its adoption, as required by KRS 238.522(1).

AMBROSE WILSON IV, Deputy Commissioner

KERRY B. HARVEY, Secretary

APPROVED BY AGENCY: October 14, 2020

FILED WITH LRC: October 14, 2020 at 2:29 a.m.

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REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Doug Hardin, Staff Attorney

(1) Provide a brief summary of:

(a) What this administrative regulation does: This regulation allows charitable organizations to utilize electronic raffle systems and online raffle systems.

(b) The necessity of this administrative regulation: In light of the COVID-19 pandemic, the cabinet secretary has signed two executive orders relating to charitable gaming. One order suspended all charitable gaming activities in the Commonwealth, and a subsequent order created a narrow exception to allow charitable organizations to sell raffle tickets online and conduct their drawings online. This regulatory amendment helps organization generate revenue while conforming to these executive orders. Additionally, the existing raffle regulations require charitable organizations to print tickets and draw a winner from a physical receptacle, and these amendments allow organizations to utilize modern technology in the conduct of raffles.

(c) How this administrative regulation conforms to the content of the authorizing statutes: Raffles are included in the definition of charitable gaming in KRS 238.505(2). Nothing in this regulation is inconsistent with the definition of raffle in KRS 238.505(7) or the statutory requirements for a raffle found in KRS 238.545(3).

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This regulation establishes standards for the conduct of raffles utilizing modern technology and establishes procedures to verify the fairness of these raffles.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This regulation gives charitable organization additional methods for conducting a raffle draw and therefore no long requires them to print paper tickets and physically draw a ticket from a receptacle.

(b) The necessity of the amendment to this administrative regulation: Charitable organizations that rely on charitable gaming as a source of fundraising have seen a significant reduction in revenue as a result of the suspension of charitable gaming. This regulation, along with the secretary's order mentioned in response to question (1) above, gives the charitable organization an option to generate revenue during the current state of emergency. Even after the State of Emergency ends, this regulation will likely reduce operating costs by allowing organizations to utilize a computer software to conduct raffles without having to incur the costs of printing paper tickets.

(c) How the amendment conforms to the content of the authorizing statutes: Raffles are included in the definition of charitable gaming in KRS 238.505(2). Nothing in this regulation is inconsistent with the definition of raffle in KRS 238.505(7) or the statutory requirements for a raffle found in KRS 238.545(3).

(d) How the amendment will assist in the effective administration of the statutes: This regulation establishes standards for the conduct of raffles utilizing online raffle systems and electronic raffle systems. This regulations and establishes procedures and technical standards to verify the fairness of these systems.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This regulation would affect the Public Protection Cabinet, the Department of Charitable Gaming, and the Department's licensees and exempt organizations. The Department currently has 551 licensed charitable organizations and 831 charitable organizations that possess a certificate of exemption. All of these organizations would be eligible to conduct raffles in the manner allowed by this regulatory amendment. Currently the Department has 22 licensed charitable organizations who are conducting online raffles pursuant to the secretary's order of March 25, 2020. The Department also currently licenses 21 manufacturers and 17 distributors.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to comply with this administrative regulation or amendment. Manufacturers will have to have their electronic raffle systems and online raffle systems certified as compliant by an independent testing lab. Distributors will be allowed to sell or lease these systems to charities for use in licensed raffle activities.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Licensees who choose to conduct electronic raffles pursuant to this regulatory amendment will have to purchase their system from a licensed distributor, and the system will have to be created by a licensed manufacturer. Purchasing the system will likely cost the charities money on the front end, but it could reduce costs in the long-run by eliminating the need to print hundreds or thousands of tickets.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This amendment will save licensees money since they will no longer be required to print paper tickets or purchase a physical receptacle from which to draw the winning ticket.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: There are no anticipated additional initial costs to administer this emergency administrative regulation.

(b) On a continuing basis: There are no anticipated additional initial costs to administer this emergency administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Implementation of this emergency administrative regulation is not anticipated to result in additional costs to the Public Protection Cabinet.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: This emergency administrative regulation will not necessitate an increase in fees or require funding to the Public Protection Cabinet for implementation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: There are no fees directly or indirectly increased by this emergency administrative regulation.

(9) TIERING: Is tiering applied? Tiering is not applied because all applicants will be subject to the application and eligibility requirements established by the emergency administrative regulation equally.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Public Protection Cabinet and Department of Charitable Gaming

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 238.505, KRS 238.500, and KRS 238.545.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This emergency administrative regulation could result in a nominal increase in revenue for the Department from the charitable gaming fee applied to the licensee's gross receipts from the sale of raffle tickets.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This emergency administrative regulation could result in a nominal increase in revenue for the Department from the charitable gaming fee applied to the licensee's gross receipts from the sale of raffle tickets.

(c) How much will it cost to administer this program for the first year? There are no anticipated additional initial costs to administer this emergency administrative regulation.

(d) How much will it cost to administer this program for subsequent years? There are no anticipated additional initial costs to administer this emergency administrative regulation. Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative

regulation. Revenues (+/-): Neutral

Expenditures (+/-): Neutral Other Explanation: None

CABINET FOR HEALTH AND FAMILY SERVICES Department for Public Health Division of Epidemiology and Health Planning (Amended After Comments)

902 KAR 2:020. Reportable disease surveillance.

RELATES TO: KRS 211.180(1), 214.010, 214.645, <u>215.520</u>, <u>216B.015</u>, <u>258.065</u>, <u>258.990</u>, <u>311.282</u>, <u>311.571</u>, <u>315.010</u>, <u>333.020</u>, <u>333.130</u>

STATUTORY AUTHORITY: KRS 194A.050, 211.090(3), 211.180(1)(a), 214.010

NECESSITY, FUNCTION, AND CONFORMITY; KRS 211.180(1)(a) requires the cabinet to implement a statewide program for the detection, prevention, and control of communicable diseases, chronic and degenerative diseases, dental diseases and abnormalities, occupational diseases and health hazards peculiar to industry, home accidents and health hazards, animal diseases that[which] are transmissible to man, and other diseases and health hazards that can[may] be controlled. KRS 214.010 requires every physician, advanced practice registered nurse, and every head of family to notify the local health department of the existence of diseases and conditions designated by administrative regulation of the cabinet. This administrative regulation establishes notification standards and specifies the diseases requiring immediate, urgent, priority, routine, or general notification, in order to facilitate rapid public health action to control diseases[,] and to permit an accurate assessment of the health status of the Commonwealth.

Section 1. Definitions. (1) "Acid fast bacilli" or "AFB" means the mycobacteria that, if stained, retains color even after having[they have] been washed in an acid solution and can[may] be detected under a microscope in a stained smear.

(2) ["Authorize" means, for a healthcare facility that participates in the Centers for Medicare and Medicaid (CMS) reporting, to confer rights to the Kentucky Department for Public Health in the NHSN database.

(3)][at the healthcare facility level.

(2) "Health facility" is defined by KRS 216B.015(13).

(3)[(4)][(3)] "Health professional" means a professional licensed under KRS Chapters 311 through 314.

(4)[(5)][(4)] "Healthcare-associated infection" or "HAI" means an infection acquired by a person while receiving treatment for a separate condition in a health care setting.[

(5) "HIV case report" means an HIV infection or AIDS diagnosis which:

(a) Has been confirmed by laboratory test results; or

(b) Meets the definition of AIDS established within the Centers for Disease Control and Prevention (CDC) guidelines.]

(5)[(6)] "Kentucky [Department for] Public Health Advisory" means a notification to health professionals, health facilities, and laboratories subject to this administrative regulation identifying a new health threat that warrants reporting through the procedures of this administrative regulation.

(6)[(7)] "Laboratory-confirmed influenza" means influenza diagnosed through testing performed using [one (1) of the following methods]:

(a) Reverse transcriptase polymerase chain reaction (RT PCR);

(b) Nucleic acid detection; or

(c) Viral culture.

(7)[(8)] "Medical laboratory" is defined by KRS 333.020(3).

(8)[(9)][(8)] "National Healthcare Safety Network" or "NHSN" means the nation's most widely used healthcare-associated infection (HAI) tracking system as provided to medical facilities by the CDC[Centers for Disease Control and Prevention].

(9)[(10)][(9)] "National reference laboratory" means a laboratory located outside of Kentucky that is[which has been] contracted by a Kentucky health professional, laboratory, or health[healthcare] facility to provide laboratory testing.

(10)[(11)] "Novel influenza A virus" means an influenza virus that causes human infection but is different from the seasonal human influenza A virus subtypes and includes viruses predominately of avian and swine origin.

(11)[(12)] "Nucleic acid amplification test" or "NAAT" means the laboratory test used to target and amplify a single deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) sequence, <u>usually for detecting a microorganism.</u> (12)[(13)] "Outbreak" means:

(a) Two (2) or more cases, including HAIs, that are epidemiologically linked or connected by person, place, or time; or

(b) A single case of an HAI not commonly diagnosed.

(13)[(14)][(11)] "Pharmacist" is defined by[meansprofessional licensed under] KRS 315.010(17).

(14)[(15)] "Post-exposure prophylaxis" or "PEP" means taking an antiretroviral medicine after being potentially exposed to HIV to prevent becoming infected.

(15)[(16)] "Pre-exposure prophylaxis" or "PrEP" means daily medicine intended to reduce the chance of getting HIV.

(16)[(17)][(12)] "Select agent" means a biological agent or toxin that could pose a severe threat to public health, plant health, animal product, or plant product as determined by the National Select Agent Registry (NSAR) at www.selectagents.gov.

(17)[(18)][(13)] "Veterinarian" is defined by[means a professional licensed under] KRS 321.181(4).

Section 2. Notification Standards. (1) Health professionals and facilities

(a) A health professional or[and] a health facility shall give notification if:

1.[(a)] The health professional or a health facility makes a probable diagnosis of a disease specified in Section 3, [5,] 6, 7, 8, 9, 12, 16, 17, 18, or 19[10, 13, 14, 15, or 16] of this administrative regulation; and

2.[(b)] The diagnosis is supported by:

a.(i)[1.a.] Clinical or laboratory criteria; and

(ii)[b.] Case classifications published by the Centers for Disease Control and Prevention at wwwn.cdc.gov/nndss; or

b.[2.] A health professional's medical opinion that the disease is present.

(b)[(2)] A single report by a health facility of a condition diagnosed by a test result from the health facility's laboratory shall constitute notification on behalf of the health facility and its laboratory.

(c)[(3)] A health facility may designate an individual to report on behalf of the health facility's laboratory, pharmacy, and the health facility's other clinical entities.

(d)[(4)] Notification shall be given to the local health department serving the county[jurisdiction] in which the patient resides.

(e)[(5)] If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(f)[(6)] The reporting health professional or health facility shall submit[furnish]:

1.[(a)] Information required in Section 5(6)[4(16)] of this administrative regulation; and

2.[(b)] Clinical, epidemiologic, and laboratory information pertinent to the disease including sources of specimens submitted for laboratory testing.

(2)[(7)] Medical Laboratories.

(a)[Upon] A laboratory test result that[which] indicates infection with an agent associated with one (1) or more of the diseases or conditions specified in Section 3, [5,] 6, 7, 8, 9, 12, 16, 17, 18, or 19[10, 13, 14 15, or 16] of this administrative regulation shall be reported [, the laboratory shall report the result] to the local health department serving the county in which the patient resides.

(b)[(8)] If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(c)[(9)] The reporting laboratory shall submit[furnish] the information required in Section 5(6)[4(16)] of this administrative regulation.

(3)[(10)] National Reference Laboratories.

(a)[Upon] A test result performed by a national reference laboratory that [which] indicates infection with an agent associated with one (1) or more of the diseases or conditions specified in Section 3, [5,] 6, 7, 8, 9, 12, 16, 17, 18, or 19[10, 13, 14, 15, or 16] of this administrative regulation shall be reported by[,] the director of a medical laboratory, a health facility, or the health professional that referred the test to the national reference laboratory [shall ensure that the result is reported by the national reference laboratory] to the local health department serving the county[jurisdiction] in which the patient resides.

(b)[(11)] If the local health department cannot be reached,

notification shall be given to the Kentucky Department for Public Health.

(c)[(12)] The report shall include the information required by Section 5(6)[4(16)] of this administrative regulation.

Section 3. Submission of Specimens to the Kentucky Department for Public Health Division of Laboratory Services. (1) A medical laboratory and a national reference laboratory in receipt of diagnostic specimens originating from the Commonwealth of Kentucky shall send <u>direct</u> specimens or <u>pure</u> clinical isolates for diseases <u>established[outlined]</u> in subsection (5) of this section to the Division of Laboratory Services for primary or confirmatory testing and related studies.

(2) A medical laboratory or national reference laboratory using non-culture techniques to identify bacterial agents of diarrheal disease, such as enzyme immunoassays (EIAs) or molecular assays, shall attempt isolation of the etiologic agent identified. Pure clinical isolates shall be submitted to the Division of Laboratory Services.

(3) If the culture attempts do not produce a clinical isolate, the direct specimen, submitted in the appropriate preservative, shall be sent to the Division of Laboratory Services. A submitting laboratory shall provide the name of the etiologic agent detected by the non-culture technique at the time of specimen submission.

(4) A medical laboratory performing this test shall continue to follow the state's requirement for the submission of appropriate materials to the state public health laboratory.

(5) A medical or national reference laboratory shall submit <u>pure[clinical]</u> isolates or, if not available, the direct specimen from the following diseases to the Division of Laboratory Services:

(a) Botulism, with prior approval from the Division of Epidemiology for testing;

(b) Brucellosis;

(c) Campylobacteriosis;

(d) Candida auris;

(e) Carbapenem-resistant Acinetobacter;

(f) Carbapenem-resistant Enterobacteriaceae;

(g) Carbapenem-resistant Pseudomonas;

(h) Cholera and diseases caused by other Vibrio species;

(i)[(e)] Diphtheria;

(j)[(f)] Escherichia coli O157:H7;

(k)[(g)] Hemolytic Uremic Syndrome (HUS) - Post Diarrheal;

(I)[(h)] Listeriosis;

(m)[(i)] Measles;

(n)[(j)] Meningococcal infections;

(o)[(k)] Rabies, animal;

(p)[(l)] Rubella;

(q)[(m)] Salmonellosis;

(r)[(n)] Shiga toxin-producing E. coli (STEC);

(s)[(o)] Shigellosis;

(t)[(p)] Tuberculosis;

(u)[(q)] Tularemia;

<u>(v)[and</u>

(r)] Typhoid fever:

(w) Vancomycin-intermediate Staphylococcus aureus;

(x) Vancomycin-resistant Staphylococcus aureus; and

(y) Zika, with prior approval from the Division of Epidemiology for testing.

(6) All direct specimens or clinical isolates from enteric disease shall be submitted within seventy-two (72) hours from collection.

Section 4. Laboratory Testing and Submission of Specimens to the Division of Laboratory Services for the Identification of M. tuberculosis.

(1) For the identification of M. tuberculosis, a medical laboratory or national reference laboratory shall perform AFB smear and culture, regardless of rapid molecular testing results ([i.e.] NAAT).

(2) Rapid molecular testing shall be performed for the identification of M. tuberculosis on:

(a) Any diagnostic specimen with an AFB smear positive result; or

(b) Any specimen that originates from an individual with clinical

or epidemiological evidence suggesting active tuberculosis.

(3) If rapid molecular testing cannot be performed by the medical laboratory or national reference laboratory, the diagnostic specimen shall be sent to the Division of Laboratory Services.

(4) A medical laboratory or national reference laboratory that has a diagnostic specimen test positive for M. tuberculosis by rapid molecular testing shall send the remainder of that specimen to the Division of Laboratory Services.

(5) Any diagnostic specimen found to be positive for M. tuberculosis by rapid molecular testing or culture testing shall be reported in accordance with Section 7 of this administrative regulation.

<u>Section 5.</u> Reporting Classifications and Methods. (1) Immediate reporting.

(a) A report required by Section <u>12[40](1)</u> and (2) of this administrative regulation to be made immediately shall be:

<u>1.[(a)]</u> Made by telephone to the local health department serving the county in which the patient resides; and

2[(b)] Followed up by electronic or fax submission to the local health department serving the county in which the patient resides within one (1) business day.

(b)[(2)] Upon receipt of a report for a disease requiring immediate reporting, the local health department shall:

1.[(a)] Notify the Kentucky Department for Public Health by telephone; and

2.[(b)] Assist the department in carrying out a public health response.

(c)[(3)] Weekend, evening, or holiday immediate notification. If local health department personnel cannot be contacted directly, notification shall be made by telephone using an emergency number provided by the local health department or the Kentucky Department for Public Health.

(d)[(4)] For the protection of patient confidentiality, a report using the emergency number shall include:

1.[(a)] The name of the condition being reported; and

2.[(b)] A telephone number that can be used by the department to contact the reporting health professional or health facility.

(2)[(5)] Urgent reporting.

(a) A report made within twenty-four (24) hours as required by Section 6[5] of this administrative regulation shall be:

<u>1.[(a)]</u> Submitted electronically, by fax, or by telephone to the local health department serving the county in which the patient resides; and

2.[(b)] If submitted by telephone, followed up by electronic or fax submission to the local health department serving the county in which the patient resides within one (1) business day.

(b)[(6)] Upon receipt of a report for a disease requiring urgent reporting, the local health department shall:

1.[(a)] Notify the Kentucky Department for Public Health; and

<u>2.[(b)]</u> Assist the department in carrying out a public health response.

(c)[(7)] Weekend, evening, or holiday urgent notification. If local health department personnel cannot be contacted directly, notification shall be made by telephone using an emergency number provided by the local health department or the Kentucky Department for Public Health.

(d)[(8)] For the protection of patient confidentiality, notification using the emergency number shall include:

1.[(a)] The name of the condition being reported; and

2[(b)] A telephone number that can be used by the department to contact the reporting health professional or health facility.

(3)[(9)] Priority reporting.

(a) A report made within one (1) business day as required by <u>Section 7, 11, 12(3), 17(4), or 18[Sections 6, 14(4), and 15]</u> of this administrative regulation shall be:

1.[(a)] Submitted electronically, by fax, or by telephone to the local health department serving the county in which the patient resides; and

2.[(b)] If submitted by telephone, followed up by electronic or fax submission of a report to the local health department serving the county in which the patient resides within one (1) business day.

(b)[(10)] Upon receipt of a report for a disease requiring priority

reporting, a local health department shall:

1.[(a)] Investigate the report and carry out public health protection measures: and

2.[(b)] Notify the Kentucky Department for Public Health of the case by electronic or fax submission within one (1) business day.

(c)[(11)] The reporting health department may seek assistance in carrying out public health measures from the Kentucky Department for Public Health.

(4)[(12)] Routine reporting.

(a) A report made within five (5) business days, as required by Section 8, 9, 10, 13(1), 16(1), 17(7), or 20(1)[Sections 7, 8, 9, 11(1), 13, 14(7), and 17] of this administrative regulation, shall be made electronically, by fax, or by mail to the local health department serving the county in which the patient resides.

(b)[(13)] Upon receipt of a report of a disease or condition requiring routine reporting, a local health department shall:

1.[(a)] Make a record of the report;

2.[(b)] Answer inquiries or render assistance regarding the report if requested by the reporting entity; and

3.[(c)] Forward the report to the Kentucky Department for Public Health by electronic or fax submission of a report, or in writing within five (5) business days.

(5)[(14)] General reporting. A report made within three (3) months, as required by Section <u>19[16]</u> of this administrative regulation, shall be made electronically, by fax, or by mail.

(6) Reporting requirements.

(a)[(15)] A report submitted by fax or by mail shall be made using one (1) of the following reporting forms:

1.[(a)] EPID 200, Kentucky Reportable Disease Form;

2.[(b)] EPID 250, Kentucky Reportable MDRO Form, to be used for priority reporting[until electronic reporting is available pursuant to Section 9(1) of this administrative regulation];

3.[(c)] EPID 394, Kentucky Reportable Disease Form, Hepatitis Infection in Pregnant Women or Child (aged five (5) years or less);

4.[(d)] EPID 399, Perinatal Hepatitis B Prevention Form for Infants:

5.[(e)] Adult HIV[/AIDS] Confidential Case Report Form; or

6.[(f)] Pediatric HIV[/AIDS] Confidential Case Report Form.

(b)[(16)] Information to be reported. Except as provided in subsections (1)(d)[(3)] and (2)(d)[(7)] of this section, a report required by this administrative regulation shall include:

1.[(a)] Patient name;

2.[(b)] Date of birth;

3.[(c)] Gender;

4.[(d)] Race; 5.[(e)] Ethnicity;

6.[(f)] Patient address;

7.[(g)] County of residence;

8.[(h)] Patient telephone number:

9.[(i)] Name of the reporting medical provider or facility;

10.[(j)] Address of the reporting medical provider or facility; and

11.[(k)] Telephone number of the reporting medical provider or facility.

(c)[(17)] A reporting health professional shall submit[furnish] the information listed in this subsection [(16) of this section] and Section 2(1)(f)[(6)(b)] of this administrative regulation.

Section 6[5]. Notifiable Infectious Conditions Requiring Urgent Notification. (1) Notification of the following diseases shall be considered urgent and shall be made within twenty-four (24) hours:

(a)[(1)] Anthrax;

(b)[(2)] Botulism;

(c)[(3)] Brucellosis (multiple cases, temporally or spatially clustered);

(d)[(4)] Diphtheria;

(e)[(5)] Hepatitis A, acute;

(f)[(6)] Measles;

(g)[(7)] Meningococcal infections;

(h) Middle East Respiratory Syndrome-associated Coronavirus (MERS-CoV) disease;

(i) Multi-system Inflammatory Syndrome in Children (MIS-C);

(i)[(8)] Novel influenza A virus infections;

(k)[(9)] Plague;

(I)[(10)] Poliomyelitis;

(m)[(11)] Rabies, animal; (n)[(12)] Rabies, human;

(o)[(13)] Rubella;

(p)[(14)] Severe Acute Respiratory Syndrome-associated Coronavirus (SARS-CoV) disease;

(q) Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (the virus that causes COVID-19);

(r)[(15)] Smallpox;

(s)[(16)] Tularemia;

(t)[(17) Varicella;

(18)] Viral hemorrhagic fevers due to:

1.[(a)] Crimean-Congo Hemorrhagic Fever virus;

2.[(b)] Ebola virus;

3.[(c)] Lassa virus;

4.[(d)] Lujo virus;

5.[(e)] Marburg virus; or

6.[(f)] New world arenaviruses including:

a.[1.] Guanarito virus;

b.[2.] Junin virus;

c.[3.] Machupo virus; and

d.[4.] Sabia virus; and

(u)[(19)] Yellow fever.

(2) To track the spread of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, notification of testing results shall include both positive and negative test results.

Section 7[6]. Notifiable Infectious Conditions and Notifiable Non-Infectious Conditions Requiring Priority Notification. Notification of the following diseases or conditions shall be considered priority and shall be made within one (1) business day:

(1) Arboviral diseases, neuroinvasive and non-neuroinvasive, including:

(a) California serogroup virus diseases, including diseases caused by:

1. California encephalitis virus;

2. Jamestown Canyon virus;

3. Keystone virus;

- 4. La Crosse virus;
- 5. Snowshoe hare virus; and
- 6. Trivittatus viruses;
- (b) Chikungunya virus disease;
- (c) Eastern equine encephalitis virus disease;
- (d) Powassan virus disease;
- (e) St. Louis encephalitis virus disease;
- (f) Venezuelan equine encephalitis disease;
- (g) West Nile virus disease;
- (h) Western equine encephalitis virus disease: and

(i) Zika virus disease or infection or the birth of a child to a mother who was Zika-positive or Zika-inconclusive during any stage of pregnancy or during the periconceptional period;

(2) Brucellosis (cases not temporally or spatially clustered);

(3) Campylobacteriosis

(4) Carbon monoxide poisoning;

- (5) Cholera;
- (6) Cryptosporidiosis;

(7) Cyclosporiasis;

(8) Dengue virus infections;

(9)[(8)] Escherichia coli O157:H7;

(10)[(9)] Foodborne disease outbreak;

(11) Giardiasis;

(5) years or less;

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(12)[(10)] Haemophilus influenzae invasive disease:

(13)[(11)] Hansen's disease (leprosy);

(14)[(12)] Hantavirus infection, non-Hantavirus pulmonary syndrome;

(15)[(13)] Hantavirus pulmonary syndrome (HPS):

(16)[(14)] Hemolytic uremic syndrome (HUS), post-diarrheal;

(20)[(18)] Newborns born to Hepatitis B positive mothers at the

(17)[(15)] Hepatitis B, acute;

(18)[(16)] Hepatitis B infection in a pregnant woman; (19)[(17)] Hepatitis B infection in an infant or a child aged five time of delivery;

(21)[(19)] Influenza-associated mortality; (22) Legionellosis; (23)[(20)] Leptospirosis; (24)[(21)] Listeriosis; (25)[(22)] Mumps; (26)[(23)] Norovirus outbreak; (27)[(24)] Pertussis; (28)[(25)] Pesticide-related illness, acute; (29)[(26)] Psittacosis; (30)[(27)] Q fever; (31)[(28)] Rubella, congenital syndrome; (32)[(29)] Salmonellosis; (33)[(30)] Shiga toxin-producing E. coli (STEC); (34)[(31)] Shigellosis; (35)[(32)] Streptococcal toxic-shock syndrome; (36)[(33)] Streptococcus pneumoniae, invasive disease; (37)[(34)] Tetanus; (38)[(35)] Toxic-shock syndrome (other than Streptococcal); (39)[(36)] Tuberculosis; (40)[(37)] Typhoid fever; (41) Varicella; (42)[(38)] Vibriosis; and (43)[(42)]((39)] Waterborne disease outbreak.

Section <u>8</u>[7]. Notifiable Infectious Conditions and Notifiable Non-Infectious Conditions Requiring Routine Notification. Notification of the following diseases shall be considered routine and shall be made within five (5) business days:

(1) Acute Flaccid Myelitis;

(2) Anaplasmosis;

(3) Babesiosis;

(4)[(2)] Coccidioidomycosis;

(5)[(3)] Creutzfeldt-Jakob disease:

(6)[(4)] Ehrlichiosis[/Anaplasmosis];

(7)[(5)] Hepatitis C, acute;

(8)[(6)] Hepatitis C infection in a pregnant woman;

(9)((7)) Hepatitis C infection in an infant or a child aged five (5) years or less;

(10)[(8)] Newborns born to Hepatitis C positive mothers at the time of delivery;

(11)[(9)] Histoplasmosis;

(12) Laboratory-confirmed influenza;

(13)[(10)] Lead poisoning;

(14)[(11) Legionellosis;

(12)] Lyme Disease;

(15)[(13)] Malaria;

(16)((14)) Spotted Fever Rickettsiosis (Rocky Mountain Spotted Fever);

(17)[(15)] Toxoplasmosis; and

(18)[(16)] Trichinellosis (Trichinosis).

Section 9[8]. Notifiable Infectious Conditions Requiring Routine Notification by Electronic Laboratory Reporting. (1) [Beginning October 1, 2016,] Notification of the following [diseases] shall be considered routine and shall be electronically reported to the Kentucky Department for Public Health through the Kentucky Health Information Exchange within five (5) business days:

(a) [Cyclosporiasis;

(b) Giardiasis;

(c)]Hepatitis B laboratory test results, which shall:

1. Be [whether] reported as positive or negative; and

<u>2.[</u>:

4.] Include the serum bilirubin levels or serum alanine aminotransferase taken within ten (10) days of the test of a patient who has tested positive; [and]

<u>(b)[ər</u>

(d)] Hepatitis C laboratory test results, which shall: <u>1. Be[whether]</u> reported as positive or negative; and

<u>2.[</u>:

4.] Include the serum bilirubin levels or serum alanine

aminotransferase taken within ten (10) days of the test of a patient who has tested positive; or

(c) Varicella laboratory test results reported as positive for:

1. Isolation of varicella virus from a clinical specimen:

2. Varicella antigen detected by direct fluorescent antibody test; or

3. Varicella-specific nucleic acid detected by polymerase chain reaction (PCR)[; or

2. Include the serum alanine aminotransferase levels taken within ten (10) days of the test of a patient who tested positive; and

(e) Varicella laboratory test results reported as positive for:

1. Isolation of varicella virus from a clinical specimen;

2. Varicella antigen detected by direct fluorescent antibody test:

3. Varicella-specific nucleic acid detected by polymerase chain reaction (PCR); or

4. A significant rise in serum anti-varicella immunoglobulin G (IgG) antibody level by a standard serologic assay].

(2) Reports made pursuant to this section shall include a diagnosis.

Section <u>10[9]</u>. Multi-Drug Resistant Organisms and Other Organisms Requiring Routine Notification by Electronic Laboratory Reporting. (1) [Beginning October 1, 2016,] Notification of the following diseases shall be considered routine and shall be electronically reported to the Kentucky Department for Public Health through the Kentucky Health Information Exchange within five (5) business days:

(a) <u>Clostridioides</u> (formerly <u>Clostridium</u>) difficile (C. difficile) identified from a positive laboratory test result for C. difficile toxin A or B (includes molecular assays {PCR} or toxin assays) or a toxinproducing organism detected by culture or other laboratory means performed on a stool sample;

(b) Enterobacteriaceae species resistant to ceftazidime, ceftriaxone, or cefotaxime[Vancomycin-intermediate Staphylococcus aureus (VISA), which includes S. aureus cultured from any specimen that the results show a minimum inhibitory concentration (MIC) of 4-8 μg/mL per standard laboratory methods;

(b) Vancomycin-resistant Staphylococcus aureus (VRSA), which includes S. aureus cultured from any specimen that the results show a minimum inhibitory concentration (MIC) of greater than or equal to 16 μ g/mL per standard laboratory methods];

(c) Methicillin-resistant Staphylococcus aureus (MRSA), which includes S. aureus cultured from any specimen that tests oxacillin-resistant, cefoxitin-resistant, or methicillin-resistant by standard susceptibility testing methods, or by a laboratory test that is FDA-approved for MRSA detection from isolated colonies. These methods may also include a positive result by any FDA-approved test for MRSA detection; and

(d) Vancomycin-resistant Enterococcus species (VRE), only those identified to the species level, that are resistant to Vancomycin by standard susceptibility testing methods or by results from any FDA-approved test for VRE detection from specific specimen sources[;

(e) Clostridium difficile (C. difficile) identified from a positive laboratory test result for a C. difficile toxin A or B (includes molecular assays {PCR} or toxin assays) or a toxin-producing organism detected by culture or other laboratory means performed on a stool sample;

(f) Carbapenem-resistant Enterobacteriaceae (CRE), which includes Escherichia coli, Klebsiella oxytoca, Klebsiella pneumonia, or Enterobacter species testing resistant to imipenem, meropenem, doripenem, or ertapenem by standard susceptibility testing methods or by production of carbapenemase by an isolate demonstrated by using a recognized test;

(g) Cephalosporin-resistant Klebsiella, which includes Klebsiella oxytoca, Klebsiella pneumonia, or a Klebsiella species testing nonsusceptible (resistant or intermediate) to ceftazidime, cefotaxime, ceftriaxone, or cefepime;

(h) Extended-spectrum beta-lactamase Gram negative organisms (ESBL) Enterobacteri-aceae species nonsusceptible (resistant or intermediate) to ceftazidime, cefepime, ceftriax-one, or

cefotaxime;

(i) Multidrug-resistant – Acinetobacter - Nonsusceptibility (resistant or intermediate) to at least one (1) agent in at least three (3) antimicrobial classes of the following six (6) classes: 1. Ampicillin-sulbactam:

2. Cephalosporins (cefepime, ceftazidime);

3. β-lactam-β-lactamase inhibitor combination (piperacillin, piperacillin-tazobactam);

4. Carbapenems (imipenem, meropenem, doripenem);

5. Fluoroquinolones (ciprofloxacin or levofloxacin); and

6. Aminoglycosides (gentamicin, tobramycin, or amikacin); and

(j) Multidrug-resistant Pseudomonas Nonsusceptibility, resistant or intermediate, to at least one (1) agent in at least three (3) antimicrobial classes of the following five (5) classes:

1. Cephalosporins (cefepime, ceftazidime);

2. β-lactam-β-lactam β-lactamase inhibitor combination (piperacillin, piperacillin-tazobactam);

3. Carbapenems (imipenem, meropenem, doripenem);

4. Fluoroquinolones (ciprofloxacin or levofloxacin); and

5. Aminoglycosides (gentamicin, tobramycin, or amikacin)].

(2) The report of an organism under this section shall include the [following]:

(a) Date of specimen collection;

(b) Source of specimen;

(c) Susceptibility pattern; and

(d) Name of the ordering health professional.

(3) Upon a test result performed by a medical laboratory <u>that[which]</u> indicates infection with an agent associated with one (1) or more of the diseases or conditions or a multi-drug resistant organism specified in this section, the director of the medical laboratory shall electronically report the result to the Kentucky Department for Public Health through the Kentucky Health Information Exchange within five (5) days.

(4) The report shall include a diagnosis.

Section 11. Multi-drug Resistant Organisms and Other Organisms Requiring Priority Reporting by EPID 250 and by Electronic Laboratory Reporting to the Kentucky Department for Public Health through the Kentucky Health Information Exchange within One (1) Business Day. Notification of the following diseases shall be considered priority:

(1) Candida auris - Laboratory Criteria for Diagnosis shall include:

(a) Confirmatory laboratory evidence for detection of Candida auris from any body site using either culture or a culture independent diagnostic test (for example[e.g.], Polymerase Chain Reaction {PCR}); or

(b) Presumptive laboratory evidence for detection of Candida haemulonii from any body site using a yeast identification method that is not able to detect Candida auris, and either the isolate or specimen is not available for further testing, or the isolate or specimen has not yet undergone further testing;

(2) Carbapenem-resistant – Acinetobacter – Any Acinetobacter species testing resistant to imipenem, meropenem, or doripenem, with MIC value greater than or equal to **eight (8)[8]** μg/mL by standard susceptibility testing methods, or by identification of a carbapenemase using a recognized test;

(3) Carbapenem-resistant Enterobacteriaceae (CRE) –[.] Any Enterobacteriaceae species testing resistant to imipenem, meropenem, or doripenem, with MIC value greater than or equal to four (4)[4] µg/mL, or ertapenem with MIC value greater than or equal to two (2)[2] µg/mL, by standard susceptibility testing methods, or by identification of a carbapenemase using a recognized test;

(4) Carbapenem-resistant – Pseudomonas – Any Pseudomonas species testing resistant to imipenem, meropenem, or doripenem, with MIC value greater than or equal to **eight (8)[8]** µg/mL by standard susceptibility testing methods, or by identification of a carbapenemase using a recognized test:

(5) Vancomycin-intermediate Staphylococcus aureus (VISA), which includes S. aureus cultured from any specimen having a minimum inhibitory concentration (MIC) of **four (4) to eight (8)[4-8**] µg/mL for vancomycin per standard laboratory methods; and (6) Vancomycin-resistant Staphylococcus aureus (VRSA), which includes S. aureus cultured from any specimen having a minimum inhibitory concentration (MIC) of greater than or equal to sixteen (16)[16] µg/mL for vancomycin per standard laboratory methods.

Section <u>12[</u>10]. Newly Recognized Infectious Agents, HAI Outbreaks, Emerging Pathogens, and Pathogens of Public Health Importance. (1) The following shall be reported immediately by telephone to the Kentucky Department for Public Health:

(a) A suspected incidence of bioterrorism caused by a biological agent;

(b) Submission of a specimen to the Kentucky Division of Laboratory Services for select agent identification or select agent confirmation testing; or

(c) An outbreak of a disease or condition that resulted in multiple hospitalizations or death.

(2) An unexpected pattern of cases, suspected cases, or deaths <u>that[which]</u> <u>could[may]</u> indicate the following shall be reported immediately by telephone to the local health department in the county where the health professional is practicing or where the facility is located:

(a) A newly-recognized infectious agent;

(b) An outbreak;

(c) An emerging pathogen <u>that[which]</u> may pose a danger to the health of the public;

(d) An epidemic; or

(e) A noninfectious chemical, biological, or radiological agent.

(3) A report of the following shall be considered priority and shall be reported to the local health department in the county where the health professional is practicing or where the facility is located within one (1) business day:

(a) Suspected Staphylococcal or other foodborne intoxication; or

(b) Salmonellosis or other foodborne or waterborne infection.

(4) The local health department shall:

(a) Investigate the outbreak or occurrence;

(b) Carry out public health protection measures to address the disease or condition involved; and

(c) Make medical and environmental recommendations to prevent future similar outbreaks or occurrences.

(5) The local health department may seek assistance from the Kentucky Department for Public Health.

Section <u>13[11]</u>. Laboratory Surveillance. (1) Medical or national reference laboratory results for the following shall be considered routine:

(a) Influenza virus isolates;

(b) PCR-positive test results for influenza virus; and

(c) DNA molecular assays for influenza virus.

(2) The report shall include specific laboratory information pertinent to the result.

(3) Upon request by the Kentucky Department for Public Health, a health facility laboratory or a medical laboratory shall report the number of clinical isolates and information regarding the antimicrobial resistance patterns of the clinical isolates at intervals no less frequently than three (3) months for [the following]:

(a) <u>Acinetobacter baumannii complex;</u>

(b) Enterobacter cloacae complex;

(c) Enterococcus species;

(d) Escherichia coli;

(e) Klebsiella oxytoca;

(f) Klebsiella pneumoniae;

(g) Pseudomonas aeruginosa;

(h) Staphylococcus aureus;[

(b) Enterococcus species;] or

(i)[(c)] An organism specified in a request that includes a justification of its public health importance.

(4) A facility that reports antimicrobial resistance (AR) data to the National Healthcare Safety Network (NHSN) AUR (Antimicrobial Use & Resistance) module shall meet this reporting requirement through NHSN reporting. Section <u>14[12]</u>. Healthcare-Associated Infection Surveillance. (1) A <u>health[healthcare]</u> facility in Kentucky that participates in CMS reporting programs shall authorize the CDC to allow the Kentucky Department for Public Health to access health careassociated infection data reported to NHSN.

(2) The Kentucky Department for Public Health shall preserve patient confidentiality and shall not disclose to the public any patient-level data obtained from any health care facility.

(3) The Kentucky Department for Public Health may issue reports to the public regarding healthcare-associated infections in aggregate data form <u>that[which]</u>:

(a) May identify individual health care facilities; and

(b) Shall comply with methodology developed by the CDC and CMS for national reporting of health care-associated infections.

(4) The Kentucky Department for Public Health may evaluate healthcare-associated infection data for accuracy and completeness.

Section 15. Antimicrobial Use Reporting. (1) A short-term acute-care hospital in Kentucky that participates in the Centers for Medicare and Medicaid Services (CMS) reporting programs shall report data on facility-wide inpatient antimicrobial use to the Kentucky Department for Public Health, Healthcare-Associated Infection/Antibiotic Resistance (HAI/AR) Prevention Program, on a guarterly basis, effective January 1, 2021. Critical access hospitals shall be exempt.

(2) Reporting deadlines shall be consistent with the CMS reporting program submission deadlines of data to the NHSN.

(3) The HAI/AR Prevention Program shall provide the specifications for data submission.

(4) Hospitals shall include aggregated antimicrobial use and patient day data for all inpatient units ([i.e.,] facility-wide inpatient) included in the NHSN Laboratory-identified (LabID) MRSA Bacteremia reporting.

(5) The antimicrobial use numerator shall be days of therapy (DOTs) as defined by the NHSN Antimicrobial Use and Resistance (AUR) Module, available at

//www.cdc.gov/nhsn/pdfs/pscmanual/11pscaurcurrent.pdf. (6) Total DOTs shall be submitted for each of the following

antimicrobials: (a) Azithromycin; (b) Cefepime; (c) Ceftazidime; (d) Ceftriaxone; (e) Ciprofloxacin; (f) Clindamycin; (g) Daptomycin; (h) Ertapenem; (i) Imipenem; (j) Levofloxacin; (k) Linezolid; (I) Meropenem; (m) Moxifloxacin; (n) Piperacillin-tazobactam; and (o) Vancomycin.

(7) Total DOTs for the listed drugs shall include only administrations via the intravenous and digestive tract routes.

(8) The denominator for antimicrobial use reporting shall be patient days as defined by the NHSN LabID Module available at https://www.cdc.gov/nhsn/pdfs/pscmanual/12pscmdro_cdadcurrent .pdf.

(9) A hospital that reports antimicrobial use data to the NHSN AUR Module shall meet this reporting requirement through NHSN reporting.

Section 16[13]. Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS) Surveillance. (1) <u>All</u> case reports shall be submitted to the HIV/AIDS Surveillance Program of the Kentucky Department for Public Health, Division of Epidemiology and Health Planning, or its designee, [A report of an HIV infection or AIDS diagnosis shall be considered routine and shall be reported] within five (5) business days of diagnosis on one (1) of the following forms: (a) Adult HIV[/AIDS] Confidential Case Report Form; or

(b) Pediatric HIV[/AIDS] Confidential Case Report Form.

(2) Health professionals and medical laboratories shall report:

(a) A positive test result for HIV infection including a result from:

1. 3rd generation immunoassay;

2. 4th generation immunoassay;

3. Western Blot;

4. PCR;

5. HIV-1 or HIV-2 differentiating such as Multispot;

6. HIV antigen;

7. HIV antibody;

8. CD4+ assay including absolute CD4+ cell counts and CD4+%;

9. HIV Viral Load Assay including detectable and undetectable values;[er]

10. HIV genetic sequencing; or

 $\underline{11.}$ A positive confirmatory serologic test result for HIV infection; or

(b) A diagnosis of AIDS that meets the definition of AIDS established within the CDC guidelines.

(3) <u>The most recent negative HIV test, if available, shall be</u> <u>submitted with the report required by **subsection** (2)[paragraph](a) or (b) of this section[subsection].</u>

(4) Any request for data related to HIV infection or AIDS shall be made to the Department for Public Health, Division of Epidemiology and Health Planning [A case report for a resident of Jefferson, Henry, Oldham, Bullitt, Shelby, Spencer, or Trimble County shall be submitted to the HIV/AIDS Surveillance Program of the Louisville-Metro Health Department.

(4) A case report for a resident of the remaining Kentucky counties shall be submitted to the HIV/AIDS Surveillance Program of the Kentucky Department for Public Health, Division of Epidemiology and Health Planning].

(5) A case report for a person with an HIV infection without a diagnosis of AIDS, or HIV infection with a diagnosis of AIDS shall include [the following information]:

(a) The patient's full name;

(b) The patient's complete address;

(c) Date of birth using the format MMDDYYYY;

(d) Gender;

(e) Race;

(f) Ethnicity;

(g) Risk factor as identified by CDC;

(h) County of residence;

(i) Name of provider and facility submitting report including contact information;

(j) Specimen collected;

(k) Date and type of HIV test performed using the format MMDDYYYY;

(I) Results of CD4+ cell counts and CD4+%;

(m) Results of viral load testing;

(n) Results of PCR, HIV culture, HIV antigen, and HIV antibody, if performed;

(o) Results of TB testing, if available;[and]

(p) Any documented HIV negative test, if available;

(q) History of PrEP or PEP treatment, if available;

(r) Antiretroviral treatment, if available;

(s) HIV status of the person's partner, spouse, or children, as applicable:

<u>(t)[-</u>

(6) A reports of an AIDS case shall include:

(a) Information in subsections (2) through (5) of this section;

(b)] Opportunistic infections diagnosed; and

(u)[(c)] Date of onset of illness.

 $\overline{(6)}(\overline{(7)})$ A report of AIDS shall be made whether or not the patient has been previously reported as having an HIV infection.

(7)[(8)] If the patient has not been previously reported as having an HIV infection, the AIDS report shall also serve as the report of HIV infection [as required by subsection (2) through (5) of this section].

Section 17[14]. Sexually Transmitted Disease (STD). (1)

Notification of a probable diagnosis of an STD as specified in subsection (4) or (7) of this section shall be made.

(2) The report shall provide [the following information]:

(a) Pregnancy status; and

(b) Clinical, epidemiologic, laboratory, and treatment information pertinent to the disease.

(3) Upon a laboratory test result <u>that[which]</u> indicates infection with an agent associated with one (1) or more of the diseases or conditions specified in subsection (4) <u>or[and]</u> (7) of this section, a medical laboratory shall report to the Kentucky Department for Public Health information required by Section <u>5(6)(b)[4(16)]</u> of this administrative regulation.

(4) Sexually Transmitted Diseases Requiring Priority Notification. A report of the following shall be considered priority and shall be made within one (1) business day:

(a) <u>Each pregnant female who has tested positive for syphilis</u> regardless of stage[Congenital syphilis]; or

(b) Syphilis - primary, secondary, or early latent.

(5) Upon receipt of a report for a disease or condition specified

in subsection (4) of this section, a local health department shall: (a) Investigate the report;

(b) Carry out public health protection measures to address the disease or condition; and

(c) Forward the report to the Kentucky Department for Public Health within one (1) business day.

(6) The local health department may seek assistance from the Kentucky Department for Public Health.

(7) Sexually Transmitted Diseases Requiring Routine Notification. A report of the following shall be considered routine and shall be made within five (5) business days:

(a) Chancroid;(b) Chlamydia trachomatis infection;

(c) Gonorrhea;

(d) Granuloma inguinale;

(e) Lymphogranuloma venereum; or

(f) Syphilis, other than primary, secondary, early latent, or congenital.

(8) Upon receipt of a report for a disease or condition specified in subsection (7) of this section, a local health department shall:

(a) Make a record of the report using Form EPID 200, Kentucky Reportable Disease Form;

(b) Forward the report to the Kentucky Department for Public Health within five (5) business days; and

(c) Render assistance if requested by the reporting entity or the Kentucky Department for Public Health.

Section <u>18[45]</u>. Tuberculosis. (1) A pharmacist shall give notice if two (2) or more of the following medications used for the initial treatment of active tuberculosis are dispensed to an inpatient in a health facility or to an ambulatory patient in a health facility or a pharmacy:

(a) <u>Ethambutol;</u>

(b) Isoniazid;

(c) Pyrazinamide; and

(d) Rifampin or rifabutin[;

(b) Isoniazid;

(c) Pyrazinamide; and

(d) Ethambutol].

(2)(<u>a)</u> A report of tuberculosis shall be considered priority and shall be reported to the local health department serving the county in which the patient resides.

(b)[(3)] If the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health.

(3)[(4)] The report shall include:

(a) Information required in Section <u>5(6)(b)[4(16)]</u> of this administrative regulation; and

(b) Names of the medications dispensed.

Section <u>19[</u>46]. Asbestosis, Coal Worker's Pneumoconiosis, and Silicosis. (1) A health professional shall report a diagnosis of the following to the Kentucky Department for Public Health within three (3) months of diagnosis: (a) Asbestosis;

(b) Coal worker's pneumoconiosis; or

(c) Silicosis.

(2) A report required under this section shall include the information required in Section 5(6)(b)[following information regarding the patient:

(a) Name;

(b) Address;

(c) Date of birth; and

(d) County of residence].

Section <u>20[</u>47]. Reporting of Communicable Diseases in Animals. (1) A diagnosis in an animal of a condition known to be communicable to humans, except for rabies, shall require routine notification.

(2) A veterinarian shall report the diagnosis within five (5) business days to the local health department serving the county in which the animal is located.

(3) If a laboratory test indicates infection of an animal with an agent associated with a condition known to be communicable to humans, the director of a medical laboratory shall report the result to the local health department serving the county in which the animal is located within five (5) business days.

(4) The local health department receiving the report shall:

(a) Investigate the report;

(b) Carry out public health protection measures for the control of communicable diseases; and

(c) Forward the report to the Kentucky Department for Public Health within five (5) business days.

(5) The local health department may seek assistance from the Kentucky Department for Public Health.

Section <u>21[18]</u>. Kentucky [Department_for] Public Health Advisory. (1) If the Secretary of the Cabinet for Health and Family Services or the Commissioner of the Department for Public Health determines that a disease not presently listed in this administrative regulation requires reporting, the secretary or commissioner shall[may] issue a Kentucky Public Health Advisory.

(2) The Kentucky Public Health Advisory shall include:

(a) Date and time the advisory is issued;

(b) A unique number to identify the advisory;

(c) Names for the disease or condition;

(d) A description of the disease or condition;

(e) Recommendations for health professionals, health facilities, and laboratories; and

(f) Notification requirements including:

1. The notification time interval; and

2. Methods for notification[; and

3. Forms to be completed and submitted with the notification].

(3) The duty to report by health professionals, health facilities, and laboratories pursuant to a Kentucky Public Health Advisory shall begin upon receipt of the advisory and shall remain in effect until the advisory is rescinded by order of the secretary or the commissioner.

Section <u>22</u>. Penalty. If the cabinet has cause to believe that a physician willfully neglects or refuses to notify the cabinet in accordance with this administrative regulation, pursuant to KRS <u>214.990(1)</u> the cabinet shall make a referral to the appropriate professional licensing board.

<u>Section 23[49]</u>. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) [Form] "EPID 200, Kentucky Reportable Disease Form", <u>4/2020[6/2016];</u>

(b) [Form] "EPID 250, Kentucky Reportable MDRO Form", **10/2000[4/2020]**[6/2014];

(c) [Form] "EPID 394, Kentucky Reportable Disease Form, Hepatitis Infection in Pregnant Women or Child (aged five <u>(5)</u> years or less)", <u>9/2020[4/2020][9/2016];</u>

(d) [Form] "EPID 399, Perinatal Hepatitis B Prevention Form for Infants", <u>6/2020[4/2012];</u>

(e) [Form] "Adult HIV Confidential Case Report Form", <u>11/2019[3/2013];</u> and

(f) [Form] "Pediatric HIV Confidential Case Report Form", <u>11/2019[3/2013]</u>.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department for Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

STEVEN J. STACK, MD, MBA, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 5, 2020

FILED WITH LRC: October 13, 2020 at 12:31 p.m.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Julie Brooks or Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes notification standards and specifies the diseases requiring immediate, urgent, priority, routine, or general notification, in order to facilitate rapid public health action to control diseases, and to permit an accurate assessment of the health status of the Commonwealth.

(b) The necessity of this administrative regulation: KRS 211.180(1) requires the cabinet to implement and maintain a statewide program for the detection, prevention, and control of reportable diseases. KRS 214.010 requires every physician, advanced practice registered nurse, and every head of family to notify the local health department of the existence of diseases and conditions designated by administrative regulation of the cabinet.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation delineates which diseases are reportable including the urgency of the notification.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will allow clinicians including every physician, advanced practice registered nurse, and head of family to notify the local health department of the existence of the diseases specified in the administrative regulation.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment to this administrative regulation updates the list of reportable diseases, which includes Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (the virus that causes COVID-19) and Multi-system Inflammatory Syndrome in Children (MSI-C), adds the provisions for submitting specimens for the identification of M. tuberculosis, updates the reporting requirements for multi-drug resistant organisms, adds the provisions for antimicrobial use reporting, updates the reporting requirements for HIV infection, adds reference to penalties for non-reporting, and updates the material incorporated by reference.

The Amended After Comments version of the administrative regulation adds varicella as a condition requiring priority reporting, retains the electronic laboratory reporting requirements for varicella, corrects the fax number on the EPID 250 form, and makes formatting changes to comply with KRS Chapter 13A drafting rules.

(b) The necessity of the amendment to this administrative regulation: The amendment to this administrative regulation is necessary to accurately capture pertinent information regarding M. tuberculosis; to maintain current reporting requirements based on the evolution of multi-drug resistant organisms; to collect data on facility-wide inpatient antimicrobial use as part of the Healthcare-Associated Infection/Antibiotic Resistance (HAI/AR) Prevention Program consistent with the CMS reporting program; to maintain a current surveillance system regarding HIV and AIDS including

genetic sequencing, documentation of HIV negative tests, history of PrEP treatment, and antiretroviral treatment; to promote compliance in the reporting of communicable diseases; and to provide updated material to be incorporated by reference.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 211.090(3) authorizes the secretary to adopt rules and regulations necessary to regulate and control all matters set forth in KRS 211.180. KRS 211.180(1) authorizes the cabinet to enforce the administrative regulations promulgated by the secretary of the Cabinet for Health and Family Services including policies, plans, and comprehensive programs relating to the detection, prevention, and control of communicable diseases. This amendment provides necessary updates needed to remain current in the accurate reporting of diseases.

(d) How the amendment will assist in the effective administration of the statutes: By updating this administrative regulation to reflect the current nature of multi-drug resistant organisms, the antimicrobial use surveillance, the provisions needed for accurate data collection regarding M. tuberculosis and HIV/AIDS, the list of reportable diseases, and the reference to penalties for non-reporting, the amendment allows for up-to-date compliance between the statutes and the administrative regulations.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The entities affected by this administrative regulation include all health facilities as defined by KRS 216B.015(13), health professionals licensed under KRS Chapters 311 through 314, medical laboratories as defined by KRS 333.020(3), national reference laboratories contracted by Kentucky health professionals, laboratories, or health facilities, pharmacists licensed under KRS Chapter 315, and veterinarians licensed under KRS Chapter 321. In addition, all citizens of the Commonwealth will be affected as a result of this amendment.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment: The regulated entities in question (3) will need to be aware of the updated lists of diseases and conditions requiring reporting including infectious agents and multi-drug resistant organisms. They will need to be aware of the specimens and isolates requiring submission to the Division of Laboratory Services. They also need to be aware of updated requirements regarding laboratory testing and submission of M. tuberculosis. Furthermore, entities need to be aware of immediate, urgent, priority, routine, and general reporting methods.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): The costs associated with compliance is unknown. Health facilities and physicians already report communicable diseases.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): As a result of compliance, the benefits of the timely and appropriate prevention and control of communicable diseases will be afforded to all citizens of the Commonwealth.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: This is an ongoing program, there are no initial costs.

(b) On a continuing basis: There is no increase in ongoing costs associated with the amendment to this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The reportable disease programs affected by this administrative regulation are funded through a mix of state general fund dollars, federal dollars, and specialized grants.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an amendment: An increase in fees or funding is not necessary to implement the changes with this amended administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. This administrative regulation does not contain fees.

(9) TIERING: Is tiering applied? Tiering is not applied. While the list of reportable diseases and conditions is separated by immediate, urgent, priority, routine, or general notification, all health facilities and physicians are required to report any known communicable disease.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts the Division of Epidemiology and Health Planning, as well as all local health departments.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.050, 211.090(3), 211.180(1), and 214.010

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation does not generate revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation does not generate revenue.

(c) How much will it cost to administer this program for the first year? There are no increased costs to administer this program in the first year.

(d) How much will it cost to administer this program for subsequent years? There are no increased costs to administer this program in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

CABINET FOR HEALTH AND FAMILY SERVICES Department for Public Health **Division of Public Health Protection and Safety** (Amended After Comments)

902 KAR 45:110. Permits and fees for retail food establishments, [food manufacturing plants, food storage warehouses, salvage processors and distributors,] vending machine companies, and restricted food concessions.

RELATES TO: KRS 217.015, 217.025, 217.035, 217.037, 217.085, 217.095, 217.125, 217.155, 217.811

STATUTORY AUTHORITY: KRS 217.125(1), (2), (4), 217.811 NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act. KRS 217.125(2) and (4) requires the secretary [of the Cabinet for Health and Family Services] to provide by administrative regulation a schedule of reasonable fees to be paid by [food manufacturing plants, food storage warehouses,] retail food establishments[, salvage distributors, salvage processing plants,] and restricted food concessions for permits to operate and for inspection activities carried out by the cabinet. KRS 217.811 requires the cabinet to provide by administrative

regulation a schedule of fees for operating a vending machine company[for Health and Family Services]. This administrative regulation establishes the schedule of fees.

Section 1. Fees. (1) [A permit fee shall be required for inspections conducted by the cabinet or the local health department to determine compliance with:

(a) 902 KAR 45:080 for a salvage distributor or a salvage processing plant; or

(b) KRS 217.025, 217.035, and 217.037 for a food manufacturing plant or food

storage warehouse.

(2) A fee for the inspection of an establishment identified in subsection (1)(a) or (b) of this section shall be assessed according to the total square footage of the establishment:

(a) Zero - 1,000 square feet - \$120;

(b) 1,001 - 5,000 square feet - \$160;

(c) 5,001 - 20,000 square feet - \$200;

(d) 20,001 - 40,000 square feet - \$300;

(e) 40,001 - 80,000 square feet - \$400;

(f) 80,001 - 150,000 square feet - \$500; or

(g) 150,001 or more square feet - \$600.

(3)] A fee shall be assessed for inspection of a retail food store or[and] food service establishment conducted by the cabinet or local health department to determine compliance with the provisions of KRS 217.025, 217.035, 217.037, and 217.125(2) pertaining to:

(a) Adulteration;

(b) Misbranding;

(c) Packaging; or

(d) Labeling of food products.

(2) A fee shall be assessed for inspection of a food service establishment conducted by the cabinet or local health department to determine compliance with the provisions of 902 KAR 45:005.

(3) The[(4) A] fee for the inspection of a retail food store or[and] a food service establishment shall be assessed according to the total square footage of the establishment:

(a) Zero - 1,000 square feet - ninety (90)[ninety-three (93)][seventy-five (75)] dollars;

(b) 1,001 - 10,000 square feet - \$155[156][125];

(c) 10,001 - 20,000 square feet - \$215[218][175];

(d) 20,001 - 30,000 square feet - \$250[200]; or

(e) 30,001 or more square feet - \$375[300]

(4)[(5)] An application for a permit to operate a mobile retail food store shall be accompanied by an annual fee of sixty

(60)[sixty-two (62)][fifty (50)] dollars. (5)[(6)] An application for a permit to operate a vending

machine company shall be accompanied by the annual permit fee of \$125 plus a fee for the total number of vending machines operated by the applicant:

(a) One (1) - twenty-five (25) machines - sixty (60) dollars[sixty-two dollars and fifty cents (62.50)];

(b) Twenty-six (26) - fifty (50) machines - ninety (90) dollars[ninety-three dollars and seventy-five cents (93.75)];

(c) Fifty-one (51) - 100 machines - \$125

(d) 101 - 150 machines - \$155[156.50]; and

(e) 151 and over machines - \$250.

(6)[(5)][the annual fee required by KRS 217.811.

[7] An application for a permit to operate a permanent food service establishment shall be accompanied by an annual fee of \$125[100], plus the following fee if applicable:

(a) Fee for the number of seats:

1. One (1) to twenty-five (25) seats - seventy-five (75)[sixty (60)] dollars;

2. Twenty-six (26) to fifty (50) seats - \$125[100];

3. Fifty-one (51) to 100 seats - \$155[156][125];

4. 101 to 200 seats - \$185[187][150]; or

5. 201 or more seats - \$215[218][175];

(b) Drive-through window - \$<u>155[156]</u>[125]; and (c) Catering operation - \$<u>135[137][110]</u>.

(7)[(8)] An application for a permit to operate a statewide mobile food unit shall be accompanied by an annual fee of \$200[160].

(8)[(7)](9)] An application for a permit to operate a temporary food service establishment shall be accompanied by a fee according to the length of the event:

(a) One (1) to three (3) day event – <u>sixty (60)[sixty-two</u> (62)][fifty (50)] dollars;

(b) Four (4) to seven (7) day event – <u>ninety (90)[ninety-three</u> (93)][seventy-five (75)] dollars; or

(c) Eight (8) to fourteen (14) day event - \$125[100].

(9)[(8)] An application for a permit to operate a farmer's market temporary food service establishment shall be accompanied by a fee of \$100.

(10)[(40)] [(10)] An application for a permit to operate a restricted food concession or mobile restricted food concession shall be accompanied by an annual fee of \$125.[100.

(11) A request for a certificate of free sale or export authorizing a Kentucky food manufacturing plant holding a valid permit to operate to export a product outside of the United States shall be accompanied by a service fee of ten (10) dollars for each certificate requested.]

Section 2. Payment of Fees. [(1)] Fees shall be made payable to the local health department having jurisdiction by a:

(1)[(a)] Retail food store;

(2)[(b)] Mobile retail food store;

(3)[(c)] Vending machine company [and commissary];

(4) Statewide [(d)] mobile food unit;

(5)[(e)] Temporary food establishment;

(6)[(f) Savage distributor;

(g)] Restricted food concession; or

(7)[(h)] Food service establishment.

(2) Fees shall be made payable to the Kentucky State Treasurer and forwarded to the Kentucky Department for Public Health by a:

(a) Food manufacturing plant;

(b) Salvage processing plant;

(c) Food storage warehouse; or

(d) Food manufacturing plant requesting a certificate for free sale or export.]

STEVEN J. STACK, MD, MBA, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 6, 2020

FILED WITH LRC: October 8, 2020 at 2:22 p.m.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Julie Brooks or Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the amount of the fees paid by retail food establishments, vending machine companies, and restricted food concessions.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish the fee structure to help support the department costs for permitting and inspecting retail food establishments, vending machine companies, and restricted food concessions.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 217.125 allows the secretary to promulgate regulations to establish a fee schedule for food processing establishments, farmer's market temporary food service establishments, temporary food service establishments, and retail food establishments. KRS 217.811 allows the secretary to establish a fee schedule for operating a vending machine company. This regulation outlines the schedule of fees to be paid for permit and inspection.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will assist with addressing the cost to

administer food permitting and inspection programs.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment to this administrative regulation establishes the reasonable fees for permitting and inspection of retail food stores, and all food service establishments. In addition, this amendment adds the fees for vending machine companies to this administrative regulation. The fee structure for food manufacturing establishments is being deleted from this administrative regulation.

The Amended After Comments version of this administrative regulation sets all fees to whole dollar amounts.

(b) The necessity of the amendment to this administrative regulation: House Bill 327 enacted during the 2018 legislative session removed the permitting and inspection fees for regulated entities covered under this administrative regulation. House Bill 129 enacted during the 2020 legislative session limits the fee increase to 25% until January 1, 2021. This amendment is necessary to establish the fee structure for entities permitted and inspected by the food safety program.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 217.125 authorizes the secretary to promulgate regulations for the efficient administration and enforcement of KRS 217.005 to 217.215 and to establish the fee structure for operating retail food establishments, food service establishments, and any temporary food service establishment. KRS 217.811 authorizes the secretary of the cabinet to promulgate administrative regulations to establish a fee for each application for permit to operate a vending machine company.

(d) How the amendment will assist in the effective administration of the statutes: This amendment revises the fee structure for all regulated entities to help offset the cabinet's cost to implement the inspection and permitting programs required by statute.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Approximately 21,000 food establishments are regulated under this administrative regulation. There are 100 vending machine companies registered with the department.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment: All permitted food service establishments, including retail food stores, will continue to be inspected by the cabinet. Vending machine companies will also continue to be inspected.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): The Amended After Comments version of the fee structure for food service establishments, including retail food stores and vending machines, is being increased by no more than 25%.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): All retail food stores, food service establishments, and vending machines are required to be inspected and permitting by the cabinet. The fees paid for inspection and permitting help to ensure retail food stores, food service establishments, and vending machine companies are in compliance with federal and state laws. This helps to ensure the safety of the food supply chain.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional costs initially.

(b) On a continuing basis: There are no additional costs on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Agency funds and revenue received from permitting and inspection

fees continue to be used to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an amendment: This amendment does result in an increase in fees paid by food service establishments and vending machine companies. There is no increase in funding necessary for this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. The Amended After Comments administrative regulation increases the current fees associated with operating a permitted food service establishment, a retail food store, a statewide mobile food unit, a restricted concession, and a mobile retail food store by no more than 25%.

The administrative costs to the cabinet are approximately \$150 per hour for inspectors of the listed food services establishments. This cost includes the salary of the inspector, fiscal year 2018 Kentucky Employee Retirement System (KERS) and Federal Insurance Contributions Act (FICA) contributions, and health and life insurance costs.

The average time for the inspection of a food service establishment is two and one-half (2.5) hours. The average costs for each inspection is \$375. The highest fee a food establishment will pay is \$375 for a retail food establishment and \$215 for a food service establishment.

The permitting fee for a vending machine company has been increased, but the schedule of fees for the number of vending machines is consistent with the previous fee schedule in KRS 217.811.

(9) TIERING: Is tiering applied? Tiering is applied. The fee structure for food service establishments and retail food stores is based on the risk level of the food preparations. Vending machine companies with fewer vending machines pay a lesser permit fee.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This amendment impacts the Department for Public Health, Division of Public Health Protection and Safety, Food Safety Branch, and all local health departments.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 217.125 and KRS 217.811.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The change in fee structure will generate an estimated \$142,000 from the regulated entities in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The change in fee structure will continue to generate an estimated \$142,000 in subsequent years.

(c) How much will it cost to administer this program for the first year? The current cost to administer all programs under the Food Safety Branch within the Division of Public Health Protection and Safety is \$5,524,622.00. There is no anticipated increase in costs to administer permitting and inspection of food service establishments, retail food stores, and vending machine companies this first year.

(d) How much will it cost to administer this program for subsequent years? There will be no change in program cost.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-): Other Explanation:

CABINET FOR HEALTH AND FAMILY SERVICES Department for Public Health Division of Public Health Protection and Safety (Amended After Comments)

902 KAR 45:180. Permits and fees for food <u>processing[manufacturing]</u> plants, food storage warehouses, salvage processors and distributors, cosmetic manufacturers, and certificate of free sale.

RELATES TO: KRS 217.015, 217.025, 217.035, 217.037, 217.085, 217.095, 217.155, **21 C.F.R. Parts 113, 114, 120, 123**

STATUTORY AUTHORITY: KRS 217.125(1), (2) NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act. KRS 217.125(2) requires the secretary to provide by administrative regulation a schedule of reasonable fees to be paid by food <u>processing[manufacturing]</u> plants, food storage warehouses, salvage distributors, salvage processing

plants, and cosmetic manufacturers for permits to operate and for inspection activities carried out by the cabinet. This administrative regulation establishes the schedule of fees. Section 1. <u>Definitions. (1) "Ready-to-eat" means food that</u> is in a form that is edible without washing, cooking, or

additional preparation by the food plant or the consumer to achieve food safety, and is expected to be consumed in that form.

(2) "Specialized processes" means foods processed under 21 C.F.R. Parts 113, 114, 120, or 123.

Section 2. Classification. Food processing and storage facilities shall be classified by the highest risk level of the food processed or stored.

(1) A facility shall be classified as a high risk food plant or risk level 1 if the facility:

(a) Is engaged in international, interstate, statewide, or regional distribution; and

(b) Uses one (1) or all of the following manufacturing processes:

<u>1. Time and temperature controlled foods that are ready-</u>to-eat;

2. High risk foods that are considered ready-to-eat; or

3. Foods that require specialized processes to decrease risk potential.

(2) A facility shall be classified as a medium risk food plant or risk level 2 if the facility processes foods that are either ready-to-eat foods or potentially hazardous foods, but not both.

(3) A facility shall be classified as a low risk food plant or risk level 3 if the facility processes foods that are not time and temperature controlled.

<u>Section 3.</u> Fees. (1) A permit fee shall be required for inspections conducted by the cabinet or the local health department to determine compliance with:

(a) 902 KAR 45:080 for a salvage distributor or a salvage processing plant;

(b) KRS 217.025, 217.035, and 217.037 for a food processing[manufacturing] plant or food storage warehouse; or

(c) KRS 217.085 and 217.095 for a cosmetic manufacturer.

(2) <u>The[A]</u> fee for the inspection of a food <u>processing[manufacturing]</u> plant or food storage warehouse shall be:

(a) Assessed according to the:

<u>1. Total yearly gross income from product sales of the facility; and</u>

2. Highest risk level of commodity manufactured by or stored at the facility: and

(b) Calculated as established in this paragraph. 1. If the income is less than \$100,000 per year, the fee:

a. For risk level 1 shall be \$250;

b. For risk level 2 shall be \$200; or

c. For risk level 3 shall be \$150.

2. If the income is equal to or greater than \$100,000 but less than \$500,000 per year, the fee:

a. For risk level 1 shall be \$400;

b. For risk level 2 shall be \$350; or

c. For risk level 3 shall be \$300.

3. If the income is equal to or greater than \$500,000 but

less than \$1,000,000 per year, the fee:

a. For risk level 1 shall be \$1,200;

b. For risk level 2 shall be \$750; or

c. For risk level 3 shall be \$450.

4. If the income is equal to or greater than \$1,000,000 per year, the fee:

a. For risk level 1 shall be \$2,800;

b. For risk level 2 shall be \$1,500; or

c. For risk level 3 shall be \$1,000[+

(a) High risk plant - \$2,400;

(b) Medium risk plant - \$1,350; or

(c) Low risk plant - \$750].

(3) A fee for the inspection of a cosmetic manufacturer shall be \$<u>150[300]</u>.

(4) A request for a certificate of free sale or export authorizing a Kentucky food processing[manufacturing] plant holding a valid permit to operate to export a product outside of the United States shall be accompanied by a service fee of fifty (50) dollars for each certificate requested.

(5)[Section 2. Payment of Fees.] Fees shall be made payable to the Kentucky State Treasurer and forwarded to the Kentucky Department for Public Health, Food Safety Branch, 275 East Main Street, Frankfort, Kentucky 40621.

STEVEN J. STACK, MD, MBA, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 6, 2020

FILED WITH LRC: October 8, 2020 at 2:22 p.m.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, KY 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Julie Brooks or Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the amount of the fees paid by food processing plants, food storage warehouses, cosmetic manufacturers, salvage processors and distributors, and requests for certificates for free sale.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish the fee structure to help support the department costs for permitting and inspecting food processing plants, food storage warehouses, cosmetic manufacturers, salvage distributors, salvage processing plants, and for issuing certificates of free sale.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 217.125 authorizes the secretary to promulgate regulations to establish a fee schedule for food processing establishments, food storage warehouses, salvage distributors, and salvage processing plants. KRS 217.155 authorizes the cabinet or its agents to inspect any factory, warehouse, or establishment in which cosmetics are manufactured. This administrative regulation outlines the schedule of fees to be paid for permit and inspection.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will assist with addressing the cost to

administer food and cosmetic permitting and inspection programs.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This is an Amended After Comments version of a new administrative regulation, not an amendment to an existing administrative regulation.

The Amended After Comments version of this new administrative regulation revises the proposed fee structure to be tiered based on income and risk level.

(b) The necessity of the amendment to this administrative regulation: This is an Amended After Comments version of a new administrative regulation, not an amendment to an existing administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is an Amended After Comments version of a new administrative regulation, not an amendment to an existing administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is an Amended After Comments version of a new administrative regulation, not an amendment to an existing administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: There are 1,072 food processors and seventy-seven (77) cosmetic manufacturers registered with the department.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment: All permitted food processing plants and storage warehouses will pay a fee based on the total yearly gross sales income and identified risk category level associated with the type of food being processed or stored. Cosmetic manufacturers are required to manufacture products in a commercial kitchen and the Food Safety Branch staff are responsible for inspecting all commercial kitchens.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): The current fee structure for food processing is based on the square footage for the facility and ranges from \$120 to \$600. This administrative regulation changes the fee structure to be based on yearly gross sales and the risk of the food manufactured. A low risk food processor who makes less than \$100,000 a year will pay \$150, while a low risk food processor who makes over one (1) million dollars a year will pay \$1,000. Cosmetic manufacturers will now be required to pay a \$150 fee for inspection

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): All food processing plants, and cosmetic manufacturers are required to be inspected and permitted by the cabinet. The fees paid for inspection and permitting help to ensure food processing plants and cosmetic manufacturers are in compliance with federal and state laws. Food processing plants with a higher risk category level will be inspected at a higher frequency as they have the greatest food safety risk.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional costs initially.

(b) On a continuing basis: There are no additional costs on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Agency funds and revenue received from permitting and inspection fees continue to be used to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an amendment: This administrative regulation does increase the fees paid by food

processing plants and institutes a new fee for cosmetic manufacturers. There is no increase in funding necessary for this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees.

This administrative regulation establishes the fees associated with operating a food processing plant or storage facility, a cosmetic manufacturer, and for the issuance of a certificate for free sale. The administrative cost to the cabinet is approximately \$150 per hour for inspectors. This cost includes the salary of the inspector, fiscal year 2018 Kentucky Employee Retirement System (KERS) and Federal Insurance Contributions Act (FICA) contributions, and health and life insurance costs.

The risk level of a food processing plant or food storage facility has an impact on the length of time required to conduct an inspection as well as the number of inspections completed per year.

Cosmetic manufacturers are currently subject to inspection but are not assessed a fee for permitting and inspection activities. This administrative regulation adds a fee of \$150 for the permitting and inspection activities of the cabinet.

(9) TIERING: Is tiering applied? Tiering is applied. The fee structure will be based on the total yearly sales income and the risk of the food being produced. Those making less than \$100,000 a year will pay a lower fee than those making over one (1) million dollars a year.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This amendment impacts the Department for Public Health, Division of Public Health Protection and Safety, Food Safety Branch, and all local health departments.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 217.125 and KRS 217.811.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The change in fee structure will generate an estimated \$796,996 from all entities regulated under this administrative regulation in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The change in fee structure will continue to generate an estimated \$796,996 in subsequent years.

(c) How much will it cost to administer this program for the first year? The current cost to administer the food processing inspection program is \$1,080,900. There is no anticipated increase in costs to administer permitting and inspection of food processing plants, food storage warehouses, food service establishments, retail food stores, cosmetic manufacturers, and vending machine companies this first year.

(d) How much will it cost to administer this program for subsequent years? There will be no change in program cost.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 21 C.F.R. Parts 113, 114, 120, and 123

2. State compliance standards. This administrative regulation adopts the federal requirements for food processing, packaging, storage, and distribution operations. The Food Safety Branch in the Department for Public Health was directed by the federal Food and Drug Administration (FDA) on which code of federal regulation to adopt to be in full compliance with the FDA food manufacturing standards.

3. Minimum or uniform standards contained in the federal mandate. KRS 217.125(1) authorizes the cabinet to promulgate regulations consistent with those promulgated under the federal act and the Fair Packaging and Labeling Act.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? No

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. There are no different, stricter, or additional responsibilities or requirements.

PROPOSED AMENDMENTS

Public comment periods are at least two months long. For other regulations with open comment periods, please also see last month's Administrative Register of Kentucky.

BOARDS AND COMMISSIONS Kentucky Board of Medical Licensure (Amendment)

201 KAR 9:081. Disciplinary proceedings.

RELATES TO: KRS 218A.205, 311.530-311.620, 311.840-<u>311.862,</u> 311.990

STATUTORY AUTHORITY: KRS 218A.205(3)(c), (d), (e), (5), 311.565(1)(a), (i), 311.595, 311.597, 311.601, 311.842, 311.850

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) and (i) and KRS 311.842 authorize the board to promulgate administrative regulations to regulate the conduct of licensees and to promote the efficient and fair conduct of disciplinary proceedings. KRS 311.595 and 311.597 authorize disciplinary action against licensees for specified offenses. KRS 311.850 authorizes disciplinary action against physician assistant licensees. KRS 218A.205(3)(c), (d), and (e) require the board to promulgate an administrative regulation establishing procedures for disciplinary action against [a] licensees who are authorized to prescribe controlled substances, including the enforcement of licensure standards to restrict the practice of a licensee or an applicant engaged in improper conduct. KRS 218A.205(5) authorizes the board to allow by administrative regulation an anonymous complaint or grievance. KRS 311.601 authorizes the board to adopt administrative regulations to effectuate and implement the provisions of 311.550 to 311.620 in regard to physicians and KRS 311.842 authorizes the board to adopt administrative regulations to license and regulate the practice of physician assistants in regard to KRS 311.840 to 311.862. This administrative regulation establishes the procedures to be followed in handling formal and informal disciplinary proceedings before the board, to conduct the proceedings with due regard for the rights and privileges of all affected parties.

Section 1. Definitions. [(1) "Act" means the Kentucky Medical and Osteopathic Practice Act, KRS 311.550 to 311.620.]

(1)[(2)] "Board" is defined by KRS 311.550(1).

(2)[(3)] "Charge" is defined by KRS 311.550(14).

(3)[(4)] "Complaint" is defined by KRS 311.550(15). (4)[(5)] "Executive director" is defined by KRS 311.550(4).

(5)[(6)] "General counsel" is defined by KRS 311.550(5).

(6)[(7)] "Grievance" is defined by KRS 311.550(13).

(7)[(8)] "Hearing officer" means the person designated and given authority by the board to preside over all proceedings pursuant to the issuance of any complaint or show cause order.

(8)[(9)] "Relating to a controlled substance" means any conviction or plea to a criminal charge, regardless of adjudication or the title of the offense named in the plea or judgment of conviction, that is determined from all available facts to have been based upon or resulted from, in whole or part, an allegation of conduct involving the improper, inappropriate, or illegal use, possession, transfer, prescribing, or dispensing of a controlled substance.

(9)[(10)] "Relating to prescribing or dispensing or administering a controlled substance" means any conviction or plea to a criminal charge, regardless of adjudication or the title of the offense named in the plea or judgment of conviction, that is determined from all available facts to have been based upon or resulted from, in whole or part, an allegation of conduct involving the improper, inappropriate, or illegal prescribing or dispensing of a controlled substance.

(10)[(11)] "Show cause order" means an order issued pursuant to KRS 311.572.

(11) "License" means a license to practice medicine or osteopathy or to practice as a physician assistant.

(12) "Licensee" means a person licensed by the board to

practice medicine or osteopathy or a person licensed by the board to practice as a physician assistant in the Commonwealth of Kentucky.

(13) "Applicant" means a person who is applying for an initial license or applying to reregister an inactive license to practice medicine or osteopathy or to practice as a physician assistant in the Commonwealth of Kentucky.

Section 2. Reception of Grievances; Investigations. (1)(a) A grievance may be submitted by any individual, organization, or entity.

(b)1. The board shall provide a copy of the Information on Filing a Grievance, the Consumer's Guide to the KBML, the Grievance Form, and the Waiver of Privilege, Agreement to Release Records to a party who wants to register a grievance against a licensee [physician].

2. Each grievance shall be filed on the Grievance Form; and

a. Include the name and address of the party filing the

grievance; or b. Be filed anonymously, subject to paragraph (d) of this subsection.

(c) A board member or employee may initiate a grievance by providing a written memorandum to the executive director.

(d) If the board receives an anonymous grievance, an investigation shall be conducted if the grievance is accompanied by sufficient corroborating evidence as would allow the board to believe, based upon a totality of the circumstances, that a reasonable probability exists that the grievance is meritorious.

(2)(a) The board shall initiate each investigation pertaining to prescribing or dispensing or administering of a controlled substance within seventy-two (72) hours of the date of receipt of the grievance.

(b) Except as provided by subsection (1)(d) of this section, each grievance shall be investigated as necessary and as promptly as possible, and presented to the inquiry panel for review.

(c) An investigation pertaining to prescribing or dispensing or administering of a controlled substance shall be presented to the inquiry panel within 120 days of the date of receipt of the grievance unless the circumstances of a particular grievance make it impossible to timely present the grievance to the inquiry panel.

(d)1. The executive director may hold an investigation pertaining to prescribing or dispensing or administering of a controlled substance in abeyance for a reasonable period of time in order to permit a law enforcement agency to perform or complete essential investigative tasks, following a request by the requesting law enforcement agency.

2. If an investigation pertaining to prescribing or dispensing or administering of a controlled substance is not presented to the inquiry panel within 120 days of the date of receipt of the grievance, the investigative report shall plainly state the circumstances of that particular grievance or investigation that made timely presentation to the inquiry panel impossible.

(e) The inquiry panel or executive director shall have the authority to direct any investigation and shall possess any and all powers possessed by the board in regard to investigations as provided by KRS 311.591 and 311.605 and 311.850(2).

(f) The inquiry panel shall further be empowered to request the attendance of any person at any meeting of the inquiry panel in regard to the investigation of any grievance or consideration of any disciplinary matter.

(g) The failure, without good cause, of any licensee [physician licensed to practice medicine or osteopathy by the board] to appear before the inquiry panel when requested shall be considered unprofessional conduct in violation of KRS 311.595(9) and 311.850(1)(s).

(3) The inquiry panel shall be empowered to request compliance with the reporting requirements of KRS 311.605 or 311.606 and may pursue an investigation, on its own initiative, in regard to an act of noncompliance or any other perceived violation of <u>board statutes [the Act]</u>.

Section 3. Reports and Recommendations; Petitions. (1) If the inquiry panel determines that a grievance warrants the issuance of a complaint against a <u>licensee</u> [physician], the inquiry panel shall cause a complaint to be prepared.

(2) If the panel chair determines that a grievance warrants the issuance of a complaint against a <u>licensee</u> [physician] and circumstances do not allow the timely presentation of the grievance to the inquiry panel, the panel chair shall cause a complaint to be prepared.

(3) If the inquiry panel determines that a disciplinary matter warrants the issuance of a show cause order against a <u>licensee</u> [physician], the inquiry panel shall cause a proposed order to be prepared.

(4) The board may issue a show cause order against a <u>licensee</u> [physician] in regard to any application for licensure, obtaining, retaining, or reobtaining licensure.

Section 4. Complaints. The complaint issued by an inquiry panel shall:

(1) Be signed and dated;

 (2) Be styled in regard to the matter of the license to practice in the Commonwealth of Kentucky held by the named <u>licensee</u> [physician] and designated with an appropriate case number; and
 (3) Set forth:

(a) The board's jurisdiction in regard to the subject matter of the complaint; and

(b) In numerical paragraphs, sufficient information to apprise the named <u>licensee</u> [physician] of the general nature of the charges.

Section 5. Show Cause Orders. The show cause order shall:

(1) Be signed and dated by an officer of the board;

(2) Be styled in regard to the license, application for license, or application for renewal, registration, or reregistration of a license to practice in the Commonwealth of Kentucky held by or submitted by the named <u>licensee</u> [physician], appropriately, and designated with an appropriate order number;

(3) Set forth:

(a) The board's jurisdiction in regard to the subject matter of the order; and

(b) In numerical paragraphs, the information which the board accepts to be true and the statutory basis for the board's finding that grounds exist for the discipline of the named <u>licensee's</u> [physician's] license; and

(4) Direct the named <u>licensee</u> [physician] to show cause why disciplinary action should not be taken in view of the matters expressed in the order.

Section 6. Orders to Respond. Upon issuance of a complaint, the inquiry panel shall notify the charged <u>licensee</u> [physician] that:

(1) A response is due within thirty (30) days after receiving notice of the complaint; and

(2) Failure to respond within that time period may be taken by the board as an admission of the charges.

Section 7. Notice and Service of Process. Each notice shall be issued as required by KRS 13B.050.

Section 8. Proceedings Pursuant to the Issuance of a Complaint or Show Cause Order. (1) Appointment of hearing officer. The board shall appoint a hearing officer in accordance with KRS 13B.030 and 13B.040.

(2) Appointment of the prosecuting attorney. The board's general counsel or assistant general counsel shall act as the prosecuting attorney in regard to any disciplinary proceeding, unless the board appoints a special prosecuting attorney. The prosecuting attorney shall not participate in any deliberations of the board pursuant to the issuance of a complaint, show cause order, or order of temporary discipline.

(3) Appointment of advisory counsel. The board may appoint a representative of the Attorney General's office, the board's general counsel, or other attorney to act as advisory counsel to the board in regard to any deliberations of the board pursuant to the issuance of a complaint, show cause order, or order of temporary discipline.

(4) The provisions of KRS Chapter13B shall govern the conduct of each proceeding.

Section 9. Mandatory Reporting; [Mandatory] Disciplinary Sanctions; Emergency Action; Expedited Proceedings. (1)(a) Except as provided by KRS 431.073(6) and 533.258(2), every applicant [for initial licensing to practice medicine or osteopathy within the Commonwealth of Kentucky] shall report upon the applicant's initial application:

(i) Any criminal conviction sustained or any plea of guilt, plea of nolo contendere, or Alford plea the applicant has entered to criminal charges in any state, regardless of adjudication;

(ii) [(b) Every applicant for initial licensing to practice medicine or osteopathy within the Commonwealth of Kentucky shall report upon the applicant's initial application] any disciplinary action taken or sanction imposed upon the applicant's license to practice [medicine or osteopathy] in any state, to include surrendering or placing the applicant's license in an inactive or retirement status to resolve a pending investigation by the licensing authority;

(iii) [(c) Every applicant for initial licensing to practice medicine or osteopathy within the Commonwealth of Kentucky shall report upon the applicant's initial application] if the applicant is currently under investigation by the licensing authority of any other state for possible violations of the licensing or regulatory statutes of that state.

(b) Failure to report a criminal conviction or plea, or action taken by another licensing board, as required of an applicant by subparagraphs (i) through (iii), shall constitute a violation of the operative licensing statutes and may be grounds for denial of a license.

(c) Upon a finding by the board that the applicant committed a violation, the board shall consider and give weight to the legislative intent expressed in KRS 218A.205(3)(f) when exercising its discretion whether to deny or grant the license or to grant the license subject to terms of restriction or limitation.

(d) If an applicant reports being the subject of a pending criminal investigation or of a pending investigation by a state licensing authority, the board shall defer any action upon that application until it has received official notice that the criminal or state licensing investigation has been completed and official notice of what action was taken as a result of the investigation.

(2)(a) [(d)] Every licensee [person licensed to practice medicine or osteopathy within the Commonwealth of Kentucky] shall report to the board:

(i) any criminal conviction or plea of guilt, nolo contendere, or Alford plea to any criminal charges, regardless of adjudication, within ten (10) days of the entry of judgment of conviction or the entry of the plea, entered into in any state. As part of this reporting, the licensee shall provide a copy of the judgment of conviction or plea documents.

(ii) [(e) Every person licensed to practice medicine or osteopathy within the Commonwealth of Kentucky shall report to the board within ten (10) days of receipt, notice of] any disciplinary action taken or sanction imposed upon the person's license in any state, including surrendering a license or placing a license into inactive or retired status to resolve a pending licensing investigation, within ten (10) days. As part of this reporting requirement, the licensee shall provide a copy of the order issued by or entered into with the other licensing board.[

(f)1. Failure to report a criminal conviction or plea, or action taken by another licensing board, as required of an applicant by paragraphs (a) through (c) of this subsection, shall constitute a violation of KRS 311.595(9) and (12).

2. Upon a finding by the board that the applicant committed a violation, the appropriate panel:

a. Shall impose a fine of up to \$5,000 and the appropriate sanction mandated by subsection (2), (3), or (4) of this section; and b. May impose any other additional sanction authorized by KRS 311.595, including denial of the application or revocation of the license previously issued based upon the incomplete information.]

(b) [(g)1.] Failure to report a criminal conviction or plea, or action taken by another licensing board as required of a licensee by <u>subparagraphs (i) through (ii)</u> [paragraphs (d) and (e) of this subsection], shall constitute a violation of the operative licensing statutes and may be grounds for discipline of a license [KRS 311.595(9) and (12)].

(c) [2-] Upon a finding by the board that the licensee committed a violation, the appropriate panel <u>shall consider and give weight to</u> the legislative intent expressed in KRS 218A.205(3)(f) when exercising its discretion whether to impose discipline, including up to indefinite restriction or revocation, against the license.[;

a. Shall impose a fine of up to \$5,000 and the appropriate sanction mandated by subsection (2), (3), or (4) of this section; and

b. May impose any other additional sanction authorized by KRS 311.595 based upon all of the information available to the panel when it takes action.

(2)(a) If an initial applicant reports being the subject of a pending criminal investigation or of a pending investigation by a state licensing authority, the board shall defer any action upon that initial application until it has received official notice that the criminal or state licensing investigation has been completed and official notice of what action was taken as a result of the investigation.

(b)1. If an initial applicant has been convicted of a felony offense or entered a plea of guilt, an Alford plea, or a plea of nolo contendere to any felony charge relating to a controlled substance, regardless of adjudication, in any state, the board shall exercise its normal discretion to grant or deny the application based upon all available facts.

2. Except as provided in paragraph 3 of this paragraph, if the board decides to grant a license to the initial applicant, the board:

a. Shall, at a minimum, permanently ban the applicant from prescribing or dispensing controlled substances as an express condition of granting the license; and

b. May impose any other conditions in addition to that permanent ban as express conditions of granting the license.

3. If the board learns from any source that an initial applicant has been convicted of or entered a plea of guilt, an Alford plea, or a plea of nolo contendere to any Class D felony offense relating to a controlled substance, and successfully participated in and completed a diversion program and had the case dismissed and the record of that offense expunged, then the board may, in its discretion, grant a license to the initial applicant contingent upon the applicant entering into an agreed order with terms and conditions deemed appropriate by the board as necessary for carrying out a minimum five (5) year period of probation.

(c) 1. Except as provided in subparagraph 2. of this paragraph, if a licensee has been convicted of or entered a plea of guilt, an Alford plea, or a plea of nolo contendere to any felony offense relating to a controlled substance, regardless of adjudication in any state, the appropriate panel:

a. Shall, at a minimum, permanently ban the licensee from prescribing or dispensing controlled substances as a disciplinary sanction; and

b. In addition to the permanent ban, may take any other disciplinary action authorized by KRS 311.595, including revocation, against the licensee.

2. If a licensee has been convicted of or entered a plea of guilt, an Alford plea, or a plea of nolo contendere to any Class D felony offense relating to a controlled substance, and successfully participated in and completed a diversion program and had the case dismissed and the record of that offense expunged, then the appropriate panel may, in its discretion, reinstate the licensee's prescribing or dispensing privileges contingent upon the licensee entering into an agreed order with terms and conditions deemed appropriate by the panel as necessary for carrying out a minimum five (5) year period of probation.

(3)(a)1. If an initial applicant has been convicted of a misdemeanor offense relating to prescribing or dispensing a controlled substance or entered a plea of guilt, an Alford plea, or plea of nolo contendere to a misdemeanor charge relating to

prescribing or dispensing a controlled substance, regardless of adjudication, in any state, the board shall exercise its normal discretion to grant or deny the application based upon all available information.

2. If the board decides to grant the application, the board:

a. Shall, at a minimum, ban the applicant from prescribing or dispensing controlled substances for a period of two (2) to five (5) years as an express condition of granting the license; and

b. May impose any other conditions in addition to that ban as express conditions of granting the license.

(b) If a licensee has been convicted of or entered a plea of guilt, an Alford plea, or a plea of nolo contendere to a misdemeanor offense relating to prescribing or dispensing a controlled substance, regardless of adjudication in any state, the appropriate panel:

1. Shall, at a minimum, ban the licensee from prescribing or dispensing controlled substances for a period of two (2) to five (5) years as a disciplinary sanction; and

2. In addition to the two (2) to five (5) year ban, may take any other disciplinary action authorized by KRS 311.595, including revocation, against the licensee.

(4)(a)1. If an initial applicant has surrendered the applicant's professional license or placed that license into an inactive or retired status to resolve a pending licensing investigation, the board shall not grant a license to that initial applicant, unless the licensing authority of that state has subsequently reissued or reinstated the license.

2. If the licensing authority of the state has subsequently reissued or reinstated the license, the board shall exercise its normal discretion in determining whether to grant or deny the application based upon the available facts.

(b) If an initial applicant has had a disciplinary action taken against or sanction imposed upon the applicant's license to practice medicine or osteopathy in any state, the board:

1.a. Shall, at a minimum, impose the same substantive sanctions imposed by the other state as an express condition of granting the license; and

b. May impose additional sanctions as an express condition of granting the license; or

2. Shall deny the application based upon the facts available at the time.

(c) If a licensee has had disciplinary action taken against or sanctions imposed upon the licensee's license to practice medicine or osteopathy in any state, the appropriate panel:

1. Shall, at a minimum, impose the same substantive sanctions, up to and including permanent revocation or surrender, as a disciplinary sanction against the licensee's Kentucky license; and

2. In addition to those minimum sanctions, may take any other disciplinary action authorized by KRS 311.595, including revocation, against the licensee.]

(d)(i) [(5)(a)] Failure to report a criminal conviction, a plea, or a disciplinary sanction by another licensing board as required by this section shall constitute a violation of law which constitutes an immediate danger to the public health, safety, or welfare [, for purposes of KRS 311.592 and 13B.125].

(ii) [(b)] If the board or one (1) of its panels learns that a licensee has suffered a qualifying criminal conviction or disciplinary sanction and has failed to report it as required by this section, the panel or its chair may immediately issue an emergency order appropriately suspending or restricting the licensee in accordance with this section.

(iii) [(c)] If an emergency order is issued and an emergency hearing is conducted pursuant to KRS 13B.125(3), the hearing officer shall not modify or amend the scope of the emergency order if there is substantial evidence to support the finding that the licensee failed to report a qualifying criminal conviction or disciplinary sanction as required by this section.

(e)(i) ((6)(a)] If the only violation charged in a complaint against the licensee is a criminal conviction or disciplinary sanction described in this section, and the conviction or disciplinary action may be proved by accompanying official certification, the board shall take appropriate steps to expedite the resolution of that complaint.

(ii) [(b)] Following receipt of the licensee's response to the complaint, board counsel shall promptly file a motion for summary disposition on the ground that no genuine issues of material fact are in dispute, pursuant to KRS 13B.090(2).

(iii) [(c)] The licensee shall file a response to the motion for summary disposition within twenty (20) days of receipt of the motion.

1. The licensee shall not re-litigate either the criminal conviction or disciplinary sanction.

2. The licensee may offer as defense that the certification of the document is fraudulent.

(iv) [(d)]1. The hearing officer shall issue a ruling upon the motion as soon as possible but no later than thirty (30) days after the motion is submitted for decision.

2. If the hearing officer issues a recommended order, the recommended order shall be presented to the board's hearing panel at its next meeting for resolution and imposition of the sanction <u>permitted</u> [required] by this section.

Section 10. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Information on Filing a Grievance", January 2013;

(b) "Consumer's Guide to the KBML", January 2013;

(c) "Grievance Form", January 2013; and

(d) "Waiver of Privilege, Agreement to Release Records", January 2013.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, Monday through Friday, 8:00 a.m. to 4:30 p.m.

SANDRA R. SHUFFETT, PRESIDENT

APPROVED BY AGENCY: October 14, 2020

FILED WITH LRC: October 14, 2020 at 10:52 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on December 21, 2020, at 9:30 a.m., at the Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222. Individuals interested in being heard at this hearing shall notify this agency in writing by 5 workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through December 31, 2020. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Leanne K. Diakov, General Counsel, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, phone (502) 429-7943, fax (502) 429-7118, email Leanne.Diakov@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Leanne K. Diakov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements for investigating grievances regarding prescribing, disciplinary proceedings, reception of grievances, meetings dates of the Board and Panels and mandatory reporting requirements.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to set forth requirements for investigating grievances regarding prescribing, disciplinary proceedings, reception of grievances, meetings dates of the Board and Panels and mandatory reporting requirements.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation acts specifically to establish the requirements for investigating grievances regarding prescribing, disciplinary proceedings, reception of grievances, meetings dates of the Board and Panels and mandatory reporting requirements.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation acts specifically to establish the requirements for investigating grievances regarding prescribing, disciplinary proceedings, reception of grievances, meetings dates of the Board and Panels and mandatory reporting requirements.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment revises language to be more inclusive of all licensees (i.e. physicians and physician assistants), who may be authorized to prescribe controlled substances. In addition, the amendment addresses a 2019 court decision which voided mandated sanctions because they conflict with discretionary sanctions in the Board's operating statute; the amendment of Section 9 now requires that the agency consider and give weight to the legislative intent for mandatory sanctions when exercising discretion.

(b) The necessity of the amendment to this administrative regulation: In 2020, the General Assembly amended the physician assistant statutes in order to allow that physician assistants may prescribe and administer Schedules III, IV and V controlled substances. KRS 218A.205 requires that each state licensing board who licenses or regulates persons who are authorized to prescribe or dispense controlled substances promulgate regulations related to investigating, reporting and disciplining for certain violations related to controlled substances. This amendment is necessary in order to regulate physician assistants who prescribe and administer controlled substances. In addition, KRS 218A.205 required that each state licensing board who licenses or regulates persons who are authorized to prescribe or dispense controlled substances promulgate regulations mandating certain sanctions for violations involving controlled substances or actions taken against a licensee in another state. In 2019, the Kentucky Court of Appeals voided mandated sanctions in the regulation because they conflict with discretionary sanctions in the Board's operating statute. The amendment is necessary to allow for the agency to give weight to the legislative intent when exercising its discretion.

(c) How the amendment conforms to the content of the authorizing statutes: In 2020, the General Assembly amended the physician assistant statutes in order to allow that physician assistants may prescribe and administer Schedules III, IV and V controlled substances. KRS 218A.205 requires that each state licensing board who licenses or regulates persons who are authorized to prescribe or dispense controlled substances promulgate regulations related to investigating, reporting and disciplining for certain violations related to controlled substances. This amendment is necessary in order to regulate physician assistants who prescribe and administer controlled substances. In addition, KRS 218A.205 required that each state licensing board who licenses or regulates persons who are authorized to prescribe or dispense controlled substances promulgate regulations mandating certain sanctions for violations involving controlled substances or actions taken against a licensee in another state. In 2019, the Kentucky Court of Appeals voided mandated sanctions in the regulations because they conflict with discretionary sanctions in the Board's operating statute. The amendment is necessary to allow for the agency to give weight to the legislative intent when exercising its discretion.

(d) How the amendment will assist in the effective administration of the statues: In 2020, the General Assembly amended the physician assistant statutes in order to allow that physician assistants may prescribe and administer Schedules III, IV and V controlled substances. KRS 218A.205 requires that each state licensing board who licenses or regulates persons who are authorized to prescribe or dispense controlled substances promulgate regulations related to investigating, reporting and disciplining for certain violations related to controlled substances.

This amendment is necessary in order to regulate physician assistants who prescribe and administer controlled substances. In addition, KRS 218A.205 required that each state licensing board who licenses or regulates persons who are authorized to prescribe or dispense controlled substances promulgate regulations mandating certain sanctions for violations involving controlled substances or actions taken against a licensee in another state. In 2019, the Kentucky Court of Appeals voided mandated sanctions in the Board's operating statute. The amendment is necessary to allow for the agency to give weight to the legislative intent when exercising its discretion.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The amendment will affect all physicians and physician assistants licensed to practice in the Commonwealth of Kentucky.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Physicians and physician assistants will be required to report sanctions taken against their license in another state or criminal convictions or pleas.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Licensed physicians and physician assistants are not expected to incur any additional costs in order to comply with the regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The Board and the Commonwealth of Kentucky will be better able to identify and curb the adverse actions of physicians and physician assistants contributing to the prescription drug epidemic.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: None.

(b) On a continuing basis: None.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: None.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change, if it is an amendment: No increase of fees or funding will be necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees nor does it directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all licensees regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Medical Licensure will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 218A.205(3)(c), (d), (e), and (5); KRS 311.565(1)(a) and (i); KRS 311.601; KRS 311.842

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. None.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities,

counties, fire departments, or school districts) for the first year? None.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None.

(c) How much will it cost to administer this program for the first year? None.

(d) How much will it cost to administer this program for subsequent years? None.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

BOARDS AND COMMISSIONS Kentucky Board of Medical Licensure (Amendment)

201 KAR 9:270. Professional standards for prescribing. [or] dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone.

RELATES TO: KRS <u>218A.205</u>, 311.530-311.620, 311.990, <u>311.840-311.862</u>

STATUTORY AUTHORITY: KRS 311.565(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) authorizes the board to promulgate administrative regulations to regulate the conduct of its licensees. KRS 218A.205(3)(a) and (b) require the board to establish mandatory prescribing and dispensing standards related to controlled substances. KRS 311.842(1)(b) requires that the board promulgate administrative regulations establishing professional standards for prescribing and administering controlled substances by physician assistants. This administrative regulation establishes the professional standards for any board licensee [physicians practicing in Kentucky] who prescribes, [prescribe or dispense] dispenses, or administers Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone in the Commonwealth of Kentucky.

Section 1. Minimum Qualifications for Prescribing, [er] Dispensing, or Administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone. Except as provided in Section 3 of this administrative regulation, a <u>licensee</u> [licensed physician] shall not prescribe, [er] dispense, or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone unless that <u>licensee</u> [physician] possesses the minimum qualifications established in this section.

(1) The <u>licensee</u> [physician] shall obtain and maintain in good standing a waiver and license as issued by the Drug Enforcement Administration (DEA) to prescribe Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for the treatment of opioid use disorder in the Commonwealth of Kentucky.

(2) The <u>licensee</u> [physician] shall successfully complete the approved educational programs required by this subsection.

(a) The prescribing <u>licensee</u> [physician] shall be a DEAlicensed prescriber of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone and shall have obtained Buprenorphine certification through completion of a Substance Abuse and Mental Health Services Administration ("SAMHSA") certified course.

(b) For each three (3) year continuing education cycle, each DEA-licensed prescriber of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone shall complete at least twelve (12) hours of continuing medical education certified in Category I specific to addiction medicine as part of the required continuing medical education hours set forth in 201 KAR 9:310 and 201 KAR 9:360.

(3) The licensee [physician] shall enroll in the Kentucky Health

Information Exchange to the extent necessary to query and pull information from the Kentucky Health Information Exchange. The <u>licensee [physician]</u> shall not report the prescribing, [er] dispensing, <u>or administering</u> [ef] Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for medically-supervised withdrawal or as maintenance treatment for a patient diagnosed with opioid use disorder into the Kentucky Health Information Exchange unless otherwise required by law.

Section 2. Professional Standards for Prescribing. [er] Dispensing, or Administering Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for Medically-Supervised Withdrawal or the Treatment of Opioid Use Disorder.

(1)(a) Except as provided in paragraph (b) of this subsection, transmucosal Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone shall only be prescribed. [er] dispensed, or administered for medically-supervised withdrawal or as a maintenance treatment for a patient diagnosed with opioid use disorder.

(b) Buprenorphine-Mono-Product or Buprenorphine-Combinedwith-Naloxone shall not be used for the treatment of pain or any other condition, unless delivered in a Federal Drug Administration (FDA) approved form and for an FDA approved purpose.

(2) Buprenorphine-Mono-Product shall not be prescribed. [er] dispensed, or administered for medically-supervised withdrawal or as a maintenance treatment for a patient diagnosed with opioid use disorder, except:

(a) To a pregnant patient;

(b) To a patient with demonstrated hypersensitivity to naloxone;

(c) As administered under supervision in a physician's office or other healthcare facility, including hospitals, urgent care settings, surgical care centers, residential treatment facilities, and correctional facilities; or

(d) To a patient transitioning from methadone to buprenorphine, limited to a period of no longer than one week.

(3)(a) Except as provided in paragraph (b) of this section, Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone shall not be prescribed. [er] dispensed, or administered to a patient who is also being prescribed benzodiazepines, other sedative hyprotics, stimulants or other opioids, without consultation of a physician who is certified by the American Board of Addiction Medicine, the American Board of Preventive Medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry.

(b) A <u>licensee</u> [physician] may prescribe. [er] dispense, or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone to a patient who is also being prescribed benzodiazepines, other sedative hypnotics, stimulants, or other opioids, without consultation in order to address an extraordinary and acute medical need not to exceed a combined period of thirty (30) days.

(4) Except as provided in Section 3 of this administrative regulation, each <u>licensee</u> [licensed physician] who prescribes, [er] dispenses, or administers Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for medically-supervised withdrawal or for the treatment of opioid use disorder shall fully comply with the professional standards established in this subsection.

(a) Prior to or at least within two (2) weeks of initiating treatment, the prescribing, [er] dispensing, or administering licensee [physician] shall:

1. Obtain and record a complete and appropriate evaluation of the patient which shall at a minimum include:

a. The patient's history of present illness;

b. The patient's history of substance use;

c. The patient's social and family history;

d. The patient's past medical and psychiatric histories;

e. A focused physical examination of the patient;

f. Screening for HIV and hepatitis serology; and

g. Arranging appropriate laboratory tests, which shall include a CBC, a drug screen, and a CMP;

2. Obtain the patient's consent and authorizations in order to obtain the patient's prior medical records.

a. Upon receipt of the medical records, the prescribing. [er] dispensing, or administering licensee [physician] shall review and incorporate the information from the records into the evaluation and treatment of the patient.

b. If the prescribing, [or] dispensing, or administering licensee [physician] is unable, despite best efforts, to obtain the patient's prior medical records, the licensee [physician] shall document those efforts in the patient's chart;

3. Obtain and review a KASPER report for that patient for the twelve (12) month period immediately preceding the initial patient encounter and appropriately utilize that information in the evaluation and treatment of the patient;

4. Explain treatment alternatives and the risks and the benefits of treatment with Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone to the patient;

5. Obtain written informed consent from the patient in a manner that meets professional standards; and

6. If the patient is a female of child-bearing age and ability, meet the requirements of paragraph (b) of this subsection.

(b) Except as provided in Section 3 of this administrative regulation, the requirements of this paragraph shall apply to the treatment of a female of child-bearing age and ability.

1. Prior to initiating treatment, the <u>licensee</u> [physician] shall require that the patient submit to a pregnancy test and, if pregnant, the <u>licensee</u> [physician] shall provide counseling as to the risk of neonatal abstinence syndrome which shall be consistent with current SAMHSA guidance.

2.a. <u>Unless the licensee is certified by the American Board of</u> <u>Addiction Medicine, the American Board of Preventive Medicine,</u> the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry or an obstetrician or maternal-fetal <u>medicine specialist</u>, a <u>licensee</u> [physician] who prescribes. [er] dispenses, or <u>administers</u> Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone to a patient who is pregnant or breastfeeding shall first obtain and document consultation with another independent physician that the potential benefit of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone use outweighs the potential risk of use.

b. The consultation shall be obtained from a physician who is certified by the American Board of Addiction Medicine, the American Board of Preventive Medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry or from an obstetrician or maternal-fetal medicine specialist.

(c) Except as provided by paragraph (d) of this subsection, while initiating treatment with Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, the <u>licensee</u> [prescribing or dispensing physician] shall comply with the requirements of this paragraph.

1. The <u>licensee</u> [prescribing or dispensing physician] shall recommend to the patient an in-office observed induction protocol.

a. Except as provided in clause b. of this subparagraph, the <u>licensee</u> [prescribing or dispensing physician] shall supervise the in-office observed induction protocol.

b. If an in-office observed induction does not occur, the <u>licensee</u> [prescribing or dispensing physician] shall appropriately record the circumstances in the patient chart.

2. The <u>licensee</u> [prescribing or dispensing physician] shall document the presence of opioid withdrawal before the first dose is given by using a standardized instrument, such as the clinic opioid withdrawal scale (COWS) or other similarly recognized instrument.

3. The <u>licensee</u> [prescribing or dispensing physician] shall initiate treatment with a dose not to exceed the dose equivalency of four (4) milligrams buprenorphine generic tablet, which:

a. May be followed by subsequent doses if withdrawal persists; and

b. Shall not exceed the dose equivalency of sixteen (16) milligrams buprenorphine generic tablet on the first day of treatment.

(d) If the patient is transferred from another treatment provider and has previously experienced withdrawal without a relapse and has not had a lapse in treatment, the <u>licensee</u> [prescribing or dispensing physician] shall:

1. Document that fact;

2. Educate the patient about the potential for precipitated withdrawal; and

3. Continue maintenance treatment of the patient on the same or less dosage as established by the previous treatment provider and then as provided in paragraph (e) of this subsection.

(e) After initial induction of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, the <u>licensee</u> [prescribing or dispensing physician] shall meet the requirements established in this paragraph.

1. If the <u>licensee [physician]</u> prescribes, [er] dispenses, or <u>administers</u> Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone medication, the <u>licensee [physician]</u> shall implement a treatment plan that requires objective behavioral modification by the patient. The behavioral modification shall include the patient's participation in a behavioral modification program that may include counseling or a twelve (12) step facilitation.

2. The <u>licensee</u> [physician] shall prescribe. [or] dispense. or administer to the patient an amount of Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone that:

a. Is necessary to minimize craving and opiate withdrawal;

b. Does not produce opiate sedation;

c. Except as provided in subclauses (i) through (iv) of this clause, is to be taken no more frequently than once daily;

(i) If the patient is pregnant, is to be taken no more than twice daily;

(ii) If the patient is receiving a daily dosage of less than 16mg, is to be taken no more than twice daily;

(iii) If the patient is simultaneously engaged in cancer treatment, hospice or palliative care, is to be taken bid or tid; or

(iv) If the patient is undergoing a major surgery, being any operative or invasive procedure or delivery, or has suffered a significant physical trauma, being any acute, blunt, blast or penetrating bodily injury that has a risk of death, physical disability or impairment, is to be taken bid or tid for up to fourteen (14) days; and

d. Is able only to supply the patient until the next <u>licensee</u> [physician] visit, which shall be scheduled as required by subparagraph 3. of this paragraph.

3.a. The <u>licensee</u> [prescribing or dispensing physician] shall ensure that the patient is seen:

(i) No later than ten (10) days after induction and then at intervals of no more than ten (10) days for the first month after induction; and

(ii) At intervals of no more than fourteen (14) days for the second month after induction.

b. (i) If the patient demonstrates objective signs of positive treatment progress, the <u>licensee</u> [prescribing or dispensing physician] shall ensure that the patient is seen at least once monthly thereafter.

(ii) If two (2) years after initiation of treatment, the patient is being prescribed Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone for opioid use disorder and the patient has demonstrated objective signs of positive treatment progress, including documented evidence that the patient has been compliant with the treatment plan and all treatment directives for at least two (2) years, then the <u>licensee</u> [prescribing or dispensing physician] may require that the patient be seen only by the <u>licensee</u> [prescribing or dispensing physician] at least once every three (3) months.

(iii) The <u>licensee</u> [prescribing or dispensing physician] shall see the patient in shorter intervals if the patient demonstrates any noncompliance with the treatment plan.

c. If extenuating circumstances arise that require a patient to unexpectedly reschedule a physician visit, the <u>licensee</u> [prescribing or dispensing physician] shall make best efforts to see the patient as soon as possible and document the circumstances in the patient chart. 4. At least every three (3) months after initiation of treatment, the <u>licensee</u> [prescribing or dispensing physician] shall evaluate the patient to determine whether the patient's dosage should be continued or modified and shall appropriately document that evaluation and clinical reasoning in the patient's chart.

5. At least once every three (3) months, the <u>licensee</u> [prescribing or dispensing physician] shall obtain KASPER reports to help guide the treatment plan.

a. If the KASPER indicates any abnormal findings, the <u>licensee</u> [prescribing or dispensing physician] shall incorporate those findings into appropriate clinical reasoning to support the continuation or modification of treatment and shall accurately document the same in the patient record.

b. Appropriate clinical reasoning may include adjustment of dose strength, adjustment_of frequency of visits, increased drug screening, a consultation with a specialist, or an alternative treatment.

c. Every twelve (12) months following initiation of treatment, if a patient's prescribed daily therapeutic dosage exceeds the dose equivalency of sixteen (16) milligrams buprenorphine generic tablet per day and the licensee [prescribing or dispensing physician] is not certified by the American Board of Addiction Medicine, the American Board of Preventive Medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry, then the licensee [prescribing or dispensing physician] shall obtain a consultation from a physician who is certified by the American Board of Addiction Medicine, the American Board of Medical Specialties (ABMS) in psychiatry, or an American Osteopathic Association (AOA) certifying board in addiction medicine or psychiatry for an opinion as to whether continued treatment and dosage is appropriate and shall accurately document the results of that consultation in the patient chart.

d. The <u>licensee</u> [prescribing or dispensing physician] shall adjust dosages according to the individual patient's condition and within acceptable and prevailing medical standards, with the goal of improving the patient's quality of life and ability to function in the community.

e. Every twelve (12) months following initiation of treatment, the <u>licensee</u> [prescribing or dispensing physician] shall evaluate for and document the medical necessity for continued treatment at the established dose.

f. The <u>licensee</u> [prescribing or dispensing physician] shall ensure that the patient is drug tested. A patient in early stages of treatment shall be tested at least once weekly and as the patient becomes more stable in treatment, the frequency of drug testing may be decreased, but shall be performed at least on a monthly basis. Individual consideration may be given for less frequent testing if a patient is in sustained remission. If the patient returns to substance use after a period of abstinence, the <u>licensee</u> [prescribing or dispensing physician] shall resume the early treatment testing schedule, in conjunction with an adapted or intensified treatment plan.

(i) Each drug screen shall at a minimum screen for buprenorphine, methadone, opioids, THC, benzodiazepines, amphetamines, and cocaine.

(ii) If a drug screen indicates any abnormal findings, the <u>licensee</u> [prescribing or dispensing physician] shall incorporate those findings into appropriate clinical reasoning to support the continuation or modification of treatment and shall accurately document the same in the patient record.

(iii) Appropriate clinical reasoning may include adjustment of dose strength, adjustment_of frequency of visits, increased drug screening, a consultation with a specialist, or an alternative treatment.

6. The <u>licensee</u> [prescribing or dispensing physician] shall document a plan for handling any lost or stolen medication, which shall not provide for the automatic replacement of medication prior to the specified interval date.

Section 3. Use of transmucosal buprenorphine-mono-product or buprenorphine-combined-with-naloxone for treatment of opioid use disorder in an emergency situation or inpatient setting. (1) In an emergency, including in a hospital emergency department or similar outpatient urgent care setting, or in an inpatient setting, <u>licensees [physicians]</u> may offer and initiate buprenorphine treatment to patients who present with opioid use disorder, without meeting the requirements established in Sections 1 and 2 of this administrative regulation and to the extent permitted by federal law, if:

(a) The <u>licensee [physician]</u> has determined that the use of buprenorphine-mono-product or buprenorphine-combined-withnaloxone will not result in a harmful interaction with other medications or substances in the patient's system, including benzodiazepines, sedative hypnotics, carisoprodol, or tramadol;

(b) The licensee [physician] obtains and documents written informed consent from the patient specific to risks and benefits of buprenorphine treatment; and

(c) The <u>licensee [physician]</u> provides the patient with written instructions and contact information for appropriate follow up care, including bridge-provider services, residential treatment providers, and outpatient treatment providers.

(2) The <u>licensee [physician]</u> shall initiate buprenorphine treatment under an observed induction protocol with an initial dose not to exceed the dose equivalency of four (4) milligrams buprenorphine generic tablet, which may be followed by subsequent doses, up to a maximum of twenty-four (24) milligrams buprenorphine generic tablet, if withdrawal persists and is not improving.

Section 4. Professional Standards for Documentation of Patient Assessment, Education, Treatment Agreement and Informed Consent, Action Plans, Outcomes, and Monitoring.

(1) Each_licensee [physician] prescribing, [er] dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone shall obtain and document all relevant information in a patient's medical record in a legible manner and in sufficient detail to enable the board to determine whether the licensee [physician] is conforming to professional standards for prescribing, [er] dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone and other relevant professional standards.

(2) If a licensee [physician] is unable to conform to professional standards for prescribing, [er] dispensing, or administering Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone as set forth in this administrative regulation due to circumstances beyond the licensee's [physician's] control, or the licensee [physician] makes a professional determination that it is not appropriate to comply with a specific standard, based upon the individual facts applicable to a specific patient's diagnosis and treatment, the licensee [physician] shall document those circumstances in the patient's record and only prescribe, [or] dispense, or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone to the patient if the patient record appropriately justifies the prescribing. [or] dispensing, or administering of Buprenorphine-Mono-Product or Buprenorphine-Combined-With-Naloxone under the circumstances and in accordance with SAMHSA guidelines.

Section 5. Violations. Failure to comply with or a violation of the professional standards established in Sections 2, 3, and 4 of this administrative regulation shall constitute a "departure from, or failure to conform to the standards of acceptable and prevailing medical practice within the Commonwealth of Kentucky," in violation of <u>KRS 311.850(1)(p) and (s)</u>, KRS 311.595(12) and (9), as illustrated by KRS 311.597(3), and may constitute a violation of <u>KRS 311.595(9)</u>, as illustrated by KRS 311.597(3), subjecting the <u>licensee</u> [licensed physician] to sanctions authorized by KRS 311.595 and KRS 311.850.

SANDRA R. SHUFFETT, PRESIDENT

APPROVED BY AGENCY: October 14, 2020

FILED WITH LRC: October 14, 2020 at 10:52 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on

December 21, 2020, at 9:30 a.m., at the Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222. Individuals interested in being heard at this hearing shall notify this agency in writing by 5 workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through December 31, 2020. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Leanne K. Diakov, General Counsel, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, phone (502) 429-7943, fax (502) 429-7118, email Leanne.Diakov@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Leanne K. Diakov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements for prescribing or dispensing Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone in the Commonwealth of Kentucky.

(b) The necessity of this administrative regulation: It is necessary to promulgate this regulation to establish acceptable and prevailing medical standards for prescribing or dispensing Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone in the Commonwealth of Kentucky.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation acts specifically to establish the requirements for Board licensees prescribing or dispensing Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone in the Commonwealth of Kentucky.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation acts specifically to establish the requirements for individual Board licensees prescribing or dispensing Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone in the Commonwealth of Kentucky.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: During the 2020 regular legislative session, the General Assembly amended the physician assistant statutes in order to allow that they may prescribe and administer controlled substances, including Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, and require that the Board adopt regulation setting forth prescribing standards for them. This administrative regulation amendment is necessary in order to hold physician assistants who prescribe or administer buprenorphine products accountable to the same standards as physicians.

(b) The necessity of the amendment to this administrative regulation: It is necessary to amend the administrative regulation in order to hold physician assistants who prescribe or administer buprenorphine products accountable to the same standards as physicians.

(c) How the amendment conforms to the content of the authorizing statutes: During the 2020 regular legislative session, the General Assembly amended the physician assistant statutes in order to allow that they may prescribe and administer controlled substances, including Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, and require that the Board adopt regulation setting forth prescribing standards for them. This administrative regulation amendment is necessary in order to

hold physician assistants who prescribe or administer buprenorphine products accountable to the same standards as physicians.

(d) How the amendment will assist in the effective administration of the statues: During the 2020 regular legislative session, the General Assembly amended the physician assistant statutes in order to allow that they may prescribe and administer controlled substances, including Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone, and require that the Board adopt regulation setting forth prescribing standards for them. This administrative regulation amendment is necessary in order to hold physician assistants who prescribe or administer buprenorphine products accountable to the same standards as physicians.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This amendment will affect all physician assistants licensed in the Commonwealth of Kentucky who prescribe, dispense or administer Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Physicians and physicians assistants will be required to follow the same professional standards for prescribing or dispensing Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone in the Commonwealth of Kentucky.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There is no cost associated with the requirements of this administrative regulation known to the Board.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Benefits to physicians and physician assistants include having consistent professional standards for prescribing or dispensing Buprenorphine-Mono-Product or Buprenorphine-Combined-with-Naloxone; benefits to the agency and the Commonwealth of Kentucky include curbing of the prescription drug epidemic and increasing patient access to appropriate treatment.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: None.

(b) On a continuing basis: None.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: None.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change, if it is an amendment: No increase of fees or funding will be necessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees nor does it directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Medical Licensure will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 218A.205(3)(a) and (b), KRS 311.565(1)(a), KRS 311.842(1)(b)

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. None.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None.

(c) How much will it cost to administer this program for the first year? None.

(d) How much will it cost to administer this program for subsequent years? None.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

EDUCATION AND WORKFORCE DEVELOPMENT CABINET Kentucky Board of Education Department of Education (Amendment)

701 KAR 5:150. Nontraditional instruction program.

RELATES TO: KRS 158.070

STATUTORY AUTHORITY: KRS 156.029, 156.070, 156.160, 158.070

NECESSITY, FUNCTION, AND CONFORMITY: KRS 156.029(7) requires the Kentucky Board of Education (KBE) to adopt policies and administrative regulations by which the Kentucky Department of Education (department) shall be governed in planning and operating programs within its jurisdiction. KRS 156.070(5) requires the KBE, upon the recommendation of the Commissioner of Education (Commissioner), to establish policy or act on all programs, services, and other matters which are within the administrative responsibility of the department. KRS 158.070 requires the KBE to promulgate an administrative regulation to prescribe the conditions and procedures for local education agencies (districts) to be approved for the nontraditional instruction program. This administrative regulation establishes the requirements and approval process for districts to be approved for the nontraditional instruction program.

Section 1. Definitions. (1) "Certified employee" means an employee of a local school district who is required to have a certification for his position pursuant to KRS 161.020.

(2) <u>"Comprehensive District Improvement Plan" shall have the</u> same meaning as defined in 703 KAR 5:225, Section 1(3).

(3) "Instructional delivery method" means the delivery system and instructional techniques to be used in meeting the learning needs of students <u>regardless of their physical location</u>.

(4) [(3)] "Minimum school term" or "school term" is defined in KRS 158.070(1)(b).

(5) [(4)] "Nontraditional instruction day" means a day during the school term that a local school district is closed for health or safety reasons that is approved by the commissioner, pursuant to KRS 158.070(9), to be the equivalent to a student attendance day.

(6) [(5)] "Nontraditional instruction plan" means the strategy approved by the commissioner and implemented by a local school district to ensure instruction on nontraditional instruction days is a continuation of learning that is occurring on regular student attendance days as required by KRS 158.070(9).

(7) [(6)] "Professional learning plan" means the strategy implemented to ensure staff in a local school district acquire, enhance, and refine the knowledge, skills, practices, and

dispositions necessary to create and support high levels of learning for all students.

(8) [(7^{2})] "Student attendance day" is defined in KRS 158.070(1)(e).

Section 2. <u>Nontraditional Instruction Plan.</u> [Initial Application Process.] (1) [Using the Nontraditional Instruction Program Initial Application, a] <u>A</u> district <u>seeking commissioner approval</u>, <u>pursuant</u> to KRS 158.070, of a nontraditional instruction plan shall annually incorporate [submitting] such within the Comprehensive District Improvement Plan [a nontraditional instruction plan to be approved by the commissioner].

(2) A nontraditional instruction plan incorporated within the Comprehensive District Improvement Plan shall [include]:

(a) Provide an overview of the district's vision for ensuring a continuation of learning when implementing nontraditional instruction;

(b) Describe in detail:

1. How instruction shall be delivered for students in nontraditional settings;

2. The steps the district shall take to ensure a continuation of learning occurs for students in nontraditional settings;

3. How, if at all and to the extent permitted by applicable statutes and administrative regulations, the district shall ensure a continuation of learning occurs for those students utilizing, for any reason, nontraditional instruction during time periods when the district may be offering and providing in-person instruction to other students;

4. How the district shall ensure a continuation of learning for students with Individual Education Plans in nontraditional settings;

5. Additional efforts that may be necessary to ensure a continuation of learning for other special populations of students in nontraditional settings;

<u>6. How the district has coordinated or will coordinate with other</u> educational entities to ensure a continuation of learning for students in nontraditional settings;

7. How teachers shall instruct, support and communicate with students in order to ensure academic progress as well as promote social and emotional wellbeing for students in nontraditional settings;

8. The professional learning activities the district shall provide certified staff to ensure they have the skills necessary to provide a continuation of learning for students in nontraditional settings;

9. How the district shall deploy all staff when school is closed to in-person instruction;

10. The partnerships the district has established with other community agencies to increase opportunities for a continuation of learning for students in nontraditional settings; and

<u>11. The district's communication plan for parents, students, and community members for students in nontraditional settings;</u>

(c) Explain how the nontraditional instruction plan relates to district goals; and[A description of the instructional delivery methods, including the use of technology, to be used on nontraditional instruction days;

(b) A description of how the district will provide access to online resources, if used, and equitable instructional materials for students who do not have access to the internet and for students needing to access information differently;

(c) A description of how the district shall ensure a continuation of learning from regular student attendance days will occur on nontraditional instruction days;

(d) A description of how the district will ensure implementation of Individual Education Programs for students with disabilities, including how an Admissions and Release Committee will be involved in planning for and making decisions related to the participation and needs of students with disabilities, on nontraditional instruction days;

(c) A description of how the district will ensure implementation of other student-specific educational plans, including Program Service Plans for English Learners, 504 Plans, and Gifted Student Service Plans for students identified as gifted and talented, on nontraditional instruction days;

(f) A description of how student participation will be measured

and how evidence of student learning will be gathered on nontraditional instruction days;

(g) A description of how each job category within the district will fulfill contractual obligations on nontraditional instruction days and how employee participation will be verified on nontraditional instruction days;

(h) An explanation of the professional learning plan the district will implement to ensure certified employees have the knowledge and capacity to provide instruction on nontraditional instruction days;

(i) A description of education agencies that are external to the district but have students of the district in attendance on a part-time or full-time basis and the considerations on nontraditional instruction days that will need to be agreed upon between the district and those external education agencies;

(j) A description of stakeholder involvement in developing and implementing nontraditional instruction days;

(k) A description of how the district will relay information about nontraditional instruction days to students and families; and

(1)] (<u>d</u>) Provide other [Other] evidence deemed necessary by the department to effectively review and approve or deny a district's nontraditional instruction plan.

(3) [(2)] The department shall provide technical assistance, upon request, to districts prior to <u>the incorporation</u> [submission] of [the] <u>a nontraditional instruction plan within the Comprehensive</u> District Improvement Plan [Nontraditional Instruction Program Initial Application].

(4) [(3)] A district shall submit <u>the nontraditional instruction plan</u> to the department by May 1 [an application at least 120 days prior to the beginning of a school term to have the application considered] for implementation at the beginning of the upcoming school term.

(5) [(4) A committee designated by the] The commissioner or <u>his designee(s)</u> shall review and [recommend the commissioner] approve or deny a completed <u>nontraditional instruction plan</u> [Nontraditional Instruction Program Initial Application] within forty-five (45) days from receipt [of the completed application].[

(5) Within thirty (30) days from receipt of the recommendation from the committee designated pursuant to subsection (4) of this section, the commissioner shall approve or deny a completed Nontraditional Instruction Program Initial Application. The Commissioner may initially approve a district to participate in the NONTRADITIONAL instruction program for up to two (2) years.]

(6)(a) A district approved to participate in the nontraditional instruction program may amend its <u>nontraditional instruction plan</u> [Nontraditional Instruction Program Initial Application] as needed at any time by submitting a written amendment request to the department.

(b) The amendment request shall contain a description of the amendment, proposed timeline for implementation, and justification for the request.

(c) [A committee designated pursuant to subsection (4) of this section] <u>The Commissioner or his designee(s)</u> shall review the amended <u>nontraditional instruction plan</u> [Nontraditional Instruction Program Initial Application] and [recommend the commissioner] approve or deny such within forty-five (45) days of the amendment submission.[

(d) Within thirty (30) days from receipt of the recommendation from the committee designated pursuant to subsection (4) of this section, the commissioner shall approve or deny an amended Nontraditional Instruction Program Initial Application. An amended Nontraditional Instruction Program Initial Application approved by the commissioner shall be in effect for the remainder of the initial period of approval pursuant to subsection (5) of this section.]

Section 3. [Renewal Application Process. (1) At the end of the term of approval, a district that has used at least one (1) nontraditional instruction day during the term of approval shall be eligible to complete the renewal application process. A district not eligible to complete the renewal application process shall be eligible to apply using the Nontraditional Instruction Program Initial Application and in compliance with Section 2 of this administrative regulation.

(2) Using the Nontraditional Instruction Program Renewal Application, a returning district submitting a nontraditional instruction plan to be approved for renewal by the commissioner shall include:

(a) A description of the nontraditional instruction program that includes:

1. Revisions to the district's nontraditional instruction program that are being proposed for the program to grow in rigor and efficacy;

2. Program adjustments that are being proposed to improve the program for stakeholders; and

3. Any changes being proposed related to how the district handles food service staff and costs on nontraditional instruction days.

(b) Other evidence deemed necessary by the department to effectively review and approve or deny a district's nontraditional instruction plan.

(3) The department shall provide technical assistance, upon request, to districts prior to submission of the Nontraditional Instruction Program Renewal Application.

(4) A district shall submit an application at least 120 days prior to the beginning of a school term to have the application considered for implementation at the beginning of the upcoming school term.

(5) A committee designated by the commissioner shall review and recommend the commissioner approve or deny a completed Nontraditional Instruction Program Renewal Application within forty-five (45) days from receipt of the completed application.

(6) Within thirty (30) days from receipt of the recommendation from the committee designated pursuant to subsection (5) of this section, the commissioner shall approve or deny a completed Nontraditional Instruction Program Renewal Application. At renewal, the commissioner may approve a district to participate in the nontraditional instruction program for up to four (4) years. (7) (a) A district approved to participate in the nontraditional instruction program may amend its Nontraditional Instruction Program Renewal Application as needed at any time by submitting a written amendment request to the department.

(b) The amendment request shall contain a description of the amendment, proposed timeline for implementation, and justification for the request.

(c) A committee designated pursuant to subsection (5) of this section shall review the amended Nontraditional Instruction Program Renewal Application and recommend the commissioner approve or deny such within forty-five (45) days of the amendment submission.

(d) Within thirty (30) days from receipt of the recommendation from the committee designated pursuant to subsection (4) of this section, the commissioner shall approve or deny an amended Nontraditional Instruction Program Renewal Application. An amended Nontraditional Instruction Program Renewal Application approved by the commissioner shall be in effect for the remainder of the renewal period of approval pursuant to subsection (6) of this section.

Section 4.] Use of Nontraditional Instruction Days. (1) Once <u>a</u> district is approved by the commissioner <u>or his designee(s)</u> [has approved a district] to participate in the nontraditional instruction program, the district may apply for and the commissioner may approve the use of nontraditional instruction days on days when the district is closed for health or safety reasons <u>pursuant to KRS</u> 158.070.

(2) [Pursuant to KRS 158.070, the district may apply for and the commissioner may approve up to the equivalent of ten (10) student attendance days per school year in nontraditional instruction days for the district.

(3)] The district shall seek approval from the commissioner to use one (1) or more nontraditional instruction days by submitting a request and appropriate supplemental documentation, as required by the department, to the department within thirty (30) days following the day(s) the district was closed for health or safety reasons.

(3) [(4)] The commissioner shall approve or deny a district's

use of one or more nontraditional instruction days within thirty (30) days from receipt of the district's request and appropriate supplemental documentation, as required by the department. A request to use (1) one or more nontraditional instruction days shall be denied by the commissioner if the district fails to supply clear evidence demonstrating a continuation of learning from regular student attendance days occurs on nontraditional instruction days. Clear evidence may include:

(a) Examples of student work;

(b) Lesson plans; or

(c) Curriculum maps.

Section <u>4.</u> [5-] Monitoring and Revocation of Nontraditional Instruction Programs. (1) At the conclusion [of the first school term of implementation of the approved Nontraditional Instruction Program Application and at the end] of each school term [thereafter for the entirety of the approval status], a district approved by the commissioner <u>or his designee(s)</u> to participate in the nontraditional instruction program may receive an annual site visit from a review team selected and trained by the department. The purpose of the site visit is to monitor the district's progress in implementing the approved <u>nontraditional instruction plan</u> [Nontraditional Instruction Program Application].

 $\ensuremath{(2)}$ If a site visit is conducted by the department, the site visit shall:

(a) Be made following adequate advanced notice to the district; and

(b) Include the gathering of information through the examination of records related to the district's implementation of the approved <u>nontraditional instruction plan</u> [Nontraditional Instruction Program Application], including [renewals and] amendments if applicable, and through interviews with district leadership, staff, and students as well as other stakeholders.

(3) In addition to any site visit that may be conducted pursuant to subsections (1) and (2) of this section of this administrative regulation, a district approved by the commissioner <u>or his</u> <u>designee(s)</u> to participate in the nontraditional instruction program shall, upon request, make the following available for inspection by the department:

(a) Documentation of the instructional delivery methods used on nontraditional instruction days; (b) Evidence demonstrating the district provides access on nontraditional instruction days to online resources, if used, and equitable instructional materials for students who do not have access to the internet and for students needing to access information differently;

(c) Clear evidence demonstrating a continuation of learning from regular student attendance days occurs on nontraditional instruction days. Clear evidence may include:

1. Examples of student work;

2. Lesson plans; or

3. Curriculum maps.

(d) Evidence demonstrating the district ensures implementation of Individual Education Programs for students with disabilities, including the involvement <u>of the</u> Admissions and Release Committee in planning for and making decisions related to the participation and needs of students with disabilities, on nontraditional instruction days;

(e) Evidence demonstrating the district ensures implementation of other student-specific educational plans, including Program Service Plans for English Learners and Gifted Student Service Plans for students identified as gifted and talented, on nontraditional instruction days;

(f) Data demonstrating student participation and student learning on nontraditional instruction days;

(g) Evidence demonstrating how each job category within the district fulfills contractual obligations on nontraditional instruction days and data, including teacher work logs, demonstrating employee participation on nontraditional instruction days;

(h) The professional learning plan implemented by the district to ensure certified staff have the knowledge and capacity to provide instruction on nontraditional instruction days and evidence demonstrating implementation;

(i) Where appropriate, agreements about nontraditional

instruction days between the district and educational agencies that are external to the district but have students of the district in attendance on a part-time or full-time basis;

(j) Evidence demonstrating stakeholder involvement in developing and implementing nontraditional instruction days;

(k) Methods used by the district to relay information about nontraditional instruction days to students and families; and

(I) Other evidence deemed necessary by the department to effectively monitor the implementation of the approved nontraditional instruction plan [Nontraditional Instruction Program Application], including [renewals and] amendments if applicable.

(4) [At the conclusion of each term of implementation of the approved Nontraditional Instruction Program Application for the entirety of the approval status, the department] The commissioner or his designee(s) may revoke approval of a district's nontraditional instruction program as a result of evidence collected pursuant to this section of this administrative regulation.

(5) Prior to having approval of its nontraditional instruction program revoked, a district shall receive a site visit from a review team selected and trained by the department. The purpose of the visit shall be to monitor the district's progress in implementing the nontraditional instruction program, collect qualitative data on the effectiveness of the nontraditional instruction program, and verify the district's compliance with all applicable laws. A site visit shall be made following adequate advance notice to the district and may include the gathering of information through:

(a) Direct observation;

(b) Interviews with staff and students; or

(c) Examination of records.[

(6) Any district that has had approval of its nontraditional instruction program revoked by the department shall wait a minimum of one (1) calendar year before submitting a new Nontraditional Instruction Program Application.

Section 6. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Nontraditional Instruction Program Initial Application," October 2018; and

(b) "Nontraditional Instruction Program Renewal Application," October 2018.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department of Education, Office of Continuous Improvement and Support, 300 Sower Boulevard, 5th Floor, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.]

This is to certify that the chief state school officer has reviewed and recommended this administrative regulation prior to its adoption by the Kentucky Board of Education, as required by KRS 156.070(5).

JASON E. GLASS, Ed.D., Commissioner of Education

LU YOUNG, Ed.D., Chairperson

APPROVED BY AGENCY: October 13, 2020

FILED WITH LRC: October 13, 2020 at 4:14 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this proposed administrative regulation shall be held on December 22, 2020, at 10:00 a.m. in the State Board Room, 5th Floor, 300 Sower Blvd, Frankfort, Kentucky. Individuals interested in being heard at this meeting shall notify this agency in writing five working days prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments on the proposed administrative regulation.

CONTACT PERSON: Todd G. Allen, General Counsel, Kentucky Department of Education, 300 Sower Boulevard, 5th Floor, Frankfort, Kentucky 40601, phone 502-564-4474, fax 502564-9321; email regcomments@education.ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Todd G. Allen

(1) Provide a brief summary of:

(a) What this administrative regulation does: This revised regulation prescribes the conditions and procedures for local education agencies to be approved by the Commissioner of Education (Commissioner) for participation in the nontraditional instruction (NTI) program.

(b) The necessity of this administrative regulation: Statewide utilization of NTI at the end of the 2019-2020 school year over a period of six to nine weeks, depending on each schools district's remaining instructional days, demonstrated a need to revisit the NTI program, including the conditions and procedures used for districts to be approved for participation, so as to promote a continuation of learning when in-person instruction may not be feasible and to support continuous improvement. Accordingly, this amended regulation, which requires a district's NTI plan be annually incorporated into the Comprehensive District Improvement Plan (CDIP), supports districts in designing and implementing a plan for a continuation of learning during times when NTI may need to be implemented, either in the short-term or long-term, in order to prevent a loss of learning.

(c) How this administrative regulation conforms to the content of the authorizing statute: The revised regulation conforms to the authority given to the Kentucky Board of Education (KBE) in KRS 158.070, which specifically requires the KBE promulgate regulations "to prescribe the conditions and procedures for districts to be approved for the nontraditional instruction program."

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This regulation assists local education agencies by providing a streamlined mechanism, namely the CDIP, by which to submit NTI plans to the Commissioner for approval.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This regulation has, primarily, been revised to require all prospective NTI districts to incorporate an NTI plan within the CDIP and to remove language distinguishing between "initial" and "renewal" NTI applicants.

(b) The necessity of the amendment to this administrative regulation: Statewide utilization of NTI at the end of the 2019-2020 school year over a period of six to nine weeks, depending on each schools district's remaining instructional days, demonstrated a need to revisit the NTI program, including the conditions and procedures used for districts to be approved for participation, so as to promote a continuation of learning when in-person instruction may not be feasible and to support continuous improvement. Accordingly, this amended regulation, which requires a district's NTI plan be annually incorporated into the CDIP, supports districts in designing and implementing a plan for a continuation of learning during times when NTI may need to be implemented, either in the short-term or long-term, in order to prevent a loss of learning.

(c) How the amendment conforms to the content of the authorizing statute: The revised regulation conforms to the authority given to the KBE in KRS 158.070, which specifically requires the KBE promulgate regulations "to prescribe the conditions and procedures for districts to be approved for the nontraditional instruction program."

(d) How the amendment will assist in the effective administration of the statutes: This regulation assists local education agencies by providing a streamlined mechanism, namely the CDIP, by which to submit NTI programs to the Commissioner for approval.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Local education agencies, the KBE, and the Kentucky Department of Education (KDE) will be impacted by this regulation.

(4) Provide an analysis of how the entities identified in question

(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: A local education agency seeking Commissioner approval of the NTI plan will now be required to annually incorporate such within the CDIP. Utilization of the CDIP process supports districts in designing and implementing a plan for a continuation of learning during times when NTI may need to be implemented, either in the short-term or long-term, in order to prevent a loss of learning.

A local education agency that has its NTI plan approved by the Commissioner will still have to comply with the monitoring and oversight provisions of this administrative regulation, which these revisions do not substantively impact.

The KBE and the KDE will implement the application procedures as well as the monitoring and oversight provisions in this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There is no anticipated budget impact related to this administrative regulation for local education agencies, the KBE, or the KDE.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This administrative regulation provides for a more streamlined, efficient NTI application process, which benefits local education agencies as well as the KBE and the KDE. This administrative regulation also provides clarity and transparency regarding the processes the KBE and the KDE will implement in monitoring and overseeing approved NTI programs, which also benefits local education agencies as well as the KBE and the KDE.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: A version of the NTI program has existed since 2011, and the KDE has been administering the program since that time. As a result, initial costs related to implementation of this administrative regulation are not anticipated.

(b) On a continuing basis: The administrative body incurs an ongoing cost of staff and resources in reviewing and approving NTI programs and in monitoring approved NTI programs. There are, though, no additional anticipated costs related to this administrative regulation for the administrative body.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: There are no additional anticipated costs for the implementation and enforcement of this administrative regulation; however, ongoing costs of staff and resources for the administrative body related to this administrative regulation and its enabling statutes are paid using state funds.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase in fees or funding is not anticipated to be necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This regulation neither establishes any fees nor directly or indirectly increases any fees.

(9) TIERING: Is tiering applied? Tiering is not applied because this administrative regulation applies equally to local education agencies, the KBE, and the KDE.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Local education agencies, the Kentucky Board of Education (KBE), and the Kentucky Department of Education (KDE).

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 156.029, KRS 156.070, KRS 156.160, and KRS 158.070.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. A version of the nontraditional instruction (NTI) program has existed since 2011, and the KDE has been administrative regulation is not expected to impact the expenditures and revenues of any state or local government agency.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? N/A $\,$

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? N/A

(c) How much will it cost to administer this program for the first year? A version of the NTI program has existed since 2011, and the KDE has been administering the program since that time. As a result, additional costs related to administering this program for the first year are not anticipated.

(d) How much will it cost to administer this program for subsequent years? A version of the NTI program has existed since 2011, and there is an ongoing cost of staff and resources in reviewing and approving NTI programs and in monitoring approved NTI programs. There are, though, no additional anticipated costs related to this administrative regulation.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): N/A Expenditures (+/-): NA Other Explanation: N/A

EDUCATION AND WORKFORCE DEVELOPMENT CABINET Kentucky Board of Education Department of Education (Amendment)

704 KAR 3:035. Annual professional development plan.

RELATES TO: KRS 156.095, 158.070

STATUTORY AUTHORITY: KRS 156.070, 156.095, 158.070(5)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 156.095 requires the Kentucky Board of Education to establish, direct, and maintain a statewide program of professional development to improve instruction in the public schools. KRS 158.070(5) requires the state board to promulgate administrative regulations establishing guidelines and procedures to be followed for the approval of the days utilized for four (4) days of the minimum school term required to be utilized by each local school district for professional development activities for the professional staff. This administrative regulation establishes the requirements for the annual professional development plan.

Section 1. Definitions. (1) <u>"Comprehensive District</u> Improvement Plan" is defined in 703 KAR 5:225, Section 1(3).

(2) "Comprehensive School Improvement Plan" is defined in 703 KAR 5:225, Section 1(4)[(3)].

(3)[(2)] "Needs assessment" means the gathering, sorting, and analysis of student, educator, and system data that lead to conclusions regarding the need for content and learning designs for professional development in identified areas related to educator performance and student achievement.

(4)[(3)] "Professional development" means professional learning that is an individual and collective responsibility, that fosters shared accountability among the entire education workforce

for student achievement, and:

(a) Aligns with <u>the</u> Kentucky<u>['s-Core]</u> Academic Standards in 704 KAR 3:303 <u>and 704 KAR Chapter 8</u>, educator effectiveness standards, individual professional growth goals, and school, school district, and state goals for student achievement;

(b) Focuses on content and pedagogy, as specified in certification requirements, and other related job-specific performance standards and expectations;

(c) Occurs among educators who share responsibility for student growth;

(d) Is facilitated by school and district leaders, including curriculum specialists, principals, instructional coaches, competent and qualified third-party facilitators, mentors, teachers or teacher leaders;

(e) Focuses on individual improvement, school improvement, and program implementation; and

(f) Is on-going.

(5)[(4)] "Professional development program" means a sustained, coherent, relevant, and useful professional learning process that is measurable by indicators and provides professional learning and ongoing support to transfer that learning to practice.

Section 2. Each local school and district shall develop a process to design a professional development plan that meets the goals established in KRS 158.6451 and in the local needs assessment. A school professional development plan shall be incorporated into the school improvement plan and shall be made public prior to the implementation of the plan. The local district professional development plan and posted to the local district Web site prior to the implementation of the plan.

Section 3. Each school and local district professional development plan shall contain the following <u>five (5)[six (6)]</u> elements:

(1) A clear statement of the school or district mission;

(2) Evidence of representation of all persons affected by the professional development plan;

(3) A needs assessment analysis;

(4) Professional development objectives that are focused on the school or district mission, derived from needs assessment, and that specify changes in educator practice needed to improve student achievement; and

(5) A process for evaluating impact on student learning and improving professional learning, using evaluation results.

Section 4. (1) The school or district improvement plan shall, in compliance with <u>703 KAR 5:225 and aligned to the goals</u> established in KRS 158.6451, address professional learning required to improve instruction.

(2) Professional development shall:

(a) Be related to the teachers' instructional assignments and the administrators' professional responsibilities;

(b) Be aligned with the school or district improvement plan or the individual professional growth plans of teachers;

(c) Occur within learning communities committed to continuous improvement, collective responsibility, and goal alignment;

(d) Be facilitated by skillful leaders who develop capacity and advocate and create support systems for professional learning;

(e) Be prioritized and monitored by the district;(f) Use a variety of sources and types of student, educator, and

system data to plan, assess, and evaluate professional learning; (g) Integrate theories, research, and models of human learning to achieve its intended outcomes;

(h) Apply current research on systems change and sustain support for implementation of professional learning for long-term instructional improvement as evidenced by student growth;

(i) Align its outcomes with educator performance and student curriculum standards; and

(j) Focus resources on areas of identified need.

(3) Professional development shall not supplant any of the six
 (6) hour instructional day.

(4) A district may report flexible professional development on

unpaid noncontact days. This shall require a district calendar change and the change shall be reported to the Department of Education.

(5) Professional development that relates to an individual professional growth plan may be used to satisfy the requirements for certification or renewal options as established by the Kentucky Education Professional Standards Board in Title 16 KAR.

(6)(a) Professional development grant dollars may reimburse college or graduate course tuition expended for a teacher to deepen content knowledge and content-specific pedagogy in math, science, English/language arts, social studies, arts and humanities, and practical living and career studies, if the teacher is assigned to teach in those areas.

(b) The use of professional development funds for tuition reimbursement shall be specified in the district improvement plan approved by the school board or the school plan approved by the school council as to funds under its control.

(c) Particular content areas and grade levels, which qualify for reimbursement, may be specified based upon information about the level of academic preparation of the teacher employed, local student performance data, and student learning needs.

(7) Professional development credit shall not be awarded for those experiences that provide remuneration beyond travel, food, lodging or tuition.

(8) A school district implementing a flexible professional development schedule shall award professional development credit for any experience that addresses the goals of the school, the goals of the district improvement plan, or the individual professional growth plans of teachers.

(9) Parent-teacher conferencing skill development shall be permissible as a professional development experience.

Section 5. The Qualifications and Duties of the District Professional Development Coordinator. (1) Qualifications for the position of district professional development coordinator shall include:

(a) A staff member meeting the certification requirement for a professional development coordinator as established by the Education Professional Standards Board in 16 KAR 4:010;

(b) A demonstrated ability to work with schools to plan, design, implement, and evaluate professional development that aligns with the requirements of this administrative regulation; and

(c) A demonstrated ability to work with schools to connect professional development with effective instructional practices and student achievement data.

(2) Duties of the district professional development coordinator shall include:

(a) Facilitating analysis of student, educator, and system data to conduct the district professional development needs assessment:

(b) Coordinating the intradistrict alignment of professional learning to achieve identified goals and objectives for professional development;

(c) Building capacity of school leaders, school council members, and other school and district leaders to plan, access resources, implement, and evaluate professional learning;

(d) Disseminating professional development information to school councils, staff members, and professional development committees;

(e) Providing technical assistance to school councils on scheduling to allow for job embedded professional learning opportunities;

(f) Coordinating the planning, implementation, and evaluation of the district professional development plan that is aligned, supportive of, and developed in conjunction with school improvement plans;

(g) Coordinating the establishment of local policies, procedures, timetables, necessary forms and letters, assignment of workshop sites, and all other practical elements of professional development, including fiscal management;

(h) Maintaining, verifying, and, if appropriate, submitting district and school professional development records, documentation, and other pertinent information to the Department of Education; (i) Explaining the district's professional development plan's objectives, results, and needs to school professionals, district staff, board members, civic and parent groups, teacher training institutions, and others, as requested;

(j) Maintaining contact with the Department of Education and other agencies involved in providing professional development; and

(k) Identifying, selecting, coordinating and evaluating the services of third-party professional development providers.

Section 6. A maximum of fifteen (15) percent of the district's professional development grant may be used for administrative purposes.

Section 7. When implementing professional development plans under KRS 158.070, a local school or district shall adhere to its school or district improvement plan.

This is to certify that the chief state school officer has reviewed and recommended this administrative regulation prior to its adoption by the Kentucky Board of Education, as required by KRS 156.070(5).

JASON GLASS, Ed.D., Commissioner

LU YOUNG, Ed.D., Chairperson

APPROVED BY AGENCY: October 13, 2020

FILED WITH LRC: October 13, 2020 at 4:14 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this proposed administrative regulation shall be held on December 22, 2020 at 10:00 a.m. in the State Board Room, 5th Floor, 300 Sower Blvd., Frankfort, Kentucky. Individuals interested in being heard at this meeting shall notify this agency in writing five (5) working days prior to this hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through December 31, 2020.

CONTACT PERSON: Todd G. Allen, General Counsel, Kentucky Department of Education, 300 Sower Boulevard, 5th Floor, Frankfort, Kentucky 40601, phone 502-564-4474, fax 502-564-9321; email regcomments@education.ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Todd G. Allen

(1) Provide a brief summary of:

(a) What this administrative regulation does: KRS 156.095 requires the Kentucky Board of Education to establish, direct, and maintain a statewide program of professional development with the purpose of the program being the improvement of instruction in the public schools. This regulation establishes the requirements for the annual professional development plan.

(b) The necessity of this administrative regulation: This administrative regulation establishes the requirements for the annual professional development plan. The professional development outlined in the school and district plans along with what teachers receive related to their individual growth plan is crucial in improving student performance.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 156.095 requires the Kentucky Board of Education to establish, direct, and maintain a statewide program of professional development to improve instruction in the public schools. KRS 158.070(5) requires the state board to promulgate administrative regulations establishing guidelines and procedures to be followed for the approval of the days utilized for four (4) days of the minimum school term required to be utilized by each local school district for professional development activities for the professional staff. This administrative regulation amends the statewide program and the established requirements for the annual professional development plan.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: Each local school and district shall develop a process to design a professional development plan that meets the goals established in KRS 158.6451 and in the local needs assessment. In order to enable the Kentucky Board of Education to properly review and approve the activities districts are providing for teachers, an annual professional development plan, from school and districts, is necessary.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment to the regulation makes technical changes in order to correct outdated information, align with language contained in other administrative regulations, and bolster consistency.

(b) The necessity of the amendment to this administrative regulation: This regulation will amend language to include a reference to the Comprehensive District Improvement Plan (CDIP) and makes an amendment to the subsection number for the Comprehensive School Improvement Plan (CSIP). It also includes a technical change to the name of the Kentucky Academic Standards and amends the regulation to cite 704 KAR Chapter 8. Section 3 includes a technical change to state the CSIP or CDIP must comply with 703 KAR 5:225 and align to the goals in KRS 158.6451.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 156.095 requires the Kentucky Board of Education to establish, direct, and maintain a statewide program of professional development to improve instruction in the public schools. KRS 158.070(5) requires the state board to promulgate administrative regulations establishing guidelines and procedures to be followed for the approval of the days utilized for four (4) days of the minimum school term required to be utilized by each local school district for professional development activities for the professional staff. The amendment to the administrative regulation makes technical changes to the established requirements for the annual professional development plan and clarifies the kinds of experiences that should be provided in a professional development plan in order to increase student achievement.

(d) How the amendment will assist in the effective administration of the statues: This amendment to the regulation makes technical changes in order to correct outdated information and align with language contained in other administrative regulations. In general, the regulation ensures the development of a school and district plan for professional learning that should lead to instructional change and, in turn, to increased student performance.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation requires local schools and 171 districts to develop a process to design a professional development plan that meets the goals established in KRS 158.6451 and in the local needs assessment.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: This administrative regulation requires that each local school and district design a professional development plan that meets the goals established in KRS 158.6451 and in the local needs assessment. A school professional development plan shall be incorporated into the school improvement plan, and the local district professional development plan shall be incorporated into the district improvement plan. The Comprehensive District Improvement Plan (CDIP) and the Comprehensive School Improvement Plan (CSIP) must comply with 703 KAR 5:225 and align to the goals in KRS 158.6451.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no costs to schools and districts.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This amendment will ensure that the professional development plan is aligned to the language found in other associated administrative regulations and adheres to the school or district improvement plan.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: No additional cost will be incurred by the agency at this time.

(b) On a continuing basis: No additional cost will be incurred, beyond the appropriation for professional development. Resources will be provided through the Continuous Improvement Technology System.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: To support school and district access to high quality professional development resources, Title II monies will be used.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change, if it is an amendment: The KDE will include, in its budget request, a call for more money to implement this regulation for the purpose of providing high quality professional development resources.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering was not appropriate for this administrative regulation because the administrative regulations applies equally to all schools and local education agencies.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Department of Education, local schools and 171 districts will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 156.095 requires the Kentucky Board of Education to establish, direct, and maintain a statewide program of professional development to improve instruction in the public schools. KRS 158.070(5) requires the state board to promulgate administrative regulations establishing guidelines and procedures to be followed for the approval of the days utilized for four (4) days of the minimum school term required to be utilized by each local school district for professional development activities for the professional staff.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No revenue will be generated as a result of this administrative regulation.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenue will be generated as a result of this administrative regulation.

(c) How much will it cost to administer this program for the first year? There will be no additional cost to the agency the first year.

(d) How much will it cost to administer this program for subsequent years? No additional cost will be incurred, beyond the appropriation for professional development. Resources will be provided through the Continuous Improvement Technology System.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): N/A Expenditures (+/-): N/A Other Explanation: N/A

EDUCATION AND WORKFORCE DEVELOPMENT CABINET Kentucky Board of Education Department of Education (Amendment)

704 KAR 3:305. Minimum requirements for high school graduation.

RELATES TO: KRS 156.160(1)(a), (d), <u>158.140(6)</u>, 158.142, 158.645, 158.6451

STATUTORY AUTHORITY: KRS 156.070, 156.160(1)(a), (d), <u>158.140(6)</u>, 158.142

NECESSITY, FUNCTION, AND CONFORMITY: KRS 156.160 requires the Kentucky Board of Education to promulgate administrative regulations relating to the courses of study for the different grades and the minimum requirements for high school graduation. KRS 158.142(3)(b) requires the board to promulgate administrative regulations establishing requirements for early graduation from high school. The content standards for the courses of study are established in the Kentucky academic standards incorporated by reference in 704 KAR 3:303 and 704 KAR Chapter 8. This administrative regulation establishes the minimum requirements necessary for entitlement to a high school diploma.

Section 1. Definitions. (1) "Early graduation" means meeting the competency-based criteria established in this administrative regulation in three (3) academic years or less.

(2) "Early Graduation Certificate" means a certificate, awarded by the district and signed by the principal and superintendent, that shall make the recipient eligible for a scholarship award equal to one-half (1/2) of the state portion of the average statewide per pupil guaranteed base funding level, to be used at a Kentucky public two (2) year community and technical college or a Kentucky four (4) year public or non-profit independent institution accredited by the Southern Association of Colleges and Schools.[

(3) "Essential workplace ethics" as described in KRS 158.1413.

(4) "Graduation prerequisite" means the requirements which will demonstrate basic competence in reading and mathematics.

(5) "Graduation qualifier" means a criterion which students have to meet in order to qualify for high school graduation.

(6) "Individual Education Program" or "IEP" is defined in 707 KAR 1:002.]

(3)[(7)] "Individual Learning Plan" or "ILP" is defined in 704 KAR 19:002.

Section 2. (1) A district shall implement an advising and guidance process throughout the middle and high schools to provide support for the development and implementation of an individual learning plan for each student. The plan shall include career development and awareness and specifically address the content as provided in the Kentucky academic standards for career studies established in [704 KAR 3:303 and] 704 KAR Chapter 8. The individual learning plan shall not be a substitute for the statement of transition service needs for students with disabilities as provided in 707 KAR 1:320.

(2) A district shall develop a method to evaluate the effectiveness and results of the individual learning plan process. The evaluation method shall include input from students, parents, and school staff. As part of the evaluation criteria, the district shall include indicators related to the status of the student in the twelve (12) months following the date of graduation.

(3) A feeder middle school and a high school shall work

cooperatively to ensure that each student and parent receives information and advising regarding the relationship between education and career opportunities. Advising and guidance shall include information about financial planning for postsecondary education.

(4) A school shall maintain each student's individual learning plan. The individual learning plan shall be readily available to the student and parent and reviewed and approved at least annually by the student, parents, and school officials.

(5) Beginning with a student's eighth grade year, the individual learning plan shall set learning goals for the student based on academic and career interests and shall identify required academic courses, electives, and extracurricular opportunities aligned to the student's postsecondary goals. The school shall use information from the individual learning plans about student needs for academic and elective courses to plan academic and elective offerings.

(6) The development of the individual learning plan for each student shall begin by the end of the sixth grade year and shall be focused on career exploration and related postsecondary education and training needs.

Section 3. (1) For students entering grade nine (9) on or before the first day of the 2018-2019 academic year, each student in a public school shall have a total of at least twenty-two (22) credits for high school graduation.

(2) Those credits shall include the content standards as provided in the Kentucky academic standards, established in 704 KAR 3:303 and KAR Chapter 8.

(3) Additional standards-based learning experiences shall align to the student's individual learning plan and shall consist of standards-based content.

(4) The required credits and demonstrated competencies shall include the following minimum requirements:

(a) Language arts - four (4) credits (English I, II, III, and IV) to include the content contained in the Kentucky academic standards for this content area and comply with the following:

1. Language arts shall be taken each year of high school; and

2. If a student does not meet the college readiness benchmarks for English and language arts as established by the Council on Postsecondary Education in 13 KAR 2:020, the student shall take an English and language arts transitional course or intervention, which is monitored to address remediation needs, before exiting high school;

(b) Social studies - three (3) credits to include the content contained in the Kentucky academic standards for this content area;

(c) Mathematics - three (3) credits to include the content contained in the Kentucky academic standards for this content area and include the following minimum requirements:

1. Algebra I, Geometry, and Algebra II. An integrated, applied, interdisciplinary, occupational, or technical course that prepares a student for a career path based on the student's individual learning plan may be substituted for a traditional Algebra I, Geometry, or Algebra II course on an individual student basis if the course meets the content standards in the Kentucky academic standards, established in 704 KAR 3:303 and 704 Chapter 8;

2. A mathematics course or its equivalent as determined by the district shall be taken each year of high school to ensure readiness for postsecondary education or the workforce;

3. Any mathematics course other than Algebra I, Geometry, or Algebra II shall be counted as an elective; and

4. If a student does not meet the college readiness benchmarks for mathematics as established by the Council on Postsecondary Education in 13 KAR 2:020, the student shall take a mathematics transitional course or intervention, which is monitored to address remediation needs, before exiting high school;

(d) Science - three (3) credits that shall incorporate lab-based scientific investigation experiences and include the content contained in the Kentucky academic standards for this content area;

(e) Health - one-half (1/2) credit to include the content contained in the Kentucky academic standards for this content

area;

(f) Physical education - one-half (1/2) credit to include the content contained in the Kentucky academic standards for this content area;

(g) Visual and performing arts - one (1) credit to include the content contained in the Kentucky academic standards for this content area or a standards-based specialized arts course based on the student's individual learning plan;

(h) Academic and career interest standards-based learning experiences - seven (7) credits including four (4) standards-based learning experiences in an academic or career interest based on the student's individual learning plan; and

(i) Demonstrated performance-based competency in technology.

Section 4. (1) Beginning with students who enter grade nine (9) on or after the first day of the 2019-2020 academic year, in order to receive a high school diploma, each student in a public school shall[:

(a) Complete one or more of the following graduation qualifiers: 1. Satisfy precollege curriculum as established by the Council on Postsecondary Education in 13 KAR 2:020;

2. Achieve benchmark score as established by the Council on Postsecondary Education in 13 KAR 2:020 in one (1) section of a college admissions or placement examination;

3. Complete three (3) postsecondary credit hours or more of a Kentucky Department of Education approved dual credit course with a grade of C or higher;

4. Complete one (1) course and corresponding assessment meeting the following criteria:

a. Advanced placement (AP) with a score of three (3) or higher;

b. Cambridge Advanced International (CAI) with a score at E or higher; or

c. International baccalaureate (IB) with a score of five (5) or higher;

5. Obtain an industry certification as approved by the Kentucky Workforce Innovation Board;

6. Complete four (4) credits from valid courses within a single Kentucky Department of Education approved career pathway;

7. Complete a Kentucky Department of Education approved process to verify 500 hours of exceptional work experience, or alternative requirements as determined by a student's Admissions and Release Committee and specified in the student's IEP;

8. Complete two (2) years in an approved Kentucky Department of Education or Kentucky Labor Cabinet preapprenticeship or apprenticeship program; and

(b)] Earn a total of at least twenty-two (22) credits for high school graduation.[

(2) Beginning with students who enter grade nine (9) on or after the first day of the 2020-2021 academic year, in order to receive a high school diploma, each student in a public school shall:

(a) Complete one (1) or more of the following graduation qualifiers:

1. Satisfy precollege curriculum as established by the Council on Postsecondary Education in 13 KAR 2:020;

2. Achieve benchmark score as established by the Council on Postsecondary Education in 13 KAR 2:020 in one (1) section of a college admissions or placement examination;

3. Complete three (3) postsecondary credit hours or more of a Kentucky Department of Education approved dual credit course with a grade of C or higher;

4. Complete one (1) course and corresponding assessment meeting the following criteria:

a. Advanced placement (AP) with a score of three (3) or higher;

b. Cambridge Advanced International (CAI) with a score of E or higher; or

c. International baccalaureate (IB) with a score of five (5) or higher;

5. Obtain an industry certification as approved by the Kentucky Workforce Innovation Board;

6. Complete four (4) credits from valid courses within a single Kentucky Department of Education approved career pathway;

7. Complete a Kentucky Department of Education approved process to verify 500 hours of exceptional work experience, or alternative requirements as determined by a student's Admissions and Release Committee and specified in the student's IEP;

8. Complete two (2) years in an approved Kentucky Department of Education or Kentucky Labor Cabinet preapprenticeship or apprenticeship program; and

(b) Meet one (1) of the following graduation prerequisites for reading and one (1) of the following graduation prerequisites for mathematics:

1. Score at or above the minimum criteria on the tenth grade state-required assessments in reading or mathematics;

a. The minimum criteria shall include earning a scale score in the apprentice student performance level or higher as approved by the Kentucky Board of Education.

b. Students who do not meet the minimum criteria on one or both of the reading or mathematics assessments may retake the assessments twice annually in the eleventh and twelfth grades of high school enrollment.

c. The student's first completion of the assessments in grade ten (10) shall contribute to the school's accountability rating; or

2. Score proficient or higher for reading or mathematics on the eighth grade state required assessment; or

3.A student collection of evidence submitted by the principal to the superintendent or designee for review and approval, or in the case of a public charter school submitted by the principal to the Commissioner of Education or designee. The collection of evidence shall include the following:

a. The student's ILP that includes student transcript;

b. If applicable, for students with IEPs, evidence that the student has achieved progress on measurable annual IEP goals as determined by the Admissions and Release Committee;

c. Performance on the tenth grade state-required assessments in reading or mathematics;

d. Appropriate interventions, targeted to the student's needs, provided to the student to ensure support was provided toward meeting the requirements outlined in this administrative regulation;

e. Student work demonstrating the students' competency in reading or mathematics; and

f. The student's post-graduation plans.

(c) Earn a total of at least twenty-two (22) credits for high school graduation.]

(2)[(3)] The required credits shall include the content standards as provided in the Kentucky academic standards, established in 704 KAR 3:303 and 704 KAR Chapter 8.

(3)[(4)] Additional standards-based learning experiences shall align to the student's individual learning plan and shall consist of standards-based content.

(4)[(5)] Each student shall be required to complete the following foundational credits and demonstrated competencies, consisting of ten (10) credits:

(a) English/language arts - two (2) credits (English I and II) to include the content contained in the Kentucky academic standards for this content area;

(b) Social studies - two (2) credits to include the content contained in the Kentucky academic standards for this content area:

(c) Mathematics - two (2) credits (Algebra I and Geometry) to include the content contained in the Kentucky academic standards for this content area;

(d) Science - two (2) credits that shall incorporate lab-based scientific investigation experiences and include the content contained in the Kentucky academic standards for this content area;

(e) Health - one-half (1/2) credit to include the content contained in the Kentucky academic standards for this content area;

(f) Physical education - one-half (1/2) credit to include the content contained in the Kentucky academic standards for this content area; and

(g) Visual and performing arts - one (1) credit to include the

content contained in the Kentucky academic standards for this content area or a standards-based specialized arts course based on the student's individual learning plan.

(5)[(6)] In addition to the foundational requirements established in subsection (4)[(5)] of this Section, every student shall earn a minimum of twelve (12) personalized credits in order to receive a high school diploma. These twelve (12) personalized credits shall include:

(a) Two (2) additional English/Language Arts credits that include the content contained in the Kentucky academic standards for this content area and are aligned to the student's individual learning plan;

(b) Two (2) additional mathematics credits that include the content contained in the Kentucky academic standards for this content area and are aligned to the student's individual learning plan; (c) One (1) additional science credit that includes the content contained in the Kentucky academic standards for this content area and is aligned to the student's individual learning plan; (d) One (1) additional social studies credit that includes the content contained in the Kentucky academic standards for this content area and is aligned to the student's individual learning plan; (d) One (1) additional social studies credit that includes the content contained in the Kentucky academic standards for this content area and is aligned to the student's individual learning plan; (e) Academic and career interest standards-based learning experiences based on the student's individual learning plan;

(f) Demonstrate performance-based competency in technology as approved by the Kentucky Department of Education;

(g) Pass a civics test as required by KRS 158.141; and

(h) Beginning with students entering grade nine (9) on or after the first day of the 2020-2021 <u>academic year</u>, successfully complete one (1) or more courses or programs that meet the financial literacy requirements pursuant to KRS 158.1411 and standards as established <u>in 704 KAR Chapter 8[by the Kentucky Board of Education].[</u>

(7) Districts shall report individual student data regarding the completion of each graduation qualifier and each graduation prerequisite to the Kentucky Department of Education which may be included in aggregate public reporting.

(8) The provisions of subsections (3) through (7) of this Section shall apply to all students referenced in subsections (1) and (2) of this Section.]

Section 5. (1) Only students who meet the criteria established in this section shall be eligible for early graduation.

(a) Those students who meet the criteria for early graduation shall receive from the school district a diploma and an Early Graduation Certificate.

(b) Students wishing to graduate early shall indicate that intent to the school principal at the beginning of grade 9 or as soon as the intent is known, but within the first thirty (30) school days of the academic year in which they wish to graduate.

(c) A student's intent to graduate early shall be entered into the student information system by the school district by October 1 of the year in which the student makes the declaration.

(d) Students working toward early graduation and receipt of a corresponding Early Graduation Certificate shall be supported by development and monitoring of an individual learning plan to support their efforts.

(2) To graduate early and earn an Early Graduation Certificate, a student shall:

(a) Score proficient or higher on the state-required assessments required by the Kentucky Board of Education in 703 KAR 5:200; and

(b) Meet the college readiness exam benchmarks established by the Council on Postsecondary Education in 13 KAR 2:020 for placement in credit-bearing courses without the need for remediation.

(3) A student who has indicated an intent to graduate early may participate in the student's state administration of the college readiness exam prior to the junior year, if needed.

Section 6. (1) A local board of education may substitute an integrated, applied, interdisciplinary, occupational, technical, or

higher level course for a required course if the alternative course provides rigorous content.

(2) For students with disabilities, a local board of education may substitute a functional, integrated, applied, interdisciplinary, occupational, technical, or higher level course for a required course if the alternative course provides rigorous content. These shall be based on grade-level content standards and may be modified to allow for a narrower breadth, depth, or complexity of the general grade-level content standards.

Section 7. (1) A local board of education may award credit toward high school graduation for satisfactory demonstration of learning based on content standards described in the Kentucky academic standards, established in 704 KAR 3:303 and 704 KAR Chapter 8, and a rigorous performance standards policy established by the local board of education. A school shall establish performance descriptors and evaluation procedures to determine if the content and performance standards have been

(2) A local board of education shall award credit toward high school graduation based on:

(a) A standards-based Carnegie unit credit that shall consist of at least 120 hours of instructional time in one (1) subject; or

(b) A performance-based credit based on standards, regardless of the number of instructional hours in one (1) subject.

(3) A local board of education which has chosen to award performance-based credit shall award a standards-based credit earned by a student enrolled in grade 5, 6, 7, or 8 if:

(a) The content of the course is the same as that described in the Kentucky academic standards, established in 704 KAR 3:303 and 704 KAR Chapter 8; and

(b) The district has criteria in place to make a reasonable determination that the middle level student is capable of success in the high school course.

(4) A local board of education which has chosen to award performance-based credit shall establish a policy for a performance-based credit system that includes:

(a) The procedures for developing performance-based credit systems and for amending the system;

(b) The conditions under which each high school may grant performance-based credits and the related performance descriptors and assessments;

(c) Objective grading and reporting procedures;

(d) Content standards established in 704 KAR 3:303 and 704 KAR Chapter 8;

(e) The extent to which state-provided assessments will be used in the local performance-based credit system;

(f) The ability for students to demonstrate proficiency and earn credit for learning acquired outside of school or in prior learning; and

(g) Criteria to ensure that internships, cooperative learning experiences, and other learning experiences in the school and community are:

1. Designed to further student progress towards the individual learning plan;

2. Supervised by qualified instructors; and

3. Aligned with state and local content and performance standards.

(5) A board of education may award standards-based, performance-based credit toward high school graduation for:

(a) Standards-based course work that constitutes satisfactory demonstration of learning in any high school course, consistent with Sections 3 and 4 of this administrative regulation;

(b) Standards-based course work that constitutes satisfactory demonstration of learning in a course for which the student failed to earn credit when the course was taken previously;

(c) Standards-based portfolios, senior year, or capstone projects;

(d) Standards-based online or other technology mediated courses;

(e) Standards-based dual credit or other equivalency courses; or

(f) Standards-based internship, cooperative learning experience, or other supervised experience in the school or the community.

(6) Each local board of education shall maintain a copy of its policy on high school graduation requirements. This policy shall include a description of how the requirements address KRS 158.6451(1)(b) and 703 KAR 4:060.

Section 8. (1) A student who satisfactorily completes the requirements of this administrative regulation and additional requirements as may be imposed by a local board of education or meets the requirements for early graduation established in Section 5 of this administrative regulation shall be awarded a graduation diploma.

(2) A local board may not adopt any high school graduation requirements that include achieving a minimum score on a statewide assessment as established in KRS 158.140.

(3) The local board of education shall award the diploma.

Section 9. This administrative regulation shall not be interpreted as prohibiting a local governing board, superintendent, principal, or teacher from awarding special recognition to a student.

Section 10. (1) If the severity of an exceptional student's disability precludes a course of study that meets the high school graduation requirements established in Sections 3 and 4 of this administrative regulation leading to receipt of a high school diploma, an alternative course of study shall be offered.

(2) This course of study shall be based upon student needs and the provisions established in 704 KAR 3:303 and 704 KAR Chapter 8, and shall be reviewed at least annually.

(3) A student who completes this course of study shall receive an alternative high school diploma to be awarded by the local board of education consistent with the graduation practices for all students.

(4) A local board of education may establish policies to award an alternative high school diploma to a former student who has received a certificate or certificate of attainment.

This is to certify that the chief state school officer has reviewed and recommended this administrative regulation prior to its adoption by the Kentucky Board of Education, as required by KRS 156.070(5).

JASON GLASS, Ed.D., Commissioner

LU YOUNG, Ed.D., Chairperson

APPROVED BY AGENCY: October 13, 2020 FILED WITH LRC: October 13, 2020 at 4:14 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this proposed administrative regulation shall be held on December 22, 2020 at 10:00 a.m. in the State Board Room, 5th Floor, 300 Sower Blvd., Frankfort, Kentucky. Individuals interested in being heard at this meeting shall notify this agency in writing five (5) working days prior to this hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through December 31, 2020.

CONTACT PERSON: Todd G. Allen, General Counsel, Kentucky Department of Education, 300 Sower Boulevard, 5th Floor, Frankfort, Kentucky 40601, phone 502-564-4474, fax 502-564-9321; email regcomments@education.ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Todd G. Allen

(1) Provide a brief summary of:

What this administrative regulation does: This administrative regulation establishes the minimum requirements necessary for entitlement to a high school diploma.

(b) The necessity of this administrative regulation: KRS 156.160 requires the Kentucky Board of Education to promulgate administrative regulations relating to the courses of study for the different grades and the minimum requirements for high school graduation. KRS 158.142(3)(b) requires the board to promulgate administrative regulations establishing requirements for early graduation from high school. The content standards for the courses of study are established in the Kentucky Academic Standards incorporated by reference in 704 KAR 3:303 and 704 KAR Chapter 8. This administrative regulation establishes the minimum requirements necessary for entitlement to a high school diploma.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 156.160 requires the Kentucky Board of Education to promulgate administrative regulations relating to the courses of study for the different grades and the minimum requirements for high school graduation. KRS 158.142(3)(b) requires the board to promulgate administrative regulations establishing requirements for early graduation from high school. The content standards for the courses of study are established in the Kentucky core academic standards incorporated by reference in 704 KAR 3:303 and 704 KAR Chapter 8. This administrative regulation establishes the minimum requirements necessary for entitlement to a high school diploma.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes. This administrative regulation establishes the minimum requirements necessary for entitlement to a high school diploma.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments to this regulation change the minimum high school graduation requirements for students entering ninth grade in the fall of 2019. It removes language relating to postsecondary readiness indicators and a minimum score on a statewide summative assessment as requirements necessary for entitlement to a high school diploma.

(b) The necessity of the amendment to this administrative regulation: The amendments to this regulation remove all graduation qualifier options and all graduation prerequisites to better align with the intent of Senate Bill (SB) 158 (2020). Yet, students will be required to meet other minimum credit requirements as established in 704 KAR 3:305. The amendment also requires local boards of education to amend local policy to eliminate any high school graduation requirements that include achieving a minimum score on a statewide assessment as established in SB 158 (2020).

(c) How the amendment conforms to the content of the authorizing statutes: KRS 156.160 requires the Kentucky Board of Education to promulgate administrative regulations relating to the courses of study for the different grades and the minimum requirements for high school graduation.

(d) How the amendment will assist in the effective administration of the statues: KRS 156.160 requires the Kentucky Board of Education to promulgate administrative regulations relating to the courses of study for the different grades and the minimum requirements for high school graduation. The amendment to this administrative regulation establishes the minimum requirements necessary for entitlement to a high school diploma.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Those affected by this regulation include: all public schools, school districts, and the KDE as it is tasked with providing guidance, support, and technical assistance, and monitoring of the implementation of new minimum high school graduation requirements.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Local boards of education may need to amend local policy. Local schools and districts and schools may need to revise their course offerings and available educational opportunities to ensure students have access to content. KDE will need to provide implementation guidance to districts and schools.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There is no additional cost the districts to implement this regulation. KDE will be impacted by staff time to answer questions and provide guidance.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This regulation provides flexibility to districts to meet the needs of students and to become transition-ready.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: Staffing patterns at the local district may need to be adjusted in light of minimum requirements and student needs. Local district budgets may be impacted by the need for resources to support interventions for students who need them. KDE staff time will be impacted by the need for implementation guidance and answering questions from the field.

(b) On a continuing basis: Staffing patterns at the local district may need to be adjusted in light of minimum requirements and student needs. Local district budgets may be impacted by the need for resources to support interventions for students who need them. KDE staff time will be impacted by the need for implementation guidance and answering questions from the field. This impact should decrease each year of implementation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State funds.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change, if it is an amendment: No increase in fees or funding will be necessary to implement this amendment.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering was not appropriate for this administrative regulation because the administrative regulations applies equally to all schools and local education agencies.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Local education agencies and the Kentucky Department of Education.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 156.160 requires the Kentucky Board of Education to promulgate administrative regulations relating to the courses of study for the different grades and the minimum requirements for high school graduation. KRS 158.142(3) (b) requires the board to promulgate administrative regulations establishing requirements for early graduation from high school. The content standards for the courses of study are established in the Kentucky core academic standards incorporated by reference in 704 KAR 3:303 and 704 KAR Chapter 8. This administrative regulation establishes the minimum requirements necessary for entitlement to a high school diploma.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenue.

(c) How much will it cost to administer this program for the first year? Staffing patterns at the local district may need to be adjusted in light of minimum requirements and student needs. Local district budgets may be impacted by the need for resources to support interventions for students who need them. KDE staff time will be impacted by the need for implementation guidance and answering guestions from the field.

(d) How much will it cost to administer this program for subsequent years? Staffing patterns at the local district may need to be adjusted in light of minimum requirements and student needs. Local district budgets may be impacted by the need for resources to support interventions for students who need them. KDE staff time will be impacted by the need for implementation guidance and answering questions from the field. This impact should decrease each year of implementation.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): N/A Expenditures (+/-): N/A Other Explanation: N/A

EDUCATION AND WORKFORCE DEVELOPMENT CABINET Kentucky Board of Education Department of Education (Amendment)

704 KAR 3:325. Effective Instructional Leadership Act.

RELATES TO: KRS 156.101

STATUTORY AUTHORITY: KRS 156.029(7), 156.070, 156.101

NECESSITY, FUNCTION, AND CONFORMITY: KRS 156.029(7) requires the Board of Education to develop policies and to promulgate administrative regulations by which the Department of Education shall be governed. KRS 156.070 authorizes the Board of Education to promulgate administrative regulations necessary for the efficient management, control, and operation of the schools and programs under its jurisdiction. KRS 156.101 requires the Kentucky Board of Education to establish specific criteria for implementing a statewide instructional leader improvement program for employees of the public schools holding valid certificates and performing responsibilities in a position for which administration certification is required by the Education Professional Standards Board pursuant to 704 KAR Chapter 20. This administrative regulation establishes criteria for the program.

Section 1. Definitions. (1) "Conference" means a scheduled professional training opportunity, sponsored by a state or national educational organization or a training provider, at which a variety of instructional leadership topics are available for participant attendance.

(2) "Cycle" means a twenty-four (24) month period beginning with July 1 of even-numbered years and ending June 30 of even-numbered years.

(3) "School year" means a twelve (12) month period beginning July 1 and ending June 30.

(4) "Training provider" means an established educational organization, local school district, or private educational consultant who sponsors training programs.

Section 2. (1) Participation in the program shall be required for a certified and employed instructional leader.

(2) To fulfill the requirements of KRS 156.101, an instructional leader shall obtain the approval of the local superintendent or designee if selecting specific training offerings from the state-approved directory or if attending education-related conferences.

(3)[(a) Until June 30, 2006, every two (2) years, a local school

district shall send a verification statement to the Kentucky Department of Education and the Education Professional Standards Board, recording the names of all instructional leaders, their position titles, their Social Security numbers, the dates they entered the two (2) year cycle, and the number of hours of training obtained during the two (2) year cycle.

(b)] Beginning July 1, 2006, a local district shall keep on file documentation of compliance with KRS 156.101(4) for each instructional leader employed by the school district, including a copy of all training certificates. Beginning August 30, 2007 and by August 30 each year thereafter, the local school district shall report to the Kentucky Department of Education the name of any instructional leader who fails to complete the twenty-one (21) hours of training required under KRS 156.101, the individual's position title, Social Security number, and the number of hours which were completed.

(4) All certificates shall be kept on file for three (3) years by each local district for each participant. If a participant becomes employed by another district, the original file shall be sent to the instructional leader and a duplicate copy to the new employing district.

Section 3. (1) Instructional leaders shall participate in a training program designed to improve and maintain the quality and effectiveness of instructional leadership in the public schools of the Commonwealth. Agencies, institutions, education cooperatives, local school districts, and private educational consultants who qualify as training providers may be approved by the Kentucky Department of Education to design, implement, and evaluate the training. Specific training approved within the program by the Department of Education shall be:

(a) Intensive and designed specifically for instructional leaders. Participation shall occur during the contract period including extended employment, if applicable. Training shall be scheduled so as to minimize disruption of the instructional program of the district;

(b) Competency-based, specifying the instructional leadership competencies to be mastered by participants. Competencies shall have applicability for improving the effectiveness of the instructional leader or be role-specific. The design of the activities shall consider the participant's stage of professional development;

(c) Comprehensive in nature and shall meet identified needs based upon the personnel evaluation, the individual professional growth plan, and self-assessments of the instructional leaders; and

(d) Evaluated for approval in terms of program content, instructional processes, and impact upon participants.

(2)(a) An instructional leader may count attendance at education conferences up to six (6) hours of credit each school year. An instructional leader shall provide verification of attendance at education conferences to be filed with the local school district.

(b) An instructional leader shall receive three (3) participanthours credit for duties performed by serving on one (1) beginning teacher committee established under KRS 161.030(6), and the instructional leader shall receive a maximum six (6) hours if the individual serves on more than one (1) committee.

(3)[(a) Until June 30, 2006, an instructional leader whose effective date of employment is within the second half of a school year shall complete a prorated requirement of twenty-one (21) hours of leadership training.

(b)] If an instructional leader is employed for 100 days in the same position during a school year, the individual shall complete the required training.

(4) A participant's verification of attendance at approved Effective Instructional Leadership Training sessions and programs and copies of program certificates shall be recorded with the professional development coordinator of the instructional leader's school district no later than June 30 of each year.

(5) Excess hours, not to exceed twelve (12) earned by a participant during the thirty (30) day period of June 1 through June 30, may be credited toward required hours for the next school year.

Section 4. The training program content shall consist of specific competencies identified in the <u>Professional Standards for</u> <u>Educational Leaders as incorporated by reference in 704 KAR</u>

<u>3:370</u>[Standards and Indicators for School Improvement established in 703 KAR 5:120].

Section 5. The training provider shall:

(1) Develop programs that meet all the criteria identified in Sections 3 and 4 of this administrative regulation;

(2) Select program faculty who have adequate, pertinent training and education, appropriate experience, and the ability to instruct effectively:

(3) Meet identified needs consistent with those listed in the Professional Standards for Educational Leaders as incorporated by reference in 704 KAR 3:370[Standards and Indicators for School Improvement established in 703 KAR 5:120];

(4) Conduct training as set forth in its proposal and as approved by the Kentucky Department of Education;

(5) Award a participant a certificate of attendance that includes the providers approval number and the number of hours completed; and

(6) Evaluate the training in terms of its content, instructional processes, impact upon the professional behavior of participants, and improved student learning.

Section 6. (1) The Department of Education shall approve training activities and providers, and maintain and communicate a directory of approved activities and providers.

(2) The Department of Education may revoke the approval of any training program not in compliance with this administrative regulation and may delete the program.

Section 7. (1) Approval of a training program shall be granted for a period of one (1) year.

(2) Approval as a provider shall be based upon:

(a) Submission of a provider's training program proposal to the Department of Education at least thirty (30) days prior to the initial presentation of the training activity; and

(b) Content consistent with the <u>Professional Standards for</u> <u>Educational Leaders as incorporated by reference in 704 KAR</u> <u>3:370[Standards and Indicators for School Improvement</u> <u>established in 703 KAR 5:120]</u>.

This is to certify that the chief state school officer has reviewed and recommended this administrative regulation prior to its adoption by the Kentucky Board of Education, as required by KRS 156.070(5).

JASON GLASS, Ed.D., Commissioner

LU YOUNG, Ed.D., Chairperson

APPROVED BY AGENCY: October 13, 2020

FILED WITH LRC: October 13, 2020 at 4:14 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this proposed administrative regulation shall be held on December 22, 2020 at 10:00 a.m. in the State Board Room, 5th Floor, 300 Sower Blvd., Frankfort, Kentucky. Individuals interested in being heard at this meeting shall notify this agency in writing five (5) working days prior to this hearing, of their intent to attend. If no notification of intent to attend the hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through December 31, 2020.

CONTACT PERSON: Todd G. Allen, General Counsel, Kentucky Department of Education, 300 Sower Boulevard, 5th Floor, Frankfort, Kentucky 40601, phone 502-564-4474, fax 502-564-9321; email regcomments@education.ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Todd G. Allen (1) Provide a brief summary of: (a) What this administrative regulation does: This administrative regulation establishes criteria for a statewide instructional leader improvement program for employees of public schools holding valid certificates and performing responsibilities in a position for which administration certification is required by the Education Professional Standards Board (EPSB).

(b) The necessity of this administrative regulation: KRS 156.101 requires the Kentucky Board of Education to establish specific criteria for implementing a statewide instructional leader improvement program for employees of public schools holding valid certificates and performing responsibilities in a position for which administration certification is required by the Education Professional Standards Board (EPSB) pursuant to 704 KAR Chapter 20.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This regulation provides the specifics for the submission and approval process for proposals for leadership training programs that are submitted to the Department of Education for approval, and for the process by which instructional leaders may complete the training requirements pursuant to KRS 156.101, the Effective Instructional Leadership Act (EILA).

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes. This regulation provides the specifics for the submission and approval process for proposals for leadership training program offerings, and for the process by which instructional leaders may complete the requirements of the EILA.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment to the administrative regulation updates language to align instructional leadership training program and provider content to the Professional Standards for Educational Leaders (PSEL). 704 KAR 3:370 incorporates the Professional Standards for Educational Leaders (PSEL) by reference.

(b) The necessity of the amendment to this administrative regulation: Sections 4, 5 and 7 of 704 KAR 3:325 refer to competencies identified in Kentucky's Standards and Indicators for School Improvement established in 703 KAR 5:120, which was repealed by 703 KAR 5:122 as of February 6, 2015. The amendment changes language to reference the PSEL (2015). These national, student-centric standards articulate the knowledge and skills expected of school leaders. The Council of Chief State School Officers (CCSSO) and National Policy Board for Educational Administration guided the two-year development process that involved a thorough review of empirical research and included the input of researchers and school and district leaders. The EPSB adopted the PSEL as the standards of preparation for all advanced educational leaders.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment aligns instructional leadership training program and provider content to the Professional Standards for Educational Leaders (PSEL). Program and provider content alignment to the PSEL is required for program proposal approval by the Department of Education.

(d) How the amendment will assist in the effective administration of the statues: The amendment to the administrative regulation updates language to align instructional leadership training program and provider content to the Professional Standards for Educational Leaders (PSEL).

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The regulation affects all personnel hired by local school districts to a position for which administrative certification is required by the Education Professional Standards Board.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The regulation applies to local school district instructional leaders. The amendment ensures that local school district instructional leaders receive continuing education aligned to the PSEL.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no additional costs associated with the regulation amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The training program content shall consist of specific competencies identified in the Professional Standards for Educational Leaders, which the EPSB adopted as the standards of preparation for all advanced educational leaders.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: There are no additional costs to implement this administrative regulation.

(b) On a continuing basis: There will be no additional costs to the agency to implement this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Agency general funds and local school district funds.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change, if it is an amendment: No increase in fees will be necessary to implement this amendment.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering was not appropriate for this administrative regulation because the administrative regulations applies equally to all those individuals or entities regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? 171 local school districts and all personnel hired by local school districts to a position for which administrative certification is required by the Education Professional Standards Board.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 156.029(7) requires the Board of Education to develop policies and to promulgate administrative regulations by which the Department of Education shall be governed. KRS 156.070 authorizes the Board of Education to promulgate administrative regulations necessary for the efficient management, control, and operation of the schools and programs under its jurisdiction. KRS 156.101 requires the Kentucky Board of Education to establish specific criteria for implementing a statewide instructional leader improvement program for employees of the public schools holding valid certificates and per-forming responsibilities in a position for which administration certification is required by the Education Professional Standards Board pursuant to 704 KAR Chapter 20. This administrative regulation establishes criteria for the program.704 KAR 3:370 incorporates the Professional Standards for Educational Leaders (PSEL) by reference.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None (c) How much will it cost to administer this program for the first year? There will be no additional costs to the agency.

(d) How much will it cost to administer this program for subsequent years? Amendment adds no additional costs.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): N/A Expenditures (+/-): N/A Other Explanation: N/A

PUBLIC PROTECTION CABINET Department of Insurance Consumer Protection Division (Amendment)

806 KAR 2:095. Accounting and reporting requirements for collecting local government premium tax.

RELATES TO: KRS 91A.080, 304.4-010 STATUTORY AUTHORITY: KRS 91A.080, 304.2-110

NECESSITY, FUNCTION, AND CONFORMITY: <u>KRS 304.2-110</u> authorizes the Commissioner of Insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code as defined in <u>KRS 304.1-010</u>. [KRS 304.2-110 authorizes the Commissioner of Insurance to make reasonable rules and administrative regulations necessary for and as an aid to the effectuation of any provision of the Kentucky Insurance Code, as defined in <u>KRS 304.1-010</u>.] KRS 91A.080 requires the Commissioner of Insurance to adopt administrative regulations for the collection and reporting of local government premium taxes. This administrative regulation establishes requirements for the accounting and reporting procedures to be used for the collection and reporting of a local government premium tax.

Section 1. Definitions. (1) "Agent" is <u>established [defined]</u> by KRS 304.9-020(1).

(2) "Commissioner" is <u>established</u> [defined] by KRS 304.1-050(1).

(3) "Insurance company" <u>shall</u> mean [means]: (a) An entity holding a certificate of authority in accordance with KRS Chapter 304, Subtitle 3; and (b) A surplus lines broker licensed in accordance with KRS 304.10-120.

(4) "Local government" is <u>established [defined]</u> by KRS 91A.0802(2[4]).

(5) "Local government premium tax<u>" shall mean</u> [means] a tax or license fee levied pursuant to KRS 91A.080.

Section 2. Quarterly Payment and Reporting of Local Government Premium Taxes. (1) Each insurance company with local government premium tax liability shall make payment of its tax liability based on premiums actually collected within a calendar quarter. Payment shall be made to each local government within thirty (30) days of the end of each calendar quarter, and shall be accompanied by a report in the following format:

(a) 1. Form LGT-141, City, County or Urban County Government Quarterly Insurance Premium Tax Return; and 2. Form LGT 142, City Credit Against County Taxes; or

(b) A form substantially similar to Form LGT-141.

(2) A copy of the report required in subsection (1) of this section shall not be filed with the commissioner.

Section 3. Annual Reports. (1) By March 31 of each year, an insurance company shall:

(a) <u>Submit to [Furnish]</u> each local government to which local government premium taxes have been paid during the preceding calendar year a report on the local government premium taxes paid during the preceding calendar year in the following format:

1. a. Form LGT-140, City, County or Urban County Government Insurance Premium Tax Annual Reconciliation; and

b. Form LGT 142, City Credit Against County Taxes; or

2. A form substantially similar to Form LGT-140; and

(b) Submit to the department a report on the local government premium taxes paid during the preceding calendar year, accompanied by a fee of five (5) dollars per insurance company, through <u>the [:</u>

1. The] Department of Insurance Web site,

https://insurance.ky.gov/doieservices/UserRole.aspx

[https://insurance.ky.gov/kentucky/secured/Eservices/default.aspx; or 2. File Transfer Protocol through prior arrangement with the Department of Insurance].

(2)(a) If an insurance company does not have any local government premium tax liability for the preceding calendar year, the insurance company shall submit a report to the department in accordance with subsection (1)(b) of this section.

(b) The reports required by paragraph (a) of this subsection shall be required if the insurance company held an active license or certificate of authority at any time during the preceding calendar year.

Section 4. Each insurance company shall maintain records adequate to support the reports required by this administrative regulation.

Section 5. Each insurance company shall file the reports required by this administrative regulation. Reports required by this administrative regulation and filed on a group basis shall not be acceptable.

Section 6. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) Form LGT-140, "City, County, or Urban County Government Insurance Premium Tax Annual Reconciliation", 1/2012;

(b) Form LGT-141, "City, County, or Urban County Government Quarterly Insurance Premium Tax Return", 1/2012; and

(c) Form LGT-142 "City Credit Against County Taxes", 1/2012.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department of Insurance, <u>Mayo-Underwood Building, 500 Mero Street, 2 SE 11,</u> [215 West Main Street], Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. This material is also available on the department's <u>Web site [website]</u> at: http://insurance.ky.gov.

SHARON P. CLARK, Commissioner

KERRY B. HARVEY, Secretary APPROVED BY AGENCY: October 12, 2020 FILED WITH LRC: October 13, 2020 at 10:02 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held at 9:00 AM on December 21, 2020 at 500 Mero Street, Frankfort, Kentucky 40602. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through 11:59 PM on December 31, 2020. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

CONTACT PERSON: DJ Wasson, Deputy Commissioner, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 564-6026, fax +1 (502) 564-1453, email dj.wasson@ky.gov

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: DJ Wasson

(1) Provide a brief summary of:

(a) What this administrative regulation does: This

administrative regulation provides the accounting and reporting procedures to be used by every insurance company or its agent, to which this administrative regulation applies, for the collection and reporting of the fees or taxes and the collection fee herein provided by ordinance of a city, county, or urban county government for engaging in the business of insurance therein.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to implement KRS 91A.080(6).

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 91A.080 authorizes the commissioner to adopt administrative regulations for the collection and reporting of local government premium taxes. This administrative regulation sets forth the process to report local government premium taxes.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will set forth the process and format for insurance companies to use for reporting local government premium taxes to both local governments and the Department of Insurance.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments will clarify the existing process of requiring insurance companies to file an annual reconciliation even if there is no tax due. Further, the amendments will incorporate by reference the current paper and electronic forms used for both quarterly and annual reporting. Finally, the amendments will bring the administrative regulation into compliance with the drafting requirements in KRS 13A.

(b) The necessity of the amendment to this administrative regulation. This necessity of this amendment to this administrative regulation is the ensure that the general public is aware of where to send any necessary correspondence(s).

(c) How the amendment conforms to the content of the authorizing statutes: The commissioner shall promulgate administrative regulations in accordance with KRS Chapter 13A that specify the disclosure forms required by subsections (b), (c), and (f) of this section.

(d) How the amendment will assist in the effective administration of the statutes: KRS 91A.080 requires the Department to promulgate regulations for the procedures of reporting local government premium tax and this amendment adds the proper reporting Web site to use in order for entities to report. This amendment also ensures that the regulation meets Chapter 13A requirements.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This regulation will affect the approximately 1,409 insurance companies that hold a certificate of authority in Kentucky and approximately 340 actively licensed surplus lines brokers that are subject to local government taxes.

(4) Provide an analysis of how the entities identified in the previous question will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions each of the regulated entities have to take to comply with this regulation or amendment: Regulated entities will be required to adhere to the standards in this regulation in order to properly report local government premium taxes.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: The process set forth in this administrative regulation clarifies a long-standing practice regarding the reporting process. As insurers have already been complying in this manner, there is no cost to implement this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities: As a result of compliance, regulated entities will be properly reporting local government premium taxes in accordance with KRS 91A.080.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: Implementation of this amendment is not anticipated to have an initial cost on the Department of Insurance.

(b) On a continuing basis: Implementation of this amendment is not anticipated to have an on-going cost on the Department of Insurance.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Department will use funds from its current operational budget to perform the tasks necessary.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase of fees will not be necessary because additional personnel is likely unnecessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not directly establish any new fees.

(9)TIERING: Is tiering applied? Tiering is not applied because this regulation applies equally to all insurance companies holding a certificate of authority in Kentucky and all licensed surplus lines brokers subject to local government taxes.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? All divisions of local governments will be impacted by this regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 91A.080(6).

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation is not expected to generate any revenue in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation is not expected to generate any revenue in subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not have a cost to implement in the first year.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not have a cost to administer subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Neutral

Expenditures (+/-): Neutral

Other Explanation: As the amendments to this administrative regulation clarify an existing process, this administrative regulation will not have a fiscal impact on the Department of Insurance.

PUBLIC PROTECTION CABINET Department of Insurance Consumer Protection Division (Amendment)

 $806\ {\rm KAR}\ 10:030.$ Surplus lines reporting and tax payment structure.

RELATES TO: KRS 304.1-070, 304.10-030, 304.10-040,

304.10-050, 304.10-170, 304.10-180, 304.99-085

STATUTORY AUTHORITY: KRS 304.2-110, 304.10-050, 304.10-170, 304.10-210,

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110 authorizes the Commissioner of Insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code as defined in KRS 304.1-010. [KRS 304.2-110 authorizes the commissioner to make reasonable rules and administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code.] KRS 304.10-050 requires a surplus lines broker to file an affidavit setting forth facts from which it can be determined whether such insurance was eligible for export under KRS 304.10-040. KRS 304.10-170 requires the commissioner to established [prescribe] the form of the verified statement of all surplus lines transactions for a preceding calendar quarter. KRS 304.10-210 requires the commissioner to promulgate administrative regulations to effectuate the surplus lines law. This administrative regulation provides for the reporting procedures to be used by surplus lines brokers for the reporting and payment of surplus lines tax pursuant to KRS 304.10-170 and 304.10-180.

Section 1. Affidavit Reporting.

(1) A licensed surplus broker shall file electronically a Kentucky Surplus Lines Affidavit of Insurance Transactions with the department within fifteen (15) days after the invoice date or effective date of each premium bearing surplus lines transaction, whichever occurs later.

(2) The affidavit shall be filed electronically through the Department of Insurance's secure Web site at https://insurance.ky.gov/doieservices/UserRole.aspx

[http://insurance.ky.gov/kentucky/secured/Eservices/default.aspx].

Section 2. Quarterly Reporting and Payment of Surplus Lines Premium Taxes for Insurance Transactions.

(1) The department shall generate a quarterly report of all surplus lines transactions reported in a preceding calendar quarter, for each surplus lines broker based on the affidavits filed in accordance with Section 1 of this administrative regulation.

(2) The department shall make the quarterly report available to a licensed surplus lines broker on its secure Web site at <u>https://insurance.ky.gov/doieservices/UserRole.aspx</u>

[https://insurance.ky.gov/kentucky/secured/Eservices/default.aspx, thirty (30) days following the

end of each calendar guarter].

(3) Each licensed surplus lines broker shall:

(a) Reconcile the surplus lines taxes owed on the quarterly report with the broker's own records;

(b) Notify the department of any discrepancy in surplus lines taxes owed; and

(c) Pay all surplus lines premium tax and any applicable penalties owed pursuant to KRS

304.99-085 within thirty (30) days of the <u>end of the calendar</u> guarter [date of the guarterly report].

(4) Surplus lines premium tax shall be:

(a) Computed at the rate of three (3) percent on the premiums, assessments, fees, charges,

or other consideration deemed part of the premium as shown on the quarterly report;

(b) Payable to the Kentucky State Treasurer; and

(c) Remitted to the Kentucky Department of Insurance electronically through the department's secure Web site at <u>https://insurance.ky.gov/doieservices/UserRole.aspx</u>

[http://insurance.ky.gov/kentucky/secured/Eservices/default.aspx].

(5) Agencies paying a surplus lines premium tax on behalf of a broker shall submit payment electronically through the broker's Eservices account using the department's secure Web site at https://insurance.ky.gov/doieservices/UserRole.aspx

[http://insurance.ky.gov/kentucky/secured/Eservices/default.aspx].

(6) The department shall consider the payment of the surplus lines premium tax and any

applicable penalty to be the submission of the broker's quarterly

report and verified statement of transactions.

Section 3. Effective Date. The administrative regulation shall be effective beginning with the calendar quarter beginning July 1, <u>2021</u> [2019].[

Section 4. Incorporation by Reference. (1) "Kentucky Surplus Lines Affidavit of Insurance Transactions", May 2019, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department of Insurance, 215 West Main Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. The material is also available on the department's secure Web site at https://insurance.ky.gov/doieservices/UserRole.aspx

http://insurance.ky.gov/kentucky/secured/Eservices/default.aspx.]

SHARON P. CLARK, Commissioner

KERRY B. HARVEY, Secretary

APPROVED BY AGENCY: October 12, 2020 FILED WITH LRC: October 13, 2020 at 10:08 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held at 9:00 AM on December 21, 2020 at 500 Mero Street, Frankfort, Kentucky 40602. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through 11:59 PM on December 31, 2020. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

CONTACT PERSON: DJ Wasson, Deputy Commissioner, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 564-6026, fax +1 (502) 564-1453, email dj.wasson@ky.gov

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: DJ Wasson

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation provides for the reporting procedures to be used by surplus lines brokers for the reporting and payment of surplus lines tax in accordance with KRS 304.10-170 and 304.10-180.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to prescribe the reporting procedures to be used by surplus lines brokers for the reporting and payment of surplus lines tax in accordance with KRS 304.10-170 and 304.10-180.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.2-110 provides that the Commissioner of Insurance may make reasonable rules and administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code, as defined in KRS 304.1-010. KRS 304.10-170 authorizes the executive director to prescribe the form of the verified statement of all surplus lines transactions for a preceding calendar quarter. KRS 340.10-210 requires the executive director to promulgate administrative regulations to effectuate the surplus lines law. This administrative regulation provides for the reporting procedures to be used by surplus lines brokers for the reporting and payment of surplus lines tax in accordance with KRS 304.10-170 and 304.10-180.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This

administrative regulation provides the process for surplus lines brokers to report and pay the required taxes on surplus lines business on a quarterly basis to the Department of Insurance.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments will clarify the existing process of requiring surplus lines broker has to file affidavits through the Department's eServices program located on the Department's website. This is to elevate the acceptance of paper checks by the Department of Insurance. The amendment also updates the Department's website link and to redacted the current form, as the Department is converting to all electronic processing. This amendment also removes the Material Incorporated due to the attempt to go "paperless", and therefor is no longer needed.

(b) The necessity of the amendment to this administrative regulation: This necessity of this amendment to this administrative regulation is the ensure that the general public is aware of where to send any necessary correspondence(s). As well as to streamline the workload of the Department staff, requiring broker's file affidavits and payments electronically.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 304.2-110 provides that the Executive Director of Insurance may make reasonable rules and administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code, as defined in KRS 304.1-010. KRS 304.10-170 authorizes the executive director to prescribe the form of the verified statement of all surplus lines transactions for a preceding calendar quarter. KRS 340.10-210 requires the executive director to promulgate administrative regulations to effectuate the surplus lines law.

(d) How the amendment will assist in the effective administration of the statutes: The amendments to this existing administrative regulation prescribe the information to be submitted by a surplus lines broker of all surplus lines insurance transacted in the previous calendar quarter. This new electronic format will streamline the process for both surplus lines brokers and Department staff.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This regulation will affect the approximately 1,147 surplus lines brokers licensed in Kentucky.

(4) Provide an analysis of how the entities identified in the previous question will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions each of the regulated entities have to take to comply with this regulation or amendment: Regulated entities will be required to follow the updated process when submitting quarterly statements and payment of taxes electronically in accordance with KRS 304.10-170 and 304.10-180 beginning July 1, 2021.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: The process set forth in this administrative regulation clarifies a long-standing practice regarding the reporting process. As insurers have already been complying in this manner, there is no cost to implement this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities: As a result of compliance, regulated entities will be in compliance with KRS 304.10-170 and 304.10-180. Additionally, quarterly reports should be submitted accurately with the initial submission, thereby eliminating the need to submit amended reports. There will also be more efficient payment times due to the acceptance of electronic payments through eServices only.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: Implementation of this amendment is not anticipated to have an initial cost on the Department of Insurance.

(b) On a continuing basis: Implementation of this amendment is not anticipated to have an on-going cost on the Department of Insurance.

(6) What is the source of the funding to be used for the

implementation and enforcement of this administrative regulation: The Department will use funds from its current operational budget to perform the tasks necessary.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase of fees will not be necessary because additional personnel is likely unnecessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not directly establish any new fees.

(9)TIERING: Is tiering applied? Tiering is not applied because this regulation applies equally to all insurance companies holding a certificate of authority in Kentucky and all licensed surplus lines brokers subject to local government taxes.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Department of Insurance will be impacted as the implementer of the regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 304.2-110, 304.10-170, 304.10-210

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation is not expected to generate any revenue in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation is not expected to generate any revenue in subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not have a cost to implement in the first year.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not have a cost to administer subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Neutral

Expenditures (+/-): Neutral

Other Explanation: As the amendments to this administrative regulation clarify an existing process, this administrative regulation will not have a fiscal impact on the Department of Insurance.

PUBLIC PROTECTION CABINET Department of Insurance Life and Health Division (Amendment)

806 KAR 12:010. Advertising.

RELATES TO: KRS <u>304.1-010</u>, <u>304.3-240</u>, 304.12-010, <u>304.12-020</u>, 304.12-060, 304.12-120, 304.12-130, STATUTORY AUTHORITY: KRS 304.2-110

NECESSITY, FUNCTION, AND CONFORMITY: <u>KRS 304.2-</u> <u>110 authorizes the Commissioner of Insurance to promulgate</u> administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code as defined in KRS 304.1-010. [KRS 304.2-110 provides that the Executive Director of Insurance shall make reasonable rules and regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code.] This administrative regulation clarifies the minimum standards for advertising as set forth in KRS 304.12-010 and 304.12-020.

Section 1. (1) An advertisement for the purpose of the advertisement regulations shall include:

(a) Printed and published material and descriptive literature of an insurer used in newspapers, magazines, radio and TV scripts, billboards and similar displays; and

(b) Descriptive literature and the sales aids of all kinds issued by an insurer for presentation to members of the public, including but not limited to circulars, leaflets, booklets, depictions, illustrations, and form letters; and

(c) Prepared sales talks, presentations and material for use by agents and brokers, and representations made by agents and brokers [in accordance therewith].

(2) Policy for the purpose of the advertisement regulations shall include any policy, plan, certificate, contract, agreement, statement of coverage, rider, or endorsement which provides accident or sickness benefits or medical, surgical or hospital expense benefits, whether on a cash indemnity, reimbursement, or service basis, except when issued in connection with another kind of insurance other than life, and except disability and double indemnity benefits included in life insurance and annuity contracts.

(3) Insurer for the purpose of the advertisement regulations shall include any corporation, association, partnership, reciprocal exchange, interinsurer, Lloyds, fraternal benefit society, and any other legal entity engaged in the advertisement of a policy [as herein defined].

Section 2. The advertisement regulations shall apply to agents and brokers to the extent that they are responsible for the advertisement of any policy.

Section 3. (1) Advertisements shall be truthful and not misleading in fact or in implication. Words or phrases the meaning of which is clear only by implication or by familiarity with insurance terminology shall not be used.

(2) Words, phrases, or illustrations shall not be used in a manner which misleads or has the capacity and tendency to deceive as to the extent of any policy benefit payable, loss covered or premium payable. An advertisement relating to any policy benefit payable, loss covered or premium payable shall be sufficiently complete and clear as to avoid deception or the capacity and tendency to deceive.[, to wit:]

(a) The words and phrases "all," "full," "complete," "comprehensive," "up to," "as high as," "this policy will pay your hospital and surgical bills," or "this policy will replace your income," or similar words and phrases shall not be used so as to exaggerate any benefit beyond the terms of the policy, but may be used only in such manner as fairly describes such benefit.

(b) A policy covering only one (1) disease or a list of specified diseases shall not be advertised [se] as to imply coverage beyond the terms of the policy. Synonymous terms shall not be used to refer to any disease [se] as to imply broader coverage than is the fact.

(c) The benefits of a policy which pays varying amounts for the same loss occurring under different conditions or which pays benefits only when a loss occurs under certain conditions shall not be advertised without disclosing the limited conditions under which the benefits referred to are provided by the policy.

(d) Phrases <u>similar to</u> [such as] "this policy pays \$1,800 for hospital room and board expenses" are incomplete without indicating the maximum daily benefit and the maximum time limit for hospital room and board expenses.

(3) When an advertisement refers to any dollar amount, period of time for which any benefit is payable, cost of policy, or specific policy benefit or the loss for which such benefit is payable, it shall also disclose those exceptions, reductions and limitations affecting the basic provisions of the policy without which the advertisement would have the capacity and tendency to mislead or deceive.[; to wit:]

(a) The term "exception" shall mean any provision in a policy <u>where</u> [whereby] coverage for a specified hazard is entirely eliminated; it is a statement of risk <u>not</u> [no] assumed under the policy.

(b) The term "reduction" shall mean any provision which reduces the amount of the benefit; a risk of loss is assumed but payment upon the occurrence of such loss is limited to some amount or period less than would be otherwise payable had <u>the</u> [such] reduction clause not been used.

(c) The term "limitation" shall mean any provision which restricts coverage under the policy other than an exception or a reduction.

(d) When a policy contains a time period between the effective date of the policy and the effective date of coverage under the policy or a time period between the date of coverage under the policy or a time period between the date a loss occurs and the date benefits begin to accrue for such loss, an advertisement shall disclose the existence of such periods.

(e) An advertisement shall disclose the extent to which any loss is not covered if the cause of such loss is traceable to a condition existing prior to the effective date of the policy. <u>If [When]</u> a policy does not cover losses traceable to preexisting conditions <u>the</u> [ne] advertisement of the policy shall <u>not</u> state or imply that the applicant's physical condition or medical history will not affect the issuance of the policy or payment of a claim [thereunder]. This limits the use of phrase "no medical examination required" and <u>similar</u> phrases [of similar import].

Section 4. An advertisement which refers to renewability, cancelability, or termination of a policy, or which refers to a policy benefit, or which states or illustrates time or age in connection with eligibility of applicants or continuation of the policy, shall disclose the provisions relating to renewability, cancelability and termination and any modification of benefits, losses covered or premiums because of age or for other reasons, in a manner which shall not minimize or render obscure the qualifying conditions.

Section 5. All information required to be disclosed by the advertisement regulations shall be set out conspicuously and in close conjunction with the statements to which the [such] information relates or under appropriate captions of [such] prominence that [is] shall not be minimized, rendered obscure or presented in an ambiguous fashion or intermingled with the context of the advertisement so as to be confusing or misleading.

Section 6. Testimonials used in advertisements <u>shall</u> [must] be genuine, represent the current opinion of the author, be applicable to the policy advertising and be accurately reproduced. The insurer, in using a testimonial <u>shall make</u> [makes] as its own all of the statements contained <u>in the advertisement</u> [therein], and all the advertisement including <u>the</u> [such] statements <u>shall be</u> [is] subject to all of the provisions of <u>this administrative regulation</u> [the advertisement regulations].

Section 7. An advertisement relating to the dollar amounts of claims paid, the number of persons insured, or similar statistical information relating to any insurer or policy shall not be used unless it accurately reflects all of the relevant facts. The [Such] advertisement shall not imply that such statistics are derived from the policy advertised unless <u>that</u> [such] is the fact.

Section 8. An offer in an advertisement of free inspection of a policy or offer of a premium refund <u>shall not be</u> [is not] a cure for misleading or deceptive statements contained in <u>the</u> [such] advertisement.

Section 9. (1) When a choice of the amount of benefits is referred to, an advertisement shall disclose that the amount of benefits provided depends upon the plan selected and that the premium will vary with the amount of the benefits.

(2) When an advertisement refers to various benefits which may be contained in two (2) or more policies, other than group master policies, the advertisement shall disclose that such benefits are provided only through a combination of such policies.

Section 10. An advertisement shall not directly or indirectly make unfair or incomplete comparisons of policies or benefits or otherwise falsely disparage competitors, their policies, services or business methods.

Section 11. (1) An advertisement which is intended to be seen or heard beyond the limits of the jurisdiction in which the insurer is licensed shall not imply licensing beyond these limits.

(2) <u>Advertisements</u> [Such advertisements] by direct mail insurers shall indicate that the insurer is licensed in a specified state or states only, or is not licensed in a specified state or states, by use of some language <u>similar to</u> [such as] "This company is licensed only in State A" or "This company is not licensed in State B."

Section 12. The identity of the insurer shall be made clear in all of <u>the insurers[its]</u> advertisements. An advertisement shall not use a trade name, service make, slogan, symbol or other device which has the capacity and tendency to mislead or deceive as to the true identity of the insurer.

Section 13. An advertisement of a particular policy shall not state or imply that prospective policyholders become group or quasi-group members and as <u>members</u> [such] enjoy special rates or underwriting privileges, unless <u>that [such]</u> is the fact.

Section 14. An advertisement shall not state or imply that a particular policy or combination of policies is an introductory, initial or special offer and that the applicant <u>shall</u> [will] receive advantages by accepting the offer, unless <u>that [such]</u> is the fact.

Section 15. (1) An advertisement shall not state or imply that an insurer or a policy has been approved or an insurer's financial condition has been examined and found to be satisfactory by a governmental agency, unless <u>that [such]</u> is the fact.

(2) An advertisement shall not state or imply that an insurer or a policy has been approved or endorsed by any individual, group of individuals, society, association or other organization, unless that [such] is the fact.

Section 16. An advertisement shall not contain untrue statements with respect to the time within which claims are paid or statements which imply that claim settlements will be liberal or generous beyond the terms of the policy.

Section 17. An advertisement shall not contain statements which are untrue in fact or by implication misleading with respect to the insurer's assets, corporate structure, financial standing, age or relative position in the insurance business.

Section 18. (1) Each insurer shall maintain at its home or principal office a complete file containing every printed, published, or prepared advertisement of individual policies and typical printed published or prepared advertisements of blanket, franchise and group policies [hereafter] disseminated in this or any other state whether or not licensed in the [such] other state, with a notation attached to each [such] advertisement which shall indicate the manner and extent of distribution and the form number of any policy advertised. The [Such] file shall be subject to regular and periodical inspection by the Department of Insurance [this office]. All [such] advertisements shall be maintained [in said file] for a period of not less than three (3) years.

(2) Each insurer required to file an annual statement in accordance with KRS 304.3-240 which is now or which [hereafter] becomes subject to the provisions of this administrative regulation shall [the advertisement regulations must] file with the Department of Insurance [this office] together with its annual statement, a certificate executed by an authorized officer of the insurer stating

[wherein it is stated] that to the best of his knowledge, information, and belief the advertisements which were disseminated by the insurer during the preceding statement year complied or were made to comply in all respects with the provisions of the insurance laws of this state [as implemented and interpreted by the advertisement regulations]. [It is requested that the chief executive officer of each insurer to which the advertisement regulations are addressed acknowledge its receipt and indicate its intention to comply therewith.]

Section 19. (1) The purpose and intent of this administrative regulation <u>shall be</u> [is] to prohibit the transmission of information in the form of advertisements or otherwise which might be deceptive, misleading or untrue. The [general] intent[, <u>therefore</u>,] and the provisions of this administrative regulation <u>shall not be</u> [not] expressly limited to a particular type of insurance <u>and[,]</u> shall be applied to all insurance on subjects of risk located in or to be performed in this state.

(2) The use of advertising material previously filed with and approved by the <u>Department of Insurance [office]</u> shall not subject the filer to any disciplinary action or penalty by <u>the department [this office]</u>, as long as such prior approval remains in effect.

(3) Any person, firm, corporation, or association who knowingly aids and abets an insurer in the violation of this administrative regulation or the applicable provisions of the Insurance Code shall be subject to the penalties provided by law.

SHARON P. CLARK, Commissioner

KERRY B. HARVEY, Secretary APPROVED BY AGENCY: October 12, 2020

FILED WITH LRC: October 13, 2020 at 10:12 a.m. PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held at 9:00 AM on December 21, 2020 at 500 Mero Street, Frankfort, Kentucky 40602. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through 11:59 PM on December 31, 2020. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

CONTACT PERSON: DJ Wasson, Deputy Commissioner, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 564-6026, fax +1 (502) 564-1453, email dj.wasson@ky.gov

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: DJ Wasson

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation provides guidelines and requirements for advertising methods of insurance products or policy.

(b) The necessity of this administrative regulation: The necessity of this regulation is promulgated by KRS 304.2-110. The administrative regulation is to ensure advertisement to the public is of sound measure and in good faith, avoiding deceitful advertising tactics.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.2-110 provides that the Commissioner of Insurance shall make reasonable rules and regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation clarifies the minimum standards for advertising as set forth in KRS 304.12-010 and 304.12-020.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments to this administrative regulation are to ensure the adherence to Chapter 13A formatting and diction. The amendment also removes the requirement for the chief executive officer of each insurer accept recipe of the advertisemnt regulation and compliance.

(b) The necessity of the amendment to this administrative regulation: This necessity of this amendment to this administrative regulation is to comply with the requirements of KRS Chapter 13A.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 304.2-110 provides that the Executive Director of Insurance may make reasonable rules and administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code, as defined in KRS 304.1-010.

(d) How the amendment will assist in the effective administration of the statutes: The amendments present in this administrative regulation are to meet the requirements of Chapter 13A.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The insurers of which are required to file annual statements including advertisement, as well as the department.

(4) Provide an analysis of how the entities identified in the previous question will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions each of the regulated entities have to take to comply with this regulation or amendment: Insurers who intend to market insurance products must file with the department prior to marketing to ensure all advertisement meet the criteria of this regulation as well as other advertising regulations.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: The process set forth in this administrative regulation clarifies a long-standing practice regarding the reporting process. As insurers have already been complying in this manner, there is no cost to implement this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities: Compliance with this regulation will allow insurers to use advertising materials publically.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: Implementation of this amendment is not anticipated to have an initial cost on the Department of Insurance.

(b) On a continuing basis: Implementation of this amendment is not anticipated to have an on-going cost on the Department of Insurance.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Department will use funds from its current operational budget to perform the tasks necessary.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase of fees will not be necessary because additional personnel is likely unnecessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not directly establish any new fees.

(9)TIERING: Is tiering applied? Tiering is not applied.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Department of Insurance will be impacted as the implementer of the regulation. (2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 304.2-110

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation is not expected to generate any revenue in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation is not expected to generate any revenue in subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not have a cost to implement in the first year.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not have a cost to administer subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Neutral

Expenditures (+/-): Neutral

Other Explanation: As the amendments to this administrative regulation clarify an existing process, this administrative regulation will not have a fiscal impact on the Department of Insurance.

PUBLIC PROTECTION CABINET Department of Insurance Life and Health Division (Amendment)

806 KAR 12:020. Fair disclosure to consumers.

RELATES TO: KRS <u>304.1-010</u>, <u>304.1-050</u>, <u>304.2-310</u>, <u>304.9-</u> 440, <u>304.12-010</u>, <u>304.12-020</u>, <u>304.12-040</u>, <u>304.12-110</u>, <u>304.12-</u> 130, <u>304.14-120</u> to <u>304.14-180</u>

STATUTORY AUTHORITY: KRS 304.2-110

NECESSITY, FUNCTION, AND CONFORMITY: <u>KRS 304.2-110</u> authorizes the Commissioner of Insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code as defined in KRS 304.1-010. [304.2-110 provides that the Executive Director of Insurance shall make reasonable rules and regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code.] This administrative regulation further interprets and implements statutory standards to assure fair disclosure to consumers.

Section 1. Definitions.

(1) "Commissioner" is defined by KRS 304.1-050(1).

(2) "Department" is defined by KRS 304.1-050(2).

(3) "Pure endowment benefit" means a guaranteed insurance benefit, actuarially determined, the payment of which is contingent upon the survival of the insured to a specified point in time.

Section 2. Deeming it to be in the highest degree of public interest that the insurance buying public will not be deceived or misled [in regard to] the purchase of life insurance, it is [therefore] considered proper and desirable to further implement and interpret the statutory standards which generally relate to the sale of life insurance.

Section 3[2]. Applicability. This administrative regulation shall

apply to:

(1)(a) Any [To any] insurance company, person, broker, or consultant, as those terms are defined in the insurance code, KRS Chapter 304;[-]

(b) Acts [(2) To acts] and practices in the advertising, promotion, solicitation, negotiation of or effecting the sale of life insurance policies; and

(c) Acts and practices whether they involve the use of language disseminated by means of sales kits, policy jackets or covers, letters, personal presentation, visual aids, or other sales media.

(2) This [(this] administrative regulation shall not apply to group insurance policies or to annuity contracts[]].[

(3) To such acts and practices whether they involve the use of language disseminated by means of sales kits, policy jackets or covers, letters, personal presentation, visual aids or other sales media.]

Section <u>4</u>[3]. Statement of Policy. (1) The purpose of this administrative regulation <u>shall be[, essentially, is]</u> to assure fair disclosure of relevant facts in the sale of life insurance <u>and [.This administrative regulation is also designed]</u> to protect purchasers and prospective purchasers of life insurance policies against the use of sales methods which are misleading because of:

(a) The omission of facts fairly describing both the subject matter of a life insurance policy and the benefits obtainable <u>under</u> the policy [thereunder].

(b) An undue emphasis upon facts which may be true but [, however, true,] are not relevant to the sales of life insurance.

(c) An undue emphasis upon features which are of incidental or secondary importance to the life insurance aspects of a policy.

(2) To assure [such] fair disclosure and to prevent the use of misleading sales methods this administrative regulation provides advance interpretations as to specific acts and practices which the <u>Department</u> [Office] of Insurance believes constitute violations of [said] statutes; provided, however, it <u>shall be</u> [is] recognized that whether particular conduct comes within the prohibition of [said] statutory provisions depends upon the facts in each case.

(3) Although this administrative regulation is addressed to selected acts and practices which have been of serious concern to the <u>Department</u> [Office] of Insurance, this delimitation <u>shall not be</u> [is net] a determination that any act of practice not specified <u>in this</u> administrative regulation [herein] is in conformance with the [aforesaid] statutory provisions. However, this administrative regulation <u>shall</u> [will] be read as a guide in considering whether any unspecified act or practice is of the kind or character which may be within the prohibitions of <u>the</u> [said] statutory provisions.

(4) In accordance with the purposes and limitations set out in Sections <u>3 and 4</u> [<u>1 and 2</u>] of this administrative regulation, the acts and practices set out in the following sections are declared to be unlawful when used in context or done under [such] circumstances or conditions as to have the capacity and tendency to mislead a purchaser or prospective purchaser to believe that he will receive, or that it is probable he will receive something other than an insurance policy, some benefit not available to other persons of the same class and equal expectation of life. Each of <u>the</u> [said] sections <u>of this administrative regulation shall</u> [will, therefore,] be construed and applied in concordance with the provisions of this section.

Section <u>5[4]</u>. Policy Forms. From the effective date of this administrative regulation <u>a company shall not [no company Shall]</u>:

(1) Include coupons as a part of policies containing pure endowment benefits: [. A pure endowment benefit is a guaranteed insurance benefit, actuarially determined, the payment of which is contingent upon the survival of the insured to a specified point in time.]

(2) Issue a policy of insurance containing pure endowment benefits unless the gross premium for these provisions is shown prominently and separately in the policy as distinct from the regular insurance gross premium. This subsection shall not apply to any policy in which the amount of any pure endowment or periodic benefit or benefits payable during any policy year is greater than the total annual premium for the [such] year.

(a) This separate gross premium for the series of pure endowments shall be based on reasonable assumptions and be consistent with the basic policy form as to interest, mortality and expense.

(b) The amount of the guaranteed series of pure endowment benefits shall be expressed in dollar amounts and shall not be presented or defined, either in the policy or any sales and advertising material, as a "percentage" of any premiums or benefits contained in the policy [therein].

(c) All policies with pure endowments sold in Kentucky [after the 60th day following the date of this order] shall include [bear] the following statement, or similar wording approved by the <u>department</u> [office] set forth, rubberstamped on the face of the policy until present stocks are exhausted: "The premium includes \$_____ for pure endowment benefits."

<u>(3)</u> Use a dividend illustration in connection with a participating life insurance policy unless <u>the [such]</u> dividend illustration is on file with the <u>commissioner</u> [Executive Director of Insurance] as a part of a rate book or as a separate filing; <u>and[-]</u>

(4) Use [such] words as "investment or investment plan," "insured investment plan," "profitsharing," "charter plan," "founders plan," or similar language in a life insurance policy, either in context or under [such] circumstances or conditions as to have the capacity and tendency to mislead a purchaser or prospective purchaser to believe that he will receive or that it is probable he will receive something other than an insurance policy, some benefit not provided in the policy, or some benefit not available to other persons of the same class and equal expectation of life.

Section <u>6.[5-]</u> Sales Presentation and Solicitation. From the effective date of this administrative regulation it shall be [deemed] unlawful to make:

(1) Reference to a policy using similar terminology as described in Section 54 of this administrative regulation and more particularly:

(a) Statements or representations that the prospective policyholder <u>shall</u> [will] receive the right to benefits from the insurance company which are not stipulated in the policy itself; or

(b) Statements or references that refer to premium payments in language stating the payment is a "deposit" unless:

1. The payment establishes a debtor-creditor relationship between the insurance company and the policyholder; or

2. The term is used in conjunction with the word "premium" in [such] a manner that clearly indicates [as to indicate clearly] the true character of the payment.

(c) Statements which describe a life insurance policy or premium payments in terms of "unit of participation" unless accompanied by other language fairly indicating their reference to a life insurance policy or to premium payments[, as the case may be]. Statements which describe a life insurance policy or premium payments in terms of units [henceforth] shall be followed by the dollar amount representing the annual premium for each unit or units described; and further wording clearly indicating that the unit or units represent a life insurance policy.

(d) Statements which infer that the guaranteed endowments available under a policy are interest, earnings, return on investment, or anything other than benefits for which the cost is taken into consideration in calculating the total premium.

(2) Reference to any policy or contract in [such] a manner as to misrepresent its true nature and more particularly:

(a) Statements which tend to lead the prospect to believe that the agent is dealing in other than a life insurance contract:[-]

(b) Statements which tend to lead the prospect to believe that life insurance is incidental to the purchase of the contract:[-]

(c) Statements or reference relating to the growth of the life insurance industry or to the tax status of life insurance companies in a context which would reasonably be understood to interest a prospect in the purchase of shares of stock in an insurance company rather than in the purchase of a life insurance policy;[-]

(d) Statements which reasonably give rise to the inference that the insured will enjoy a status common to a stockholder or will acquire a stock ownership interest in the insurance company by virtue of purchasing the policy: and[-]

(e) References or statements to a company's "investment department," "insured investment department," or similar terminology in such a manner as to imply that the policy was sold, or issued, or is serviced by the investment department of the insurance company.

(3) References regarding the payment of dividends in [such] a manner as to misrepresent their true nature, and more particularly:

(a) Providing any illustration as to projected dividends unless the dividend scale is based on the experience currently used by the company for dividends, and unless the illustration is expressed in dollar amounts;[-]

(b) Statements which use the words "dividends," "cash dividends," "surplus," or similar phrases in [such] a manner as to state or imply that the payment of dividends is guaranteed or certain to occur;[-]

(c) Statements or references that a purchaser of a policy will share in a stated percentage or portion of the earnings of the company:[-]

(d) Statements which use the word "dividend," "cash dividends," "surplus," or similar terminology shall be expressed only in dollar amounts. This shall apply to projected dividends as well as past experience on dividends; and[-]

(e) Statements or inferences that projected dividends under a participating policy will be or can be sufficient at any time to assure the receipt of benefits[, such as a paid-up policy,] without the further payment of premiums unless the statement is accompanied by an adequate explanation as to:

1. What benefits or coverage would be provided: and [at such time.]

2. The conditions under which this would occur.

(4) Reference to any policy or contract in [such] a manner as to suggest that certain policyholders will receive preferential treatment, and more particularly:

(a) Statements or references which would reasonably tend to imply that by purchasing a policy, the purchaser or prospective purchaser will become a member of a limited group of persons who may receive in the payment of dividends, special advantages, benefits, or favored treatment. This paragraph has no relation or applicability to policies under which insured persons of one (1) class of risk may receive dividends of a higher rate than persons of another class of risk:[-]

(b) Statements or references that each policyholder is given the right to allocate a specific number of policies:[-]

(c) Statements or inferences that only a limited number of person or a limited class of persons, will be eligible to buy a particular kind of policy, unless <u>the [such]</u> limitation is related to recognized underwriting practices:[-]

(d) Statements or inferences that policyholders who act as "centers of influence" for an insurance company in that capacity will share in the company's surplus earnings in some manner not available to policyholders of the same class; and[-]

(e) Comparisons to the past experience of other life insurance companies where the comparison is based on an arbitrary selection as to either the companies or the statistics or other data which are used. This paragraph <u>shall be</u> [is] intended to protect policyholders from being misled as to the character of a policy or its benefits, through the presentation of experience of companies with reverse experience.

Section <u>7[6]</u>. Dividends. (1) Policyholder premium or gross cost reductions on participating policies <u>shall</u> [will] be designated dividends. No other items shall be designated as dividends. Dividends shall not be guaranteed as to amount, percentage or premium, or other basis. The decision for declaration of a dividend shall be determined by the insurance company's board of directors, based solely on operating results or projection for those policies designated ["]participating["] policies.

(2) When dividends are ["]declared["] for a policy year classification [{]based on specific plan <u>or</u> [and/or] age classifications as they relate to contribution of company ability to declare dividends[], dividends <u>shall</u> [will] be apportioned to all policies so entitled in that policy year.

(3) The date dividends are declared shall be the date liability is established for the dividends and the reserve established for this liability <u>shall</u> [will] be the full amount of the dividends declared.

Section <u>8</u>[7]. Other Provisions. (1) <u>An</u> [In order to implement this administrative regulation the office will exercise its right at its discretion to require the submission of any or all sales material.

(2) Each company will be held responsible for disseminating this administrative regulation to its representatives and assuring compliance.

(3) The provisions of this administrative regulation are intended to apply only to policies issued on or after its effective date for delivery in this state, and it does not apply to contracts issued prior to the effective date nor to contracts issued prior to the effective date nor to contracts issued for delivery outside the state. The adoption of this administrative regulation should not disturb or cast doubt about the validity of previously issued contracts described herein.

(4) No] insurance company, insurance agent, consultant, <u>or</u> [nor] insurance company representative shall <u>not</u> [as a competitive or "twisting" device,] inform any policyholder or prospective policyholder that any insurance company was required to change a policy form or related material to comply with the provisions of this administrative regulation.

(5) The <u>commissioner</u> [executive director] may suspend or revoke any license or <u>certificate of</u> authority for violation of the provisions of this administrative regulation after a hearing upon written notice as required by <u>KRS 304.2-310</u> [the insurance code].

SHARON P. CLARK, Commissioner

KERRY B. HARVEY, Secretary

APPROVED BY AGENCY: October 12, 2020

FILED WITH LRC: October 13, 2020 at 10:12 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held at 9:00 AM on December 21, 2020 at 500 Mero Street, Frankfort, Kentucky 40602. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through 11:59 PM on December 31, 2020. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

CONTACT PERSON: DJ Wasson, Deputy Commissioner, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 564-6026, fax +1 (502) 564-1453, email dj.wasson@ky.gov

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: DJ Wasson

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation further interprets and implements statutory standards to assure fair disclosure to consumers.

(b) The necessity of this administrative regulation: This administrative regulation further interprets and implements statutory standards to assure fair disclosure to consumers.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.2-110 provides that the Commissioner of Insurance shall make reasonable rules and regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: Deeming it to be in the highest degree of public interest that the insurance buying public will not be deceived or misled in regard to the purchase of life insurance, it is considered proper and desirable to further implement and interpret the statutory standards which generally relate to the sale of life insurance.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment to this administrative regulation ensure compliance with Chapter 13A requirements as well as adding definition section to help articulate the regulation.

(b) The necessity of the amendment to this administrative regulation: The amendments made are necessary to meet the requirements of KRS Chapter 13A as well as restructure the effectuation of the regulation itself.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 304.2-110 provides that the Commissioner of Insurance shall make reasonable rules and regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code.

(d) How the amendment will assist in the effective administration of the statutes: KRS Chapter 13A authorizes specific drafting rules for administrative regulations; more specifically 13A.222 states that definitions shall be defined for the effectuation of the regulation. The amendments made to this regulation are to meet Chapter 13A requirements.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Insurers and the department.

(4) Provide an analysis of how the entities identified in the previous question will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions each of the regulated entities have to take to comply with this regulation or amendment: The processes explained in this regulation are long-standing and therefor insurers have already been required to follow these best practices.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: The process set forth in this administrative regulation clarifies a long-standing practice regarding fair disclosure. As insurers have already been complying in this manner, there is no cost to implement this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities: Compliance with this regulation will allow insurers to use advertising materials publically.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: Implementation of this amendment is not anticipated to have an initial cost on the Department of Insurance.

(b) On a continuing basis: Implementation of this amendment is not anticipated to have an on-going cost on the Department of Insurance.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Department will use funds from its current operational budget to perform the tasks necessary.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase of fees will not be necessary because additional personnel is likely unnecessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not directly establish any new fees.

(9) TIERING: Is tiering applied? Tiering is not applied.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Department of Insurance will be impacted as the implementer of the regulation. (2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 304.2-110

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation is not expected to generate any revenue in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation is not expected to generate any revenue in subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not have a cost to implement in the first year.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not have a cost to administer subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Neutral

Expenditures (+/-): Neutral

Other Explanation: As the amendments to this administrative regulation clarify an existing process, this administrative regulation will not have a fiscal impact on the Department of Insurance.

PUBLIC PROTECTION CABINET Department of Insurance Life and Health Division (Amendment)

806 KAR 12:180. Military sales practices.

RELATES TO: KRS 304.1-040, 304.5-020, 304.5-030, <u>304.9-020(10)</u> [304.9-020(7)], 304.12-010, 304.12-030, 304.15-310, 12 C.F.R. 205, 230, 707, 10 U.S.C. 992, 12 U.S.C. 4301, 26 U.S.C. 401(a), (k), 403(b), 408(k), (p), 414, 457, 501(c)(23), 29 U.S.C. 1001, 38 U.S.C. 1965, Pub.L. 109-290

STATUTORY AUTHORITY: KRS 304.2-110, 304.12-257, 10 U.S.C. 992(9)(a)(2)

NECESSITY, FUNCTION AND CONFORMITY: KRS 304.12-257 authorizes the commissioner [executive director] to promulgate administrative regulations to protect service members of the United States Armed Forces from dishonest insurance marketing and sales practices. [EO 2008-507, effective June 16, 2008, reorganized the Office of Insurance as the Department of Insurance and established the Commissioner of Insurance, rather than executive director, as head of the department.] 10 U.S.C. 992 sec 9(a)(2) requires the states to collectively work with the Secretary of Defense to ensure implementation of appropriate standards to protect members of the Armed Forces from dishonest and predatory insurance sales practices while on a military installation of the United States, and further requires each state to identify its role in promoting the standards in a uniform manner, not later than twelve (12) months after the date of enactment of the federal law. This administrative regulation sets forth standards to protect active duty service members of the United States Armed Forces from dishonest and predatory insurance sales practices by declaring certain identified practices to be false, misleading, deceptive or unfair.

Section 1. Definitions. (1)(a) "Active duty" means full-time duty in the active military service of the United States and includes members of the reserve component, both the National Guard and Reserve, while serving under published orders for active duty or full-time training.

(b) "Active duty" does not include members of the reserve component who are performing active duty or active duty for training under military calls or orders specifying periods of less than thirty-one (31) calendar days.

(2) "Ánnuity" is established[defined] in KRS 304.5-030.

(3) "Commissioner" means the Commissioner of the Department of Insurance <u>as established in KRS 304.1-050(1)</u>.

(4) "Department of Defense Personnel" means all active duty service members and all civilian employees, including nonappropriated fund employees and special government employees, of the Department of Defense.

(5) "Door to door" means a solicitation or sales method in which an insurance producer proceeds randomly or selectively from household to household without a prior specific appointment.

(6) "General advertisement" means an advertisement having as its sole purpose the promotion of the reader's or viewer's interest in the concept of insurance, or the promotion of the insurer or the insurance producer.

(7) "Insurable needs" means the risks associated with premature death taking into consideration the financial obligations and immediate and future cash needs of the applicant's estate or survivors or dependents.

(8) "Insurer" is established[defined] in KRS 304.1-040.

(9) "Insurance producer" is <u>established[defined]</u> in KRS <u>304.9-</u> <u>020(10)</u> [304.9-020(7)].

(10) "Known" or "knowingly" means the insurance producer or insurer had actual awareness, or in the exercise of ordinary care should have known, when the act or practice complained of occurred, that the person solicited is a service member.

(11) "Life insurance" is <u>established[defined]</u> in 304.5-020.

(12) "Military installation" means any federally owned, leased, or operated base, reservation, post, camp, building, or other facility to which service members are assigned for duty, including barracks, transient housing, and family quarters.

(13) "MyPay" means the Defense Finance and Accounting Service Web-based system that enables service members to process certain discretionary pay transactions or provide updates to personal information data elements without using paper forms.

(14) "Other military survivor benefits" mean the death gratuity, funeral reimbursement, transition assistance, survivor and dependents' educational assistance, dependency and indemnity compensation, TRICARE healthcare benefits, survivor housing benefits and allowances, federal income tax forgiveness, and Social Security survivor benefits.

(15) "SGL^I" means the Servicemembers' Group Life Insurance as <u>established[authorized]</u> by 38 U.S.C. section 1965.

(16) "Service member" means an active duty officer, both commissioned and warrant, or enlisted member of the United States Armed Forces.

(17)(a) "Side fund" means a fund or reserve that is part of or otherwise attached to a life insurance policy by rider, endorsement, or other mechanism which accumulates premium or deposits with interest or by other means.

(b) "Side fund" shall [does] not mean:

1. Accumulated value or cash value or secondary guarantees provided by a universal life policy;

2. Cash values provided by a whole life policy which are subject to standard nonforfeiture law for life insurance; or

3. A premium deposit fund which:

a. Contains only premiums paid in advance which accumulate at interest;

b. Imposes no penalty for withdrawal;

c. Does not permit funding beyond future required premiums;

- d. Is not marketed or intended as an investment; and
- e. Does not carry a commission, either paid or calculated.

(18) "Specific appointment" means a prearranged appointment agreed upon by both parties and definite as to place and time.

(19) "United States Armed Forces" means all components of the Army, Navy, Air Force, Marine Corps, and Coast Guard.

(20) "VGLI" means the Veterans' Group Life Insurance, as

authorized by 38 U.S.C. section 1965.

Section 2. Scope. This administration regulation shall apply only to the solicitation or sale of a life insurance policy or annuity by an insurer or insurance producer to an active duty service member of the United States Armed Forces.

Section 3. Exemptions. (1) This administrative regulation shall not apply to solicitations or sales involving:

(a) Credit insurance;

(b) Group life insurance or group annuities if

1. An in-person, face-to-face solicitation of individuals by an insurance producer is not

made; or

2. The contract or certificate does not include a side fund;

(c) An application to the existing insurer that issued the existing policy or contract if:

1. A contractual change or a conversion privilege is being exercised;

2. The existing policy or contract is being replaced by the same insurer pursuant to a program filed with and approved by the commissioner; or

3. A term conversion privilege is exercised among corporate affiliates;

(d) Individual stand-alone health policies, including disability income policies;

(e) Contracts offered by SGLI or VGLI;

(f) Life insurance contracts offered through or by a non-profit military association, qualifying under 26 U.S.C. 501(c) (23), and which are not underwritten by an insurer; or

(g) Contracts used to fund:

1. An employee pension or welfare benefit plan that is covered by the Employee Retirement and Income Security Act, 29 U.S.C. 1001;

2. A plan described by 26 U.S.C. 401(a), 401(k), 403(b), 26 U.S. C. 408(k) or 408(p), as amended, if established or maintained by an employer;

3. A government or church plan defined in 26 U.S.C. 414;

4. A government or church welfare benefit plan, or a deferred compensation plan of a state or local government or tax exempt organization under 26 U.S.C. 457;

5. A nonqualified deferred compensation arrangement established or maintained by an employer or plan sponsor;

6. Settlements of or assumptions of liabilities associated with personal injury litigation or any dispute or claim resolution or process; or

7. Prearranged funeral contracts.

(2) This administrative regulation shall not be construed to abrogate the ability of a nonprofit organization or another organization to educate members of the United States Armed Forces in accordance with Department of Defense Instruction 1344.07, "Personal Commercial Solicitation on DoD Installations."

(3)(a) General advertisements, direct mail, and internet marketing shall not constitute solicitation.

(b) Telephone marketing shall not constitute solicitation if the caller:

1. Explicitly and conspicuously discloses that the product concerned is life insurance; and

2. Does not make a statement that avoids a clear and unequivocal statement that life insurance is the subject matter of the solicitation.

(c) This subsection shall not be construed to exempt an insurer or insurance producer from the requirements of this administrative regulation in any in-person, face-to-face meeting established as a result of the exemptions identified in this subsection.

Section 4. Practices Declared False, Misleading, Deceptive or Unfair on a Military Installation. (1) The following acts or practices, if committed on a military installation by an insurer or insurance producer, with respect to the in-person, face-to-face solicitation of life insurance shall be false, misleading, deceptive or unfair:

(a) Knowingly soliciting the purchase of any life insurance product:

1. Door to door; or

2. Without first establishing a specific appointment for each meeting with the prospective purchaser;

(b) Soliciting service members in a group or mass audience or in a captive audience where attendance is not voluntary;

(c) Knowingly making appointments with or soliciting service members during their normally scheduled duty hours;

(d) Making appointments with or soliciting service members in

1. Barracks;

2. Day rooms;

3. Unit areas;

4. Transient personnel housing; or

5. Other areas where the installation commander has prohibited solicitation;

(e) Soliciting the sale of life insurance without first obtaining permission from the installation commander or the commander's designee;

(f) Posting unauthorized bulletins, notices, or advertisements;

(g) Failing to present Department of Defense Form 2885, "Personal Commercial Solicitation Evaluation," to service members solicited or encouraging service members solicited not to complete or submit a Department of Defense Form 2885; or

(h) Knowingly accepting an application for life insurance or issuing a policy of life insurance on the life of an enlisted member of the United States Armed Forces without first obtaining for the insurer's files a completed copy of a required form which confirms that the applicant has received counseling or fulfilled any other similar requirement for the sale of life insurance established by regulations, directives or rules of the Department of Defense or any branch of the Armed Forces.

(2) The following acts or practices if committed on a military installation by an insurer or insurance producer constitute corrupt practices, improper influences, or inducements and shall be false, misleading, deceptive, or unfair:

(a) Using Department of Defense personnel, directly or indirectly, as a representative or agent in any official or business capacity with or without compensation with respect to the solicitation or sale of life insurance to service members; and

(b) Using an insurance producer to participate in any United States Armed Forces sponsored education or orientation program.

Section 5. Practices Declared False, Misleading, Deceptive, or Unfair Regardless of Location.

(1) The following acts or practices by an insurer or insurance producer constitute corrupt practices, improper influences, or inducements and shall be false, misleading, deceptive, or unfair:

(a)1. Submitting, processing, or assisting in the submission or processing of any allotment form or similar device used by the United States Armed Forces to direct a service member's pay to a third party for the purchase of life insurance including using or assisting in using a service member's "MyPay" account or other similar internet or electronic medium for those purposes;

2. This subsection does not prohibit assisting a service member by providing insurer or premium information necessary to complete an allotment form;

(b)1. Knowingly receiving funds from a service member for the payment of premium from a depository institution with which the service member does not have a formal banking relationship;

2. For purposes of this section, a formal banking relationship is established if the depository institution:

a. Provides the service member a deposit agreement and periodic statements and makes the disclosures required by the Truth in Savings Act, 12 U.S.C. 4301 <u>*et seq.*</u> and 12 C.F.R. 205, 230, and 707; and

b. Permits the service member to make deposits and withdrawals unrelated to the payment or processing of insurance premiums;

(c) Employing a device or method or entering into an agreement if funds received from a service member by allotment for the payment of insurance premiums are identified on the service member's leave and earnings statement or equivalent or successor form as "savings" or "checking" and where the service member has no formal banking relationship;

(d) Entering into any agreement with a depository institution for the purpose of receiving funds from a service member if the depository institution, with or without compensation, agrees to accept direct deposits from a service member with whom it has no formal banking relationship;

(e) Using Department of Defense personnel, directly or indirectly, as a representative or agent in an official or unofficial capacity with or without compensation with respect to the solicitation or sale of life insurance to service members who are junior in rank or grade, or to the family members of such personnel;

(f) Offering or giving anything of value, directly or indirectly, to Department of Defense personnel to procure their assistance in encouraging, assisting, or facilitating the solicitation or sale of life insurance to another service member;

(g) Knowingly offering or giving anything of value to a service member for the member's attendance at any event where an application for life insurance is solicited; or

(h) Advising a service member to change the member's income tax withholding or state of legal residence for the sole purpose of increasing disposable income to purchase life insurance.

(2) The following acts or practices by an insurer or insurance producer lead to confusion regarding source, sponsorship, approval, or affiliation and shall be false, misleading, deceptive, or unfair:

(a)1. Making any representation, or using any device, title, descriptive name or identifier that has the tendency or capacity to confuse or mislead a service member into believing that the insurer, insurance producer, or product offered is affiliated, connected or associated with, endorsed, sponsored, sanctioned, or recommended by the U.S. Government, the United States Armed Forces, or any state or federal agency or government entity;

2. This section shall not be construed to prohibit a person from using a professional designation awarded after the successful completion of a course of instruction in the business of insurance by an accredited institution of higher learning; or

(b) Soliciting the purchase of any life insurance product through the use of or in conjunction with a third party organization that promotes the welfare of or assists members of the United States Armed Forces in a manner that has the tendency or capacity to confuse or mislead a service member into believing that either the insurer, insurance producer, or insurance product is affiliated, connected or associated with, endorsed, sponsored, sanctioned or recommended by the U.S. Government or the United States Armed Forces.

(3) The following acts or practices by an insurer or insurance producer lead to confusion regarding premiums, costs, or investment returns and shall be false, misleading, deceptive, or unfair:

(a) Using or describing the credited interest rate on a life insurance policy in a manner that implies that the credited interest rate is a net return on premium paid; or

(b) Excluding individually issued annuities, misrepresenting the mortality costs of a life insurance product, including stating or implying that the product "costs nothing" or is "free."

(4) The following acts or practices by an insurer or insurance producer regarding SGLI or VGLI shall be false, misleading, deceptive, or unfair:

(a) Making any representation regarding the availability, suitability, amount, cost, exclusions or limitations to coverage provided to a service member or dependents by SGLI or VGLI, which is false, misleading, or deceptive;

(b) Making any representation regarding conversion requirements, including the costs of coverage, or exclusions or limitations to coverage of SGLI or VGLI to private insurers which is false, misleading, or deceptive; or

(c) Suggesting, recommending, or encouraging a service member to cancel or terminate his or her SGLI policy or issuing a life insurance policy which replaces an existing SGLI policy unless the replacement shall take effect upon or after the service member's separation from the United States Armed Forces.

(5) The following acts or practices by an insurer or insurance producer regarding disclosure shall be false, misleading, deceptive, or unfair:

(a) Deploying, using, or contracting for a lead generating material designed exclusively for use with service members that does not clearly and conspicuously disclose that the recipient will be contacted by an insurance producer, if that is the case, for the purpose of soliciting the purchase of life insurance;

(b) Failing to disclose that a solicitation for the sale of life insurance will be made if establishing a specific appointment for an in-person, face-to-face meeting with a prospective purchaser;

(c) Excluding individually issued annuities, failing to clearly and conspicuously disclose the fact that the product being sold is life insurance;

(d) Failing to make, at the time of sale or offer to an individual known to be a service member, the written disclosures required by Section 10 of the "Military Personnel Financial Services Protection Act," Pub. L. No. 109-290, p.16; or

(e) Excluding individually issued annuities, if the sale is conducted in-person face-to-face with an individual known to be a service member, failing to provide the applicant if the application is taken:

1. An explanation of a free look period with instructions on how to cancel if a policy is issued; and

2.a. A copy of the application; or

b.(i) A written disclosure.

(ii) The copy of the application or the written disclosure shall set out the type of life insurance and the death benefit applied for and <u>the policy or benefit [its]</u> expected first year cost. A basic illustration that meets the requirements of 806 KAR 12:140 shall be sufficient to meet this requirement for a written disclosure.

(6) The following acts or practices by an insurer or insurance producer with respect to the sale of certain life insurance products shall be false, misleading, deceptive, or unfair:

(a) Excluding individually issued annuities, recommending the purchase of any life insurance product which includes a side fund to a service member unless the insurer has reasonable grounds for believing that the life insurance death benefit, standing alone, is suitable;

(b) Offering for sale or selling a life insurance product which includes a side fund to a service member who is:

1. Currently enrolled in SGLI; and

2. Presumed unsuitable unless, after the completion of a needs assessment, the insurer demonstrates that the applicant's SGLI death benefit, together with any other military survivor benefits, savings and investments, survivor income, and other life insurance are insufficient to meet the applicant's insurable needs for life insurance;

(c) Excluding individually issued annuities, offering for sale or selling a life insurance contract that includes a side fund:

1. Unless interest credited accrues from the date of deposit to the date of withdrawal and permits withdrawals without limit or penalty;

2. Unless the applicant has been provided with a schedule of effective rates of return based upon cash flows of the combined product.

a. The effective rate of return shall consider all premiums and cash contributions made by the policyholder and all cash accumulations and cash surrender values available to the policyholder in addition to life insurance coverage.

b. The schedule shall be provided for at least each policy year from one (1) to ten (10) and for every subsequent fifth policy year ending at age 100, policy maturity, or final expiration; and

3. That by default diverts or transfers funds accumulated in the side fund to pay, reduce, or offset any premiums due; or

(d) Excluding individually issued annuities, offering for sale or selling a life insurance contract that after considering all policy benefits, does not comply with KRS 304.15-310.

Section 6. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Department of Defense Instruction Number 1344.07, Personal Commercial Solicitation on DoD Installations", (March 30, 2006); and

(b) "Department of Defense Form 2885, Personal Commercial Solicitation Evaluation", (April 2006).

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department of Insurance, <u>Mayo-Underwood Building, 500 Mero Street [215 West Main Street]</u>, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. <u>This material is also available on the department's website at: http://insurance.ky.gov.</u>

SHARON P. CLARK, Commissioner

KERRY B. HARVEY, Secretary

APPROVED BY AGENCY: October 12, 2020 FILED WITH LRC: October 13, 2020 at 10:12 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held at 9:00 AM on December 21, 2020 at 500 Mero Street, Frankfort, Kentucky 40602. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through 11:59 PM on December 31, 2020. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

CONTACT PERSON: DJ Wasson, Deputy Commissioner, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 564-6026, fax +1 (502) 564-1453, email dj.wasson@ky.gov

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: DJ Wasson

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes standards to protect active duty service members of the United State Armed Forces from dishonest and predatory insurance sales practices by declaring certain identified practices to be false, misleading, deceptive and unfair.

(b) The necessity of this administrative regulation: 10 U.S.C. 992 sec. 9(a)(2) requires the states to collectively work with the Secretary of Defense to ensure implementation of appropriate standards to protect members of the Armed Forces from dishonest and predatory insurance sales practices while on a military installation of the United States, and further requires each state to identify its role in promoting the standards in a uniform manner, not later than twelve (12) months after the date of enactment of the federal law. Additionally, the Kentucky Department of Insurance has investigated complaints about improper sales of insurance on military bases. The standards set forth in this administrative regulation are necessary to protect the service members serving on military installations in Kentucky.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.2-110 authorizes the Commissioner of the Department of Insurance to make reasonable rules and regulations necessary for the effectuation of any provision of the Kentucky Insurance Code. 10 U.S.C. 992 sec 9(a)(2) requires the states to collectively work with the Secretary of Defense to ensure implementation of appropriate standards to protect members of the Armed Forces from dishonest and predatory insurance sales practices while on a military installation of the United States, and further requires each state to identify its role in promoting the standards in a uniform manner, not later than twelve (12) months after the date of enactment of the federal law. This administrative regulation will define specific practices that are false, misleading and deceptive in the sale of life insurance and annuities on military installations.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes appropriate uniform standards for the sale of life insurance and annuities to service members on military installations. It further specifies practices that will be considered false, misleading or deceptive. This administrative regulation is based on the National Association of Insurance Commissioners Model Regulation.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

(b) The necessity of the amendment to this administrative regulation: The amendments made are necessary to meet the requirements of KRS Chapter 13A, as well as to remove the Emergency Order no longer in effect.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 304.2-110 provides that the Commissioner of Insurance shall make reasonable rules and regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code.

(d) How the amendment will assist in the effective administration of the statutes:

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This regulation will affect the approximately 449 insurers that are licensed to offer life insurance in Kentucky, and the approximately 70,348 insurance agents that are licensed to sell life insurance in Kentucky.

(4) Provide an analysis of how the entities identified in the previous question will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions each of the regulated entities have to take to comply with this regulation or amendment: Regulated entities will be required to sell life insurance and annuities on military installations in accordance with the guidelines set forth in this administrative regulation. The amendments to this administrative regulation are technical in nature to conform to KRS 13A requirements and will not change current practices.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: As the amendments to this administrative regulation are technical to comply with KRS 13A, there will not be any cost to the entities.

(c) As a result of compliance, what benefits will accrue to the entities: Compliance with this administrative regulation will allow insurers to use advertising materials publically. The amendments to this administrative regulation are technical only and will not require additional implementation by the regulated entities.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: Implementation of this amendment is not anticipated to have an initial cost on the Department of Insurance.

(b) On a continuing basis: Implementation of this amendment is not anticipated to have an on-going cost on the Department of Insurance.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Department will use funds from its current operational budget to perform the tasks necessary.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase of fees will not be necessary because additional personnel is likely unnecessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not directly establish any new fees.

(9) TIERING: Is tiering applied? Tiering is not applied.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Department of Insurance will be impacted as the implementer of the regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 304.2-110, 304.12-257, 10 U.S.C. 992(9)(a)(2)

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation is not expected to generate any revenue in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation is not expected to generate any revenue in subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not have a cost to implement in the first year.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not have a cost to administer subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Neutral

Expenditures (+/-): Neutral

Other Explanation: As the amendments to this administrative regulation are technical amendments to comply with KRS 13A, this administrative regulation will not have a fiscal impact on the Department of Insurance.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate. The federal statute requiring promulgation of this administrative regulation is Pub. L. 109-290, the Military Personnel Financial Services Protection Act.

(2) State compliance standards. The federal Military Personnel Financial Services Protection Act requires states to collectively work with the Secretary of Defense to implement appropriate military personnel protection standards regarding dishonest and predatory insurance sales practices on U.S. military installations, including those abroad. Each state must identify its role in promoting these standards in a uniform manner no later than September 29, 2007

(3) Minimum or uniform standards contained in the federal mandate. The states, through the National Association of Insurance Commissioners (NAIC), worked with the Department of Defense to develop minimum standards. These standards were adopted in the NAIC Military Sales Practices Model Regulation.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation imposes the following requirements in addition to the federal mandate:

The federal mandate is limited to the development of standards to protect service members from dishonest and predatory insurance sales practices occurring on military installations. However, the model includes practices that occur off base as well. This expansion was based on the NAIC Working Group's research which found that many of the more egregious practices were not confined to the military reservation, such as solicitations in agents' offices or young trainees being invited to "pizza parties" where insurance was solicited. The Department of Defense fully supports this expansion of the scope of the federal mandate.

The NAIC model regulation limited the suitability requirements

to specific pay grades. This administrative regulation requires the suitability standards for all service members, regardless of pay grade.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

With regard to the expansion of the scope of the administrative regulation, the expansion was based on the NAIC Working Group's research which found that many of the more egregious practices were not confined to the military reservation, such as solicitations in agents' offices or young trainees being invited to "pizza parties" where insurance was solicited. The Department of Defense fully supports this expansion of the scope of the federal mandate.

The decision to expand the application of suitability standards was based on Kentucky-specific investigations. Prior to the federal legislation, the Department of Insurance participated in investigations of predatory practices in the sale of life insurance on the military bases in Kentucky. Those investigations did not reveal that the predatory practices were limited to service members in specific pay grades. Therefore, the Department of Insurance believes that all service members deserve this protection.

PUBLIC PROTECTION CABINET Department of Insurance Consumer Protection Division (Amendment)

806 KAR 13:020. Excess rates; consent form.

RELATES TO: KRS <u>304.1-010, 304.13-051,</u> 304.13-100 STATUTORY AUTHORITY: KRS 304.2-110

NECESSITY, FUNCTION, AND CONFORMITY: <u>KRS 304.2-110</u> authorizes the Commissioner of Insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code as defined in KRS 304.1-010. [KRS 304.2-110 provides that the Executive Director of Insurance may make reasonable rules and administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code.] This administrative regulation requires an insurer and applicant to file a form <u>confirming</u> [showing] applicant's consent to the, if any, excess rate charged to him.

Section 1. (1) For rates required to be filed with the department in accordance with KRS 304.13-051, when [When] an insurer and an applicant for insurance contemplated by KRS Chapter 304, Subtitle 13, consent to rates to be charged in any specific instance in excess of those filed by or on behalf of <u>the</u> [such] insurer, the insurer shall, within ten (10) days following the effective date of the policy, file with the <u>commissioner</u> [executive director in triplicate] a <u>statement</u> [writing] signed by the applicant which shall <u>include</u> [recite] the following:

(a) [(1)] The policy number;

(b) [(2)] The inception and expiration dates;

(c) [(3)] The name and address of the agent of record;

(d) [(4)] The name of the insurer;

(e) [(5)] The name and address of the insured;

(f) [(6)] The limits of coverage;

(g) [(7)] The total premium charged;

(h) [(8)] The fact that the rate exceeds [exceed] the filed rate;

(i) [(9)] The reasons that the rate exceeds the filed rate [therefor]; and

(j) [(10)] That the insured has consented to the excess rate [thereto].

(2) For rates not required to be filed with the department pursuant to KRS 304.13-051, when an insurer and an applicant for insurance contemplated by KRS Chapter 304, Subtitle 13, consent to rates to be charged in any specific instance in excess of those utilized by the insurer, the insurer shall prepare a statement signed by the applicant which shall include the information required by subsection (1)(a) through (1)(j) of this subsection. The insurer shall not be required to file the statement with the department. Section 2. A copy of <u>the</u> [such] consent to rate <u>statement</u> required by <u>Section 1 of this administrative regulation</u> shall be <u>submitted</u> [furnished] to the insured.

Section 3. The <u>commissioner</u> [executive director] shall <u>approve</u> <u>or deny the consent</u> [take such action as he deems appropriate, as in the case of all rates filed], and shall return to the agent and to the insurer, one (1) copy of <u>the</u> [such] consent, <u>indicating the action</u> <u>taken</u> [with his action indicated thereon].

SHARON P. CLARK, Commissioner

KERRY B. HARVEY, Secretary

APPROVED BY AGENCY: October 12, 2020 FILED WITH LRC: October 13, 2020 at 10:09 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held at 9:00 AM on December 21, 2020 at 500 Mero Street, Frankfort, Kentucky 40602. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through 11:59 PM on December 31, 2020. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

CONTACT PERSON: DJ Wasson, Deputy Commissioner, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 564-6026, fax +1 (502) 564-1453, email dj.wasson@ky.gov

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: DJ Wasson

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation requires an insurer and applicant to file a form showing applicant's consent to the, if any, excess rate charged to him.

(b) The necessity of this administrative regulation: This necessity of this administrative regulation is to have proof of insurer's and applicant's consent if there is any excess rate charged.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.2-110 provides that the Commissioner of Insurance may make reasonable rules and administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will set forth the process and format for applicant's and insurers to disclose written consent to the department of excess rate charged to him.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments is not requiring insurer or applicant to file a statement of consent to the department for rates not required to be filed with the department pursuant to KRS 304.13-051. This amendment also cleans up language and formatting as required in Chapter 13A.

(b) The necessity of the amendment to this administrative regulation: This necessity of this amendment to this administrative regulation is to differentiate when and if an insurer of applicant has to file a statement of consent for rates required in KRS 304.13-051 with the department and to meet Chapter 13A requirements.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 304.2-110 provides that the Commissioner of Insurance may make reasonable rules and

administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code.

(d) How the amendment will assist in the effective administration of the statutes: The amendments to this administrative regulation are to up date old procedures to ensure that the filing of consent or rate change are filed properly. The amendments of this regulation are also to meet Chapter 13A requirements.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation will affect all insurers or insurance applicants that will be charged excess rates, if necessary, pursuant to KRS 304.13-051.

(4) Provide an analysis of how the entities identified in the previous question will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions each of the regulated entities have to take to comply with this regulation or amendment: Regulated entities will be required to adhere to the standards in this regulation in order to properly report consent of excess rates charged.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: There will be no cost to either entity.

(c) As a result of compliance, what benefits will accrue to the entities: As a result of compliance, regulated entities will be properly reporting consent disclosures to the department.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: Implementation of this amendment is not anticipated to have an initial cost on the Department of Insurance.

(b) On a continuing basis: Implementation of this amendment is not anticipated to have an on-going cost on the Department of Insurance.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Department will use funds from its current operational budget to perform the tasks necessary.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase of fees will not be necessary because additional personnel is likely unnecessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not directly establish any new fees.

(9) TIERING: Is tiering applied? Tiering is not applied.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The department as the implementer.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 304.2-110

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation is not expected to generate any revenue in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation is not expected to generate any revenue in subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not have a cost to implement in the first year.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not have a cost to administer subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Neutral

Expenditures (+/-): Neutral

Other Explanation: As the amendments to this administrative regulation clarify an existing process, this administrative regulation will not have a fiscal impact on the Department of Insurance.

PUBLIC PROTECTION CABINET Department of Insurance Financial Standards and Examination Division (Amendment)

806 KAR 38:100. Risk-based capital for health organizations.

RELATES TO: KRS 304.2-150, 304.2-250(3), 304.2-260, 304.2-270, 304.32-140, 304.38-070, 304.38A-080, 304.38A-110

STATUTORY AUTHORITY: KRS 304.32-140(1), 304.38-070, 304.38A-080, 304.38-150, 304.38A-110(2)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.38-150 authorizes the Commissioner of the Kentucky Department of Insurance to promulgate administrative regulations necessary for the proper administration of KRS [Chapter] 304.38. KRS 304.32-140(1), 304.38-070, 304.38A-080, and 304.38A-110(2) require the Commissioner of the Kentucky Department of Insurance to promulgate administrative regulations establishing requirements for risk-based capital. KRS 304.38-150 provides that the Commissioner of Insurance may make reasonable administrative regulations necessary for the proper administration of KRS 304 [Chapter 30]. [Subtitle] 38. This administrative regulation establishes requirements for health maintenance organizations, limited health service corporations, and nonprofit health service corporations to comply with risk-based capital reporting requirements to aid in the department's financial monitoring.

Section 1. Definitions. (1) "Adjusted RBC report" means an RBC report which has been adjusted by the commissioner in accordance with Section 2(5) of this administrative regulation.

(2) "Authorized control level event" means any of the following events:

(a) The filing of an RBC report by the health organization that indicates that the health organization's total adjusted capital is greater than or equal to its Mandatory Control Level RBC but less than its Authorized Control Level RBC;

(b) The notification by the commissioner to the health organization of an adjusted RBC report that indicates the event in paragraph (a) of this subsection, if the health organization does not challenge the adjusted RBC report under Section 7 of this administrative regulation;

(c) If, pursuant to Section 7 of this administrative regulation, the health organization challenges an adjusted RBC report that indicates the event in paragraph (a) of this subsection, notification by the commissioner to the health organization that the commissioner has, after a hearing, rejected the health organization's challenge;

(d) The failure of the health organization to respond to a corrective order, if the health organization has not challenged the corrective order under Section 7 of this administrative regulation; or

(e) If the health organization has challenged a corrective order under Section 7 of this administrative regulation and the commissioner has, after a hearing, rejected the challenge or modified the corrective order, the failure of the health organization to respond to the corrective order subsequent to rejection or modification by the commissioner.

(3) "Commissioner" is <u>established[defined]</u> by KRS 304.1-050(1).

(4) "Company action level event" means any of the following events:

(a) The filing of an RBC report by a health organization that indicates that the health organization's total adjusted capital is greater than or equal to its Regulatory Action Level RBC but less than its Company Action Level RBC;

(b) Notification by the commissioner to the health organization of an adjusted RBC report that indicates an event in paragraph (a) of this subsection, if the health organization does not challenge the adjusted RBC report under Section 7 of this administrative regulation; [or]

(c) Pursuant to Section 7 of this administrative regulation, if a health organization challenges an adjusted RBC report that indicates the event in paragraph (a) of this subsection, the notification by the commissioner to the health organization that the commissioner has, after a hearing, rejected the health organization's challenge; or[.]

(d) A health maintenance organization that has total adjusted capital which is greater than or equal to its Company Action Level RBC but less than the product of its Authorized Control Level RBC and 3.0 and triggers the trend test determined in accordance with the trend test calculation included in the NAIC 2019 Risk-Based Capital Forecasting & Instructions, Health.

(5) "Corrective order" means an order issued by the commissioner specifying corrective actions which the commissioner has determined are required, under the provisions of this administrative regulation.

(6) "Department" is defined by KRS 304.1-050(2).

(7) "Domestic health organization" means a health organization domiciled in this state.

(8) "Foreign health organization" means a health organization that is licensed to do business in this state under KRS Chapter 304. [Subtitle] 38, _38A or _32 but is not domiciled in this state.

(9) "Health organization" means a health maintenance organization, limited health service organization, dental or vision plan, hospital, medical and dental indemnity or service corporation or other managed care organization licensed under KRS Chapter 304 Subtitle 38, 38A, or 32, except for an organization that is licensed as either a life and health insurer or a property and casualty insurer under KRS Chapter 304 Subtitle 24 or 3 and that is otherwise subject to either the life or property and casualty RBC requirements.

(10) "Mandatory control level event" means any of the following events:

(a) The filing of an RBC report which indicates that the health organization's total adjusted capital is less than its Mandatory Control Level RBC;

(b) Notification by the commissioner to the health organization of an adjusted RBC report that indicates the event in paragraph (a) of this subsection, if the health organization does not challenge the adjusted RBC report under Section 7 of this administrative regulation; or

(c) Pursuant to Section 7 of this administrative regulation, the health organization challenges an adjusted RBC report that indicates the event in paragraph (a) of this subsection, notification by the commissioner to the health organization that the executive director has, after a hearing, rejected the health organization's challenge.

(11) "NAIC" means the National Association of Insurance Commissioners.

(12) "RBC" means risk-based capital.

(13) "RBC instructions" means the RBC report including riskbased capital instructions adopted by the NAIC, as these RBC instructions may be amended by the NAIC from time to time in accordance with the procedures adopted by the NAIC.

(14) "RBC level" means a health organization's company action level RBC, regulatory action level RBC, authorized control level RBC, or mandatory control level RBC where:

(a) "Company Action Level RBC" means, with respect to any

health organization, the product of 2.0 and its Authorized Control Level RBC;

(b) "Regulatory Action Level RBC" means the product of one and five-tenths (1.5) and its Authorized Control Level RBC;

(c) "Authorized Control Level RBC" means the number determined under the risk-based capital formula in accordance with the RBC instructions; and

(d) "Mandatory Control Level RBC" means the product of 70 and the Authorized Control Level RBC.

(15) "RBC plan" means a comprehensive financial plan containing the elements specified in Section 3(2) of this administrative regulation.

(16) "RBC report" means the report required in Section 2 of this administrative regulation.

(17) "Regulatory action level event" means, with respect to a health organization, any of the following events:

(a) The filing of an RBC report by the health organization that indicates that the health organization's total adjusted capital is greater than or equal to its Authorized Control Level RBC but less than its Regulatory Action Level RBC;

(b) Notification by the commissioner to a health organization of an adjusted RBC report that indicates the event in paragraph (a) of this subsection, provided the health organization does not challenge the adjusted RBC report under Section 7 of this administrative regulation;

(c) If, pursuant to Section 7 of this administrative regulation, the health organization challenges an adjusted RBC report that indicates the event in paragraph (a) of this subsection, the notification by the commissioner to the health organization that the commissioner has, after a hearing, rejected the health organization's challenge;

(d) The failure of the health organization to file an RBC report by the filing date, unless the health organization has provided an explanation for the failure and has cured the failure within ten (10) days after the filing date;

(e) The failure of the health organization to submit an RBC plan to the commissioner within the time period set forth in Section 3(3) of this administrative regulation;

(f) Notification by the commissioner to the health organization that:

1. The RBC plan or revised RBC plan submitted by the health organization is unsatisfactory; and

2. Notification constitutes a regulatory action level event with respect to the health organization, if the health organization has not challenged the determination under Section 7 of this administrative regulation;

(g) If, pursuant to Section 7 of this administrative regulation, the health organization challenges a determination by the commissioner under this paragraph, the notification by the commissioner to the health organization that the commissioner has, after a hearing, rejected the challenge;

(h) Notification by the commissioner to the health organization that the health organization has failed to adhere to its RBC plan or revised RBC plan, but only if the failure has a substantial adverse effect on the ability of the health organization to eliminate the company action level event in accordance with its RBC plan or revised RBC plan and the commissioner has so stated in the notification, if the health organization has not challenged the determination under Section 7 of this administrative regulation; or

(i) If, pursuant to Section 7 of this administrative regulation, the health organization challenges a determination by the commissioner under this paragraph, the notification by the commissioner to the health organization that the commissioner has, after a hearing, rejected the challenge.

(18) "Revised RBC plan" means an RBC plan that:

(a) Was rejected by the commissioner; and

(b) Was revised by the health organization, with or without the commissioner's recommendation.

(19) "Total adjusted capital" means the sum of:

(a) A health organization's statutory capital and surplus (i.e., net worth) as determined in accordance with the statutory accounting applicable to the annual financial statements required to be filed under KRS 304.3-240 or 304.32-090; and

(b) Other items, if any, as the RBC instructions may provide.

Section 2. RBC Reports. (1) A domestic health organization shall, on or prior to each March 1 (the "filing date"), prepare and submit to the commissioner a report of its RBC levels as of the end of the calendar year just ended, in the "NAIC 2019 Risk-Based Capital Forecasting & Instructions Health" [2013 NAIC Health Risk-Based Capital Report Including Overview and Instructions for Companies]. In addition, a domestic health organization shall file its RBC report:

(a) With the NAIC in accordance with the RBC instructions; and

(b) With the insurance commissioner in any state in which the health organization is authorized to do business, if the insurance commissioner has notified the health organization of its request in writing, in which case the health organization shall file its RBC report not later than the later of:

1. Fifteen (15) days from the receipt of notice to file its RBC report with that state; or

2. The filing date.

(2) A health organization's RBC shall be determined in accordance with the formula set forth in the RBC instructions. The formula shall take the following into account, and may adjust for the covariance between, determined in each case by applying the factors in the manner set forth in the RBC instructions:

(a) Asset risk;

(b) Credit risk;

(c) Underwriting risk; and

(d) All other business and relevant risks as are set forth in the RBC instructions.

(3) If a domestic health organization files an RBC report that in the judgment of the commissioner is inaccurate, then the commissioner shall adjust the RBC report to correct the inaccuracy and shall notify the health organization of the adjustment. The notice shall contain a statement of the reason for the adjustment. An RBC report as so adjusted is referred to as an "adjusted RBC report".

Section 3. Company Action Level Event. (1) If a company action level event occurs, the health organization shall prepare and submit to the commissioner an RBC plan that shall:

(a) Identify the conditions that contribute to the company action level event;

(b) Contain proposals of corrective actions that the health organization intends to take and that would be expected to result in the elimination of the company action level event;

(c) Provide projections of the health organization's financial results in the current year and at least the two (2) succeeding years, both in the absence of proposed corrective actions and giving effect to the proposed corrective actions, including projections of statutory balance sheets, operating income, net income, capital and surplus, and RBC levels. The projections for both new and renewal business may include separate projections for each major line of business and separately identify each significant income, expense and benefit component;

(d) Identify the key assumptions impacting the health organization's projections and the sensitivity of the projections to the assumptions; and

(e) Identify the quality of, and problems associated with, the health organization's business, including its assets, anticipated business growth and associated surplus strain, extraordinary exposure to risk, mix of business and use of reinsurance, if any, in each case.

(2) The RBC plan shall be submitted

(a) Within forty-five (45) days of the company action level event; or

(b) If the health organization challenges an adjusted RBC report pursuant to Section 7 of this administrative regulation, within forty-five (45) days after notification to the health organization that the commissioner has, after a hearing, rejected the health organization's challenge.

(3) Within sixty (60) days after the submission by a health organization of an RBC plan to the commissioner, the

commissioner shall notify the health organization whether the RBC plan shall be implemented or is unsatisfactory. If the commissioner determines the RBC plan is unsatisfactory, the notification to the health organization shall set forth the reasons for the determination, and may set forth proposed revisions which will render the RBC plan satisfactory. Upon notification from the commissioner, the health organization shall prepare a revised RBC plan, which may incorporate by reference any revisions proposed by the commissioner, and shall submit the revised RBC plan to the commissioner:

(a) Within forty-five (45) days after the notification from the commissioner; or

(b) If the health organization challenges the notification from the commissioner under Section 7 of this administrative regulation, within forty-five (45) days after a notification to the health organization that the commissioner has, after a hearing, rejected the health organization's challenge.

(4) If the commissioner notifies a health organization that the health organization's RBC plan or revised RBC plan is unsatisfactory, the commissioner may, subject to the health organization's right to a hearing under Section 7 of this administrative regulation, specify in the notification that the notification constitutes a regulatory action level event.

(5) Every domestic health organization that files an RBC plan or revised RBC plan with the commissioner shall file a copy of the RBC plan or revised RBC plan with the insurance commissioner in any state in which the health organization is authorized to do business if:

(a) The state has an RBC provision substantially similar to Section 8(1) of this administrative regulation; and

(b) The insurance commissioner of that state has notified the health organization of its request for the filing in writing, in which case the health organization shall file a copy of the RBC plan or revised RBC plan in that state no later than the later of:

1. Fifteen (15) days after the receipt of notice to file a copy of its RBC plan or revised RBC plan with the state; or

2. The date on which the RBC plan or revised RBC plan is filed under subsections (3) and (4) of this section.

Section 4. Regulatory Action Level Event. (1) If a regulatory action level event occurs, the commissioner shall:

(a) Require the health organization to prepare and submit an RBC plan or, if applicable, a revised RBC plan;

(b) Perform an examination or analysis of the assets, liabilities, and operations of the health organization including a review of its RBC plan or revised RBC plan; and

(c) Subsequent to the examination or analysis, issue an order specifying corrective actions as the commissioner shall determine are required.

(2) In determining corrective actions, the commissioner may take into account relevant factors with respect to the health organization, based upon the commissioner's examination or analysis of the assets, liabilities, and operations of the health organization, including the results of any sensitivity tests undertaken pursuant to the RBC instructions. The RBC plan or revised RBC plan shall be submitted:

(a) Within forty-five (45) days after the occurrence of the regulatory action level event;

(b) If the health organization challenges an adjusted RBC report pursuant to Section 7 of this administrative regulation and the challenge is made in good faith within forty-five (45) days after the notification to the health organization that the commissioner has, after a hearing, rejected the health organization's challenge; or

(c) If the health organization challenges a revised RBC plan pursuant to Section 7 of this administrative regulation and the challenge is made in good faith, within forty-five (45) days after the notification to the health organization that the commissioner has, after a hearing, rejected the health organization's challenge.

(3) The commissioner may retain actuaries and investment experts and other consultants as may be necessary to review the health organization's RBC plan or revised RBC plan, examine or analyze the assets, liabilities, and operations, including contractual relationships, of the health organization and formulate the corrective order with respect to the health organization. The fees, costs, and expenses relating to consultants shall be borne by the affected health organization or other party as directed by the commissioner.

Section 5. Authorized Control Level Event. If an authorized control level event occurs with respect to a health organization, the commissioner shall:

(1) Take action as required under Section 4 of this administrative regulation regarding a health organization with respect to which an regulatory action level event has occurred; or

(2) If the commissioner determines it to be in the best interests of the policyholders and creditors of the health organization and of the public, take action as necessary to cause the health organization to be placed under regulatory control under KRS Chapter 304 Subtitle 33. If the commissioner takes action, the authorized control level event shall be sufficient grounds for the commissioner to take action under KRS Chapter 304 Subtitle 33, and the commissioner shall have the rights, powers, and duties with respect to the health organization as are set forth in KRS Chapter 304 Subtitle 33. If the commissioner takes actions under this paragraph pursuant to an adjusted RBC report, the health organization shall be entitled to protections as are afforded to health organizations under the provisions of Section KRS 304.33-130 pertaining to summary proceedings.

Section 6. Mandatory Control Level Event. (1) If a mandatory control level event occurs, the commissioner shall take action as necessary to place the health organization under regulatory control under KRS Chapter 304 Subtitle 33. The mandatory control level event shall be sufficient grounds for the commissioner to take action under KRS Chapter 304 Subtitle 33, and the commissioner shall have the rights, powers, and duties with respect to the health organization as are set forth in KRS Chapter 304 Subtitle 33.

(2) If the commissioner takes actions pursuant to an adjusted RBC report, the health organization shall be entitled to the protections of Section KRS 304.33-130 pertaining to summary proceedings.

(3) The commissioner may forego action for up to ninety (90) days after the mandatory control level event if the commissioner finds there is a reasonable expectation that the mandatory control level event may be eliminated within the ninety (90) day period.

Section 7. Hearings. Upon the occurrence of any of the following events the health organization shall have the right to a confidential departmental hearing, on a record, at which the health organization may challenge any determination or action by the commissioner. The health organization shall notify the commissioner of its request for a hearing within five (5) days after the notification by the commissioner of any of the following events:

(1) Notification to a health organization by the commissioner of an adjusted RBC report;

(2) Notification to a health organization by the commissioner that:

(a) The health organization's RBC plan or revised RBC plan is unsatisfactory; and

(b) Notification constitutes a regulatory action level event with respect to the health organization;

(3) Notification to a health organization by the commissioner that the health organization has failed to adhere to its RBC plan or revised RBC plan and that the failure has a substantial adverse effect on the ability of the health organization to eliminate the company action level event with respect to the health organization in accordance with its RBC plan or revised RBC plan; or

(4) Notification to a health organization by the commissioner of a corrective order with respect to the health organization.

Section 8. Confidentiality; Prohibition on Announcements, Prohibition on Use in Ratemaking. (1)(a) If in the possession or the control of the Department of Insurance, the following shall be confidential:

1. RBC reports, to the extent that the information is not

required to be set forth in a publicly available annual statement schedule; and

2. RBC plans, including the results or report of any examination or analysis of a health organization performed pursuant to this statute and any corrective order issued by the commissioner pursuant to examination or analysis with respect to a domestic health organization or foreign health organization.

(b) The commissioner may use the documents, materials, or other information in paragraph

(a) of this subsection, in accordance with KRS 304.2-150, 304.2-250(3), 304.2-260, and 304.2-270.

(2) In order to assist the performance of the commissioner's duties, the commissioner:

(a) May share documents, materials, or other information obtained under this administrative regulation, in accordance with KRS 304.2-150, 304.2-250(3), 304.2-260(5), and 304.2-270;

(b) May receive documents, materials, or information, including otherwise confidential and privileged documents, materials, or information, from the NAIC and its affiliates and subsidiaries, and from regulatory and law enforcement officials of other foreign or domestic jurisdictions, and shall maintain as confidential or privileged any document, material, or information received with notice or the understanding that it is confidential or privileged under the laws of the jurisdiction that is the source of the document, material, or information; and

(c) May enter into agreements governing sharing and use of information consistent with this section.

(3)(a) Except as otherwise required or authorized under the provisions of this administrative regulation, a health organization, agent, broker, or other person engaged in any manner in the insurance business shall not make an assertion, representation, or statement with regard to the RBC levels of any health organization, or any component derived in the calculation, by:

1.a. Making, publishing, disseminating, circulating, or placing before the public; or

b. Causing, directly or indirectly, to be made published, disseminated, circulated, or placed before the public; and

2. Using:

a. A newspaper, magazine, or other publication;

b. A notice, circular, pamphlet, letter, or poster;

c. A radio or television station;

d. An advertisement, announcement, or statement; or

e. Any other means which places the information before the public.

(b) A health organization may publish an announcement in a written publication:

1. If the sole purpose is to rebut:

a. A materially false statement with respect to the comparison of the health organization's total adjusted capital to its RBC levels; or

b. An inappropriate comparison of any other amount to the health organization's RBC levels;

2. If these materially false statements or inappropriate comparisons are published in a written publication; and

3. If the health organization is able to demonstrate to the commissioner, with substantial proof, the falsity or inappropriateness of the statement.

(4) The RBC instructions, RBC reports, adjusted RBC reports, RBC plans, and revised RBC plans are intended solely for use by the commissioner in monitoring the solvency of health organizations and the need for possible corrective action with respect to health organizations and shall not be used by the commissioner for ratemaking, nor considered or introduced as evidence in any rate proceeding, nor used by the commissioner to calculate or derive any elements of an appropriate premium level or rate of return for any line of insurance that a health organization or any affiliate is authorized to write.

Section 9. Supplemental Provisions; Rules; Exemption. (1) The provisions of this administrative regulation are supplemental to any other provisions of the laws of this state, and shall not preclude or limit any other powers or duties of the commissioner under the law, including KRS Chapter 304 Subtitles 32, 33, 37 or 38, 304.2-065 or

806 KAR 3:150.

(2) The commissioner may exempt from the application of this administrative regulation a domestic health organization that:

(a) Writes direct business only in this state;(b) Assumes no reinsurance in excess of five (5) percent of direct premium written; and

(c) Writes direct annual premiums for comprehensive medical business of \$2,000,000 or less or is a limited health service organization that covers less than 2,000 lives.

Section 10. Foreign Health Organizations. (1)(a) A foreign health organization shall, upon the written request of the commissioner, submit to the commissioner an RBC report as of the end of the calendar year just ended the later of:

1. The date an RBC report would be required to be filed by a domestic health organization under this administrative regulation; or

2. Fifteen (15) days after the request is received by the foreign health organization.

(b) A foreign health organization shall, at the written request of the commissioner, promptly submit to the commissioner a copy of any RBC plan that is filed with the insurance commissioner of any other state.

(2)(a) The commissioner may require a foreign health organization to file an RBC plan if a company action level event, regulatory action level event, or authorized control level event occurs with respect to the foreign health organization:

1. As determined under the RBC statute applicable in the foreign health organization's state of domicile;

2. Under the provisions of this administrative regulation, if no RBC statute is in force in the state of domicile; or

3. If the insurance commissioner of the state of domicile fails to require the foreign health organization to file an RBC plan in the manner specified under the RBC statute of the domicile state.

(b) If the commissioner chooses to require the filing specified in paragraph (a) of this subsection, the failure of the foreign health organization to file the RBC plan shall be grounds to order the organization to cease and desist from writing new insurance business in the state of Kentucky.

(3) If a mandatory control level event occurs with respect to a foreign health organization, and no domiciliary receiver has been appointed with respect to the foreign health organization under the rehabilitation and liquidation statute applicable in the state of domicile of the foreign health organization:

(a) The commissioner may make application to the Franklin Circuit Court permitted under the KRS Chapter 304 Subtitle 33 with respect to the liquidation of property of foreign health organizations found in this state; and

(b) The occurrence of the mandatory control level event shall be considered adequate grounds for the application.

Section 11. Incorporation by Reference. (1) <u>"NAIC 2019 Risk-Based Capital Forecasting & Instructions Health" ["2013 NAIC Health Risk-Based Capital Report Including Overview and Instructions for Companies, National Association of Insurance Commissioners, 9/6/2013,] is incorporated by reference.</u>

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department of Insurance, <u>Mayo-Underwood Building, 500 Mero Street</u>, [215 West Main Street], Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

SHARON P. CLARK, Commissioner

KERRY B. HARVEY, Secretary

APPROVED BY AGENCY: October 12, 2020

FILED WITH LRC: October 13, 2020 at 10:11 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held at 9:00 AM on December 21, 2020 at 500 Mero Street, Frankfort, Kentucky 40602. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be

canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through 11:59 PM on December 31, 2020. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

CONTACT PERSON: DJ Wasson, Deputy Commissioner, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 564-6026, fax +1 (502) 564-1453, email dj.wasson@ky.gov

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: DJ Wasson

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes risk-based capital requirements for all health maintenance organizations authorized to transact insurance business in Kentucky. This regulation also sets forth the required actions to be taken by both the commissioner and the insurer if the health maintenance organization fails to meet the risk-based capital requirements.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to provide the department with the appropriate monitoring and enforcement tools to ensure the financial solvency of health maintenance organizations doing business in Kentucky.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.38-070 requires risk-based capital to be determined in accordance with the risk-based capital requirements established under KRS 304, Subtitle 38 and any administrative regulations promulgated pursuant to KRS 13A. KRS 304.38-150 provides that the Commissioner of Insurance may make reasonable administrative regulations necessary for the proper administration of KRS Chapter 304, Subtitle 38. This administrative regulation requires health maintenance organizations to comply with risk-based capital reporting requirements to aid in the department's financial monitoring of health maintenance organizations.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation sets forth the process that the department will use in monitoring solvency and the required corrective action for a health maintenance organization that does not meet the riskbased capital requirements.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment to this administrative regulation establishes the conformity with Chapter 13A formatting guidelines, updates the physical address of the department as well as the material incorporate by reference. This amendment also adds new regulatory RBC guidelines for trend tests based on the newly incorporated materials.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to provide the Department of Insurance with appropriate regulatory tools to take appropriate regulatory action against a health maintenance organization, limited service health maintenance organization and non-profit health service corporation that is exhibiting a negative trend in its financial status. The amended to this regulation was noted as a required element for the Department's financial accreditation.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 304.38-070 requires risk-based capital to be determined in accordance with the risk-based capital requirements established under KRS Chapter 304, Subtitle 38 and any administrative regulations promulgated pursuant to KRS 13A. KRS 304.38-150 provides that the Commissioner of Insurance may make reasonable administrative regulations necessary for the

proper administration of KRS Chapter 30 Subtitle 38. This administrative regulation requires the health maintenance organizations, limited health service corporations, and nonprofit health service corporations to comply with risk-based capital reporting requirements to aid in the department's financial monitoring. KRS 304.32-140(1) requires a corporation subject to the requirements of KRS 304, Subtitle 32 to comply with the risk-based capital requirements as established in administrative regulations promulgated by the commissioner.

(d) How the amendment will assist in the effective administration of the statutes: This amendment sets forth the process that the department will use in monitoring solvency of a health maintenance organizations, limited service health benefit plans and non-profit health service corporation

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Approximately 25 regulated entities will be impacted by this administrative regulation.

(4) Provide an analysis of how the entities identified in the previous question will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions each of the regulated entities have to take to comply with this regulation or amendment: Regulated entities are responsible for maintaining capital and surplus in accordance with the requirements set forth in this administrative regulation. Should a regulated entity fail to maintain the capital and surplus required by this administrative regulation, the entity is responsible for following the corrective action set forth in this administrative regulation

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: Regulated entities have been complying with these requirements for numerous years. There should not be a cost for complying with the updates included in this amendment.

(c) As a result of compliance, what benefits will accrue to the entities: As a result of compliance, regulated entities will be able to fulfill their financial obligations to their insureds.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: Implementation of this amendment is not anticipated to have an initial cost on the Department of Insurance.

(b) On a continuing basis: Implementation of this amendment is not anticipated to have an on-going cost on the Department of Insurance.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Department will use funds from its current operational budget to perform the tasks necessary.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase of fees will not be necessary because additional personnel is likely unnecessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not directly establish any new fees.

(9) TIERING: Is tiering applied? Explain why or why not. Tiering is not applied.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Department of Insurance will be impacted as the implementer of the regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 304.32-140(1), 304.38-070, 304.38-150, 304.38A-110(2)

(3) Estimate the effect of this administrative regulation on the

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expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation is not expected to generate any revenue in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation is not expected to generate any revenue in subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not have a cost to implement in the first year.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not have a cost to administer subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Neutral

Expenditures (+/-): Neutral

Other Explanation: The amendment to this existing administrative regulation adds requirements to an existing analysis performed by the Department and will not have a revenue impact.

PUBLIC PROTECTION CABINET Department of Insurance Fraud Division (Amendment)

806 KAR 47:010. Fraud prevention.

RELATES TO: KRS 304.2-140, 304.47-010, 304.47-020, 304.47-040, 304.47-050, <u>304.47-055</u>, 304.47-080

STATUTORY AUTHORITY: KRS 304.2-110

NECESSITY, FUNCTION, AND CONFORMITY: <u>KRS 304.2-110</u> authorizes the Commissioner of Insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code as defined in <u>KRS 304.1-010</u>. [KRS 304.2-110 authorizes the Commissioner of Insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code.] This administrative regulation establishes insurer requirements and a comprehensive process for reporting and investigating fraudulent insurance acts.

Section 1. Definitions.

(1) "Division" is established[defined] by KRS 304.47-010(6).

(2) "Special investigative unit" or "SIU" means a unit to investigate fraudulent insurance acts as <u>established [required]</u> by KRS 304.47-080.

Section 2. Scope. This administrative regulation shall apply to all insurers admitted to do business in the Commonwealth that are not otherwise exempted by KRS 304.47-080(1).

Section 3. Primary Anti-fraud Contacts. To facilitate communication with the division, an insurer shall designate two (2) primary contact persons, one (1) of whom shall be the head of the SIU, who shall communicate with the division on matters relating to the reporting, investigation, and prosecution of suspected fraudulent insurance acts, as defined in KRS 304.47-020.

Section 4. Special Investigative Units and Anti-fraud Plans.

(1) An insurer shall maintain an SIU to fulfill the requirements of KRS 304.47-080.

(2) In conjunction with its SIU, an insurer shall:

(a) Implement systematic and effective methods to detect and investigate suspected fraudulent insurance claims;

(b) Educate and train all claims handlers to identify possible insurance fraud;

(c) Develop policies for the SIU to cooperate, coordinate, and communicate with:

1. The insurer's claims handlers, legal personnel, technical support personnel, and database support personnel; and

2. The division and other relevant law enforcement agencies; and

(d) Develop and submit to the division a written anti-fraud plan, which shall include:

1. Acknowledgment of duty to report to the division, including mandatory reporting of the determination that a suspected fraudulent act has been committed within fourteen (14) days;

2. SIU contact information;

3. SIU investigative ethics;

4. Procedures to detect and deter fraud; and

5. Continuing education plans for SIU staff.

Section 5. Compliance Report.

(1) Within ninety (90) days of admission, and at least once every two (2) years, an insurer shall submit to the division a written report setting forth the manner in which the insurer is complying with Section 4 of this administrative regulation. The report shall also include:

(a) The total number of SIU investigative staff responsible for cases in Kentucky, and whether any staff member also investigate cases in other jurisdictions; and

(b)1. If the insurer formed the SIU in house and solely governs it, the year that the SIU was Legislative Research Commission PDF Version Page: 2 formed; or

2. If the insurer has contracted SIU services through another company, the identity of the company providing SIU services and the initial year of the contract between the insurer and the company.

(2) Within thirty (30) days of a material change of the information provided in the compliance report, the insurer shall amend the compliance report and resubmit it to the division.

Section 6. Reporting Fraudulent Insurance Acts.

(1) All persons identified in KRS 304.47-050(2) shall report suspected fraudulent insurance acts to the division within fourteen (14) days of determination that a suspected fraudulent act has been committed. Reports submitted to a person or entity other than the division shall not satisfy the reporting duty of KRS 304.47-050(2). Reports shall be submitted by:

(a) Completing a report on the department's electronic services portal at https://insurance.ky.gov/eservices/default.aspx; or

(b) Submitting a completed Uniform Suspected Insurance Fraud Reporting Form.

(c) 1. To supplement the report required by subsection (1) of this section, persons identified in KRS 304.47-050 may also report suspected fraudulent insurance acts through intermediaries including:

<u>a. the National Association of Insurance Commissioners'</u> Online Fraud Reporting System;

b. The National Health care Anti-Fraud Association; or

c. The National Insurance Crime Bureau.

2. A report submitted through an intermediary shall be subject to the confidentiality provisions in KRS 304.47-055.

(2) All persons identified in KRS 304.47-050(1) may report suspected fraudulent insurance acts to the division by:

(a) Completing a report on the department's electronic services portal at https://insurance.ky.gov/eservices/default.aspx; or

(b) Submitting a completed Uniform Suspected Insurance Fraud Reporting Form.

Section 7. Incorporation by Reference.

(1) The "Uniform Suspected Insurance Fraud Reporting Form," 7/2019, is incorporated by reference.

(2) This material may be inspected, copied, or obtained,

subject to applicable copyright law, at the Department of Insurance, <u>Mayo-Underwood Building, 500 Mero Street</u> [215 W. Main St.], Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

SHARON P. CLARK, Commissioner KERRY B. HARVEY, Secretary APPROVED BY AGENCY: October 12, 2020 FILED WITH LRC: October 13, 2020 at 10:11 a.m. PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held at 9:00 AM on December 21, 2020 at 500 Mero Street, Frankfort, Kentucky 40602. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through 11:59 PM on December 31, 2020. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

CONTACT PERSON: DJ Wasson, Deputy Commissioner, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 564-6026, fax +1 (502) 564-1453, email dj.wasson@ky.gov

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: DJ Wasson

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation amends the name of the Insurance Fraud Unit to the Division of Insurance Fraud Investigation and requires all insurance companies authorized to do business in Kentucky to designate at least one contact person to communicate with the Department regarding suspected insurance fraud.

(b) The necessity of this administrative regulation: This administrative regulation updates the name of the division to make it consistent with related statutes. It also requires companies to provide a contact name/address/phone number to further efforts to investigate allegations of insurance fraud.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.2-110 provides that the Commissioner of Insurance may make reasonable administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code. KRS 304.47-040 creates a Division of Insurance Fraud Investigation within the Department of Insurance and sets up the authority of special investigators within that division. KRS 304.47-080 requires all insurance companies operating in Kentucky to maintain a method to identify, investigate and report instances of insurance fraud..

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation sets forth the process that the Department of Insurance and insurance company special investigation units use to identify, investigate, deter and report instances of suspected insurance.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment to this administrative regulation establishes the conformity with Chapter 13A formatting guidelines, updates the physical address of the department. This amendment also incorporates 304.47-055 into the regulation, which ensures documentation, and reports are confidential with the Commissioner and the department's intermediaries. Individuals may now file reports with the NAIC's fraud reporting tool, The National Health care Anti-Fraud Association; or The National Insurance Crime Bureau.

(b) The necessity of the amendment to this administrative regulation: The necessity of this amendment is to ensure the formatting meets Chapter 13A requirements, inform the public that all information reported to the Department and its intermediaries is confidential as well as providing outlets outside of the Department to report fraudulent activity.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 304.47-055 states that all documents, materials, or other information in the possession or control of the commissioner shall be confidential by law and privileged. KRS 304.2-110 provides that the Commissioner of Insurance may make reasonable administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code, KRS 304.1-010.

(d) How the amendment will assist in the effective administration of the statutes: This amendment cites the confidentiality subtitle under the Kentucky Revised Statutes, providing more security and trust in those individuals desiring to file a report.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: There will be no impact.

(4) Provide an analysis of how the entities identified in the previous question will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions each of the regulated entities have to take to comply with this regulation or amendment: No actions are required.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: There should not be a cost for complying with the updates included in this amendment.

(c) As a result of compliance, what benefits will accrue to the entities: There are no additional benefits associated with the amendment.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: Implementation of this amendment is not anticipated to have an initial cost on the Department of Insurance.

(b) On a continuing basis: Implementation of this amendment is not anticipated to have an on-going cost on the Department of Insurance.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Department will use funds from its current operational budget to perform the tasks necessary.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: An increase of fees will not be necessary because additional personnel is likely unnecessary.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not directly establish any new fees.

(9)TIERING: Is tiering applied? Explain why or why not. Tiering is not applied.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Department of Insurance will be impacted as the implementer of the regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 304.2-110, 304.47-040, 304.47-080

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. If

specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation is not expected to generate any revenue in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation is not expected to generate any revenue in subsequent years.

(c) How much will it cost to administer this program for the first year? This administrative regulation will not have a cost to implement in the first year.

(d) How much will it cost to administer this program for subsequent years? This administrative regulation will not have a cost to administer subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Neutral

Expenditures (+/-): Neutral

Other Explanation: The amendment to this existing administrative regulation offers technical clarifications and will not have a revenue impact.

PUBLIC PROTECTION CABINET Department of Housing, Buildings and Construction Division of Plumbing (Amendment)

815 KAR 20:150. Inspections and tests.

RELATES TO: KRS 318.090, 318.130, 318.134, 318.140, 318.160, 318.170

STATUTORY AUTHORITY: KRS 198B.040(10), 318.130

NECESSITY, FUNCTION, AND CONFORMITY: KRS 318.130 requires the department to promulgate an administrative regulation establishing the Kentucky State Plumbing Code. KRS 318.160 requires a person who constructs, installs, or extensively alters any plumbing, sewerage, or water supply system of any public building or establishment to obtain approval of the department in writing. This administrative regulation establishes the requirements for the tests and inspections that are necessary in order to ensure compliance with 815 KAR Chapter 20, the Kentucky State Plumbing Code.

Section 1. Required Inspections and Tests. (1) Required inspections. The department shall inspect the following to ensure compliance with the code:

(a) The water distribution system;

(b) The soil, waste, and vent system;

(c) The fixtures and fixture traps;

(d) Appurtenances; and

(e) All connections in a plumbing system.

(2) Required tests. Tests shall be made separately or as follows:

(a) The house sewer and its branches from the property line to the house drain;

(b) The house drain including its branches;

(c) The soil, waste, and vent system;

(d) Inside rain water conductors; and

(e) The final inspection and air test which shall include the complete plumbing system as required by Section 3(2) of this administrative regulation, exclusive of the house sewer.

(3) Rough-in inspection.

(a) The plumbing system shall not be covered until it has been inspected, tested, and approved.

(b) A rough-in inspection shall be conducted prior to the covering or concealment of the plumbing system.

(c) If any part of a plumbing system is covered or concealed before being inspected, tested, and approved, it shall be uncovered, or unconcealed and tested as required.

(4) Condemned buildings. In buildings condemned by other authorities because of unsanitary conditions of the plumbing system, necessary alterations shall be considered a new plumbing system.

(5) Tests of alterations, extensions, or repairs. Any alterations, repairs, or extensions that require more than ten (10) feet of soil, waste, or vent piping shall be inspected and tested as required by Section 3(2) of this administrative regulation.

Section 2. Permit Holder Requirements. The person procuring the plumbing permit shall:

(1) Furnish all equipment, material, and labor necessary for inspections and tests;

(2) Notify the department representative and request a roughin inspection for the plumbing system prior to the plumbing system being concealed or covered within the floors or walls of a building; and

(3) Notify a department representative and request a final inspection and air test upon completion of the installation.

Section 3. Requirements for Remote Inspection. (1) A master plumber may request a plumbing inspection from the department conducted by live video or submission of recorded video or photograph if the master plumber holds a certificate of completion issued by the department.

(2) Certificate of completion. (a) The department shall issue a certificate of completion to a master plumber who has successfully completed a training course provided by the department that shall cover the following topics:

1. Technology necessary for effective remote inspection;

2. Information to be conveyed and shown by the master plumber to the department; and

<u>3. How to show corrections made to installations that failed</u> remote inspection.

(b) A certificate of completion issued to a master plumber pursuant section 3(2)(a) of this administrative regulation shall be valid for a period of three (3) years from the date of issuance, after which the certificate shall expire. A master plumber whose certificate of completion has expired shall not be eligible to request or receive remote inspections.

(c) A certificate holder may renew their certificate of completion by completing a training course described in section 3(2)(a) of this administrative regulation.

(3) The department may deny a request for remote inspection if:

(a) The scope of the work is too complex for remote inspection; (b) Remote inspection is not feasible or practical; or

(c) Any other reason is articulated in writing to the certificate holder by the department.

(4) Remote inspection seals. (a) A certificate holder may request numbered remote inspection seals from the department to place on completed plumbing installations that are approved for remote inspection by submitting a completed form PLB-4, Application for Plumbing Remote Inspection Seals, to the department.

(b) Except for the initial request for remote inspection seals, a certificate holder requesting seals shall submit a completed form PLB-5, Plumbing Remote Inspection Seal Verification, to the department prior to receiving remote inspection seals.

(c) A certificate holder shall:

<u>1. Affix a seal to a completed plumbing installation for which he</u> or she has been approved for remote inspection:

2. Not affix a seal to a plumbing installation when he or she has not submitted videos or photographs of the installation to the department or participated in a live video inspection with the department; and

3. Not allow seals he or she received from the department to be used by another.

(d) The department shall:

1. Assign an inspection number to the permit and seal for a

plumbing installation that has successfully passed all required remote inspections and tests; and

2. Complete remote inspections that are not live video within three (3) business days of receipt of videos or photographs of the completed plumbing installation eligible for remote inspection.

(e) A property owner, property owner's designee, or certificate holder shall write the inspection number assigned by the department on the seal the inspection number is assigned to upon successful passage of all required inspections and tests.

(5) Notification of noncompliance. The department shall immediately issue a notification of noncompliance in writing to the certificate holder upon finding deficiencies in the documentation submitted for remote inspection.

(6) Corrections to noncompliant installations. A plumbing installation found to be noncompliant through remote inspection shall be corrected within ten (10) business days upon receiving notice of noncompliance from the department. Failure to make the required corrections may result in the termination of the certificate holder's certificate of completion.

(7) Penalties. A certificate holder who knowingly engages in activity intended to defraud or deceive a plumbing inspector or any other agent of the department shall be subject to certificate and license revocation or suspension.

Section 4[3]. Testing of Systems. (1) The water distribution system, as well as the water service, shall be:

(a) Tested with air or water under a pressure of not less than the maximum working pressure under which it is to be used; and

(b) Free from leaks.

(2)(a) Except as provided in subsection (3) of this section, a water test shall be performed:

1. On the entire soil, waste, and vent system; or

2. In sections.

(b) If it is applied to the entire system, all openings shall be closed, except the highest opening and the system shall be filled with water to the point of overflow.

(c) If the system is tested in sections, each opening shall be tightly plugged, except the highest opening and it shall be tested with not less than a ten (10) foot head of water. In testing successive sections, at least the upper ten (10) feet of the preceding section shall be retested.

(3) In lieu of a water test, an air pressure test may be used by attaching an air compressor or test apparatus to any suitable opening. All other inlets and outlets to the system shall be closed, forcing air into the system until there is a uniform pressure of five (5) pounds per square inch (PSI). The pressure shall be maintained for fifteen (15) minutes.

(4) After the plumbing fixtures have been set and their traps filled with water and before the building is occupied, the final air test shall test the entire soil, waste, and vent system including the fixtures and appurtenances, other than a house sewer, by connecting an air machine to any suitable opening or outlet and applying air pressure equivalent to a one (1) inch water column. It shall be maintained for at least a fifteen (15) minute period. If there are no leaks or forcing of trap seals as may be indicated by the functioning of a drum, float, or water column, the system shall be determined as airtight.

(5) A garage drainage system shall be tested in the same manner as the soil, waste, and vent system.

(6) A house sewer shall be tested by a water, air, or smoke test. A four (4) inch test tee or Y connection shall be provided at the property line for testing.

(7) The department may require the removal of any clean-outs to ascertain if the pressure has reached all parts of the system

(8) A building sewer not drained by gravity shall have a minimum of twenty-four (24) inches of cover and shall be tested with five (5) pounds per square inch for a period of fifteen (15) minutes.

(9) Inside rain water conductors shall be tested with water, air, or smoke test.

Section 5[4]. Defective Work. If an inspection or a test indicates defective work or material, it shall be replaced and the

inspection and the test repeated.

Section <u>6[5]</u>. Testing Defective Plumbing. An air test shall be used in testing the condition of a plumbing system if there is reason to believe it has become defective.

Section $\underline{7}$ [6]. Certificate of Approval. The department shall issue a certificate of approval upon the satisfactory completion and final test of the plumbing system.

Section 8. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Application for Plumbing Remote Inspection Seals", Form PLB-4, June 2020; and

(b) "Plumbing Remote Inspection Seal Verification", Form PLB-5, June 2020.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department of Housing, Buildings and Construction, 500 Mero Street, Frankfort, Kentucky 40601-5412, Monday through Friday, 8 a.m. to 4:30 p.m. and is available online at dhbc.ky.gov.

KERRY B. HARVEY, Secretary

RICK RAND, Commissioner APPROVED BY AGENCY: October 9, 2020 FILED WITH LRC: October 9, 2020 at 4:06 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on December 27, 2020 at 10:00 a.m., EDT, in the Department of Housing, Buildings and Construction, 500 Mero Street, First Floor, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five working days prior to the hearing of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through December 31, 2020 at 11:59 p.m., EDT. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation by the above date to the contact person:

CONTACT PERSON: Benjamin Siegel, General Counsel, Department of Housing, Buildings and Construction, 500 Mero Street, 1st Floor, Frankfort, Kentucky 40601, phone (502) 782-0604, fax (502) 573-1057, email benjamin.siegel@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Benjamin Siegel

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements for the tests and inspections that are necessary in order to ensure compliance with 815 KAR Chapter 20, the Kentucky State Plumbing Code.

(b) The necessity of this administrative regulation: This administrative regulation is necessary in order to assist the Division of Plumbing in carrying out its duty to monitor and inspect the construction, installation, and alteration of plumbing and plumbing fixtures and appliances in the Commonwealth. This administrative regulation is also necessary to establish the plumbing inspection protocols required by KRS 318.160.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 318.130 requires the department to promulgate an administrative regulation establishing the Kentucky State Plumbing Code to regulate plumbing. KRS 198B.040(10) requires the department to promulgate administrative regulations for the safe installation and operation of plumbing and plumbing fixtures. KRS 318.160 requires a person who constructs, installs, or extensively alters any plumbing, sewerage, or water supply system of any public building or establishment to obtain approval by the department in writing.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes the requirements for the tests and inspections that are necessary in order to ensure compliance with KRS Chapter 318 and 815 KAR Chapter 20, the Kentucky State Plumbing Code. This administrative regulation establishes the processes required for a plumbing inspection for a person to obtain approval from the department.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment establishes procedures and requirements for the department and licensed plumbers to conduct remote inspections of plumbing installations.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary in order to assist the Division of Plumbing in carrying out its duty to monitor and inspect the construction, installation, and alteration of plumbing and plumbing fixtures and appliances in the Commonwealth. In the wake of the COVID-19 pandemic, the Division of Plumbing discovered a high demand for remote inspections of plumbing installations, particularly installations in existing residential buildings. This amendment is necessary to establish procedures and requirements for the department and licensed plumbers to conduct remote inspections of plumbing installations while also maintain an equivalent or greater level of safety for the inspectors, building occupants, and plumbers involved.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment aids the department in regulating plumbing, including the inspection and testing of plumbing systems.

(d) How the amendment will assist in the effective administration of the statutes: This amendment establishes procedures and requirements for the department and licensed plumbers to conduct remote inspections of plumbing installations. Making this option available is anticipated to increase the number of inspections that are successfully completed.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: All individuals engaged in the plumbing industry in Kentucky and Department of Housing, Buildings and Construction personnel.

(4) Provide an analysis of how the entities identified in the previous question will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions each of the regulated entities have to take to comply with this regulation or amendment: This amendment will require additional action only if a master plumber wishes to participate in the remote inspection process. This is optional.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: This amendment will not impose any additional costs on any of the regulated entities identified in question (3).

(c) As a result of compliance, what benefits will accrue to the entities: It will help licensed master plumbers fulfill their duty to obtain the required inspections of plumbing installations. It will help the department fulfill its duty to inspect plumbing installations. This will help both the department and licensed master plumbers save time and money while still ensuring the safety of plumbing installations.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no anticipated additional initial costs to administer these regulatory amendments.

(b) On a continuing basis: There are no anticipated additional costs on a continuing basis to administer these regulatory amendments.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Implementation of these amendments is anticipated to result in no

additional costs to the department. Any costs resulting from these administrative amendments will be met with existing agency funds.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: This amendment will not necessitate an increase in fees or require funding from the department for implementation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: There are no fees established by this administrative regulation amendment. There are also no fees directly or indirectly increased by this administrative regulation amendment.

(9) TIERING: Is tiering applied? Explain why or why not. Tiering is not applied as all individuals in the plumbing industry and department personnel are affected by the amended requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

The Department of Housing, Buildings and Construction, Division of Plumbing will be impacted by this administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. This administrative regulation is authorized and required by KRS 198B.040(10) and KRS 318.130.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment is not anticipated to generate additional revenue for the state or local government in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment is not anticipated to generate additional revenue for the state or local government in subsequent years.

(c) How much will it cost to administer this program for the first year? There are no anticipated additional costs to administer this regulatory amendment for the first year.

(d) How much will it cost to administer this program for subsequent years? There are no anticipated additional costs to administer this regulatory amendment for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Neutral Expenditures (+/-): Neutral Other Explanation: None

PUBLIC PROTECTION CABINET Department of Housing, Buildings and Construction Electrical Division (Amendment)

815 KAR 35:015. Certification of electrical inspectors.

RELATES TO: KRS 198B.060, 198B.090, 211.350, 227.450, 227.480, 227.489, 227.491, 227.492, 227.495

STATUTORY AUTHORITY: KRS 227.489

NECESSITY, FUNCTION, AND CONFORMITY: KRS 227.489 requires the commissioner of the Department of Housing, Buildings and Construction to require electrical inspectors to be certified based on standards of the National Electrical Code. This administrative regulation establishes the procedures for achieving

and maintaining [a] certification as an electrical inspector.

Section 1. Applicability. This administrative regulation shall apply to electrical inspectors in Kentucky and applicants for certification as an electrical inspector in Kentucky.

Section 2. Classifications of Electrical Inspectors. (1) An electrical inspector shall be classified as either:

(a) An electrical inspector one (1) and two (2) family shall be a person who has:

1. Passed an examination focused on electrical installations in one (1) or two (2) family dwellings with a score of seventy (70) percent or greater by a test provider approved by the department; and

2. At least four (4) years experience immediately preceding the application in the installation and design of residential wiring systems installed in accordance with the National Electrical Code, NFPA 70 incorporated by reference in 815 KAR 7:120 and 815 KAR 7:125; or

(b) An electrical inspector general shall be a person who has:

1. Passed an examination focused on electrical installations in residential, commercial, and industrial buildings with a score of seventy (70) percent or greater by a test provider approved by the department; and

2. At least eight (8) years of experience immediately preceding the application in the installation and design of residential, commercial, and industrial wiring systems installed in accordance with the National Electrical Code, NFPA 70, incorporated by reference in 815 KAR 7:120 and 815 KAR 7:125.

(2) The requirements in subsections 1(a) and 1(b) shall be satisfied if the person is:

(a) A registered professional electrical engineer engaged in that profession for at least three (3) years immediately preceding the application; or

(b) Currently licensed as a master electrician, <u>having obtained</u> their license after successful passage of an exam in accord with <u>815 KAR 35:060 Section 4</u>, and actively engaged in the electrical trade in that capacity immediately preceding the application.

(3)(a) An electrical inspector one (1) and two (2) family shall be certified to inspect and approve an electrical installation related to a:

1. One (1) or two (2) family dwelling; or

2. Manufactured home or mobile home.

(b) An electrical inspector general shall be certified to inspect and approve an electrical installation related to any type of residential, commercial, industrial, or any other property that requires electrical inspection.

(4) A passing score as described in subsection (1)(a)1. and 1(b)1. shall be valid for a period of three (3) years.

Section 4. Application Requirements for Certification. (1) An applicant for certification as an electrical inspector shall submit to the department:

(a) A completed Application for Electrical Inspector Certification on Form EL-11;

(b) Proof of successful completion of the examination applicable to the certification sought pursuant to Section 2(1)(a) and (b) of this administrative regulation;

(c) Except for electrical inspectors employed by the department, a fee of \$100 dollars payable to the Kentucky State Treasurer.

(d) Proof of the applicant's experience as required by Section 3(1)(a)2. and (b)2. of this administrative regulation.

(e) A passport-sized, color photograph of the applicant taken within the past six (6) months; and

(f) Proof of a bond in the amount of \$5,000 in compliance with KRS 227.487(4), unless employed by the department or a local government rules otherwise.

(2) An applicant shall possess:

(a) The ability to read and write the English language; and

(b) A general educational level at least adequate to perform his or her duties.

(3) Proof of listed experience shall be provided by:

1. A federal or state tax form; or

2. An affidavit by another license holder who worked with the applicant.

(4) An applicant shall receive credit for an electrical course satisfactorily completed from an accredited vocational school or college on a year-for-year basis. Credit for education to replace an applicant's experience requirements shall be limited to a total of two (2) years.

(5) The department shall issue a certification for an electrical inspector only to an individual. A corporation, partnership, company, or other entity shall not be issued a certification.

Section 5. Certificate Renewal. (1) Certification period.

(a) Each electrical inspector's certification shall expire on the last day of the electrical inspector's birth month each year.

(b) The department shall send each electrical inspector a renewal application form prior to the date of expiration.

(2) Filing for renewal. Each electrical inspector seeking certification renewal shall submit to the department:

(a) A completed Application for Electrical Inspector Certification on Form EL-11;

(b) A renewal fee off fifty (50) dollars;

(c) Proof of compliance with the continuing education requirements established in 815 KAR 2:010;

(d) If the electrical inspector is employed by a local government, documented proof of continued employment signed by the hiring authority responsible for administering the local jurisdiction's inspection and code enforcement program;

(e) For each local jurisdiction with which the applicant is contracted to act as an electrical inspector, a copy of the current contract naming the applicant and establishing the terms and conditions of his or her authority; and

(f) For each local jurisdiction with which the applicant is contracted to act as an electrical inspector, a copy of the ordinance fixing the schedule of fees authorized to be charged for electrical inspections within that jurisdiction.

(3) Current information. An applicant who has previously submitted a document required by subsection (2)(e) and (f) of this section for a prior renewal shall not be required to resubmit that document if it remains current and effective at the time of the current renewal.

(4) Change of information. Within ten (10) days of the occurrence, <u>an[a]</u> electrical inspector shall provide the department:

(a) Notice of any establishment, change, or termination of the electrical inspector's contract or employment with a local jurisdiction;

(b) A copy of any new or revised contract entered into with a local jurisdiction; and

(c) For any local jurisdiction with which the electrical inspector is employed or contracted, a copy of any ordinance amending the schedule of fees authorized to be charged for electrical inspections within that jurisdiction.

(5) Late renewal.

(a) An electrical inspector who fails to submit the renewal application and renewal fee on or before the last day of his or her birth month shall be a late renewal fee of fifty (50) dollars in addition to the renewal fee.

(b) If both fees are not paid or all required continuing education is not completed within sixty (60) days after the last day of the electrical inspector's birth month, the certification shall be terminated.

(6) Reinstatement.

(a) A certificate that has been terminated may be reinstated at the discretion of the commissioner upon a petition in writing, demonstrating just cause why the petitioner failed to comply with the renewal requirements established by this section.

(b) An application for reinstatement shall:

1. Pay a reinstatement fee of \$100 in addition to the late renewal fee required by subsection (5) of this section;

2. Comply with the requirements established by subsection (2) of this section;

3.a. Submit proof of required continuing education pursuant to 815 KAR 2:010 for the number of hours required in one (1) year; or

b. Submit proof of having passed the examination applicable to the certification to be reinstated, as established by Section 2(1)(a) and (b) of this administrative regulation, within the current year.

(7) The requirements of this section shall not apply to a stateemployed electrical inspector.

Section 6. Duties and Responsibilities. (1) In addition to the National Electrical Code, the electrical inspector shall be familiar with all applicable building codes and fire safety codes governing buildings in the area in which the electrical inspector performs an inspection.

(2) Record retention.

(a) Each electrical inspector shall make a complete record of each inspection. The record shall contain, as a minimum:

1. Sufficient information to identify the location of the structure inspected;

2. The date of the inspection;

3. The type of structure, whether residential, commercial, industrial, or other;

4. The designation of a required permit and the agency granting the permit;

5. The size and complexity of the structure; and

6. Any deficiencies in meeting code requirements and the actions required to comply.

(b) If the electrical inspector is employed by a local government, the electrical inspector or the local government shall maintain the records in compliance with 725 KAR 1:061.

(c) If the electrical inspector contracts with a local government, the local government shall maintain the records in compliance with 725 KAR 1:061.

(d) If the electrical inspector is an employee of the department, the electrical inspector shall submit the reports to the department in compliance with KRS 227.487(1).

Section 7. Complaints and Grievance Procedures. (1) A person may file a complaint against an electrical inspector if the person believes that an act or omission of the electrical inspector in the performance of his or her duties is in violation of the administrative regulation or other law or has caused an undue hardship to the person.

(2) A complaint or allegation of misconduct shall be submitted in writing to the department and shall:

(a) Include the nature of the alleged misconduct, with specific details as to acts, names, dates, and witnesses; and

(b) Specify the action requested of the department.

(3) Following an investigation, the department shall:

(a) Set the matter for public hearing; or

(b) Take other appropriate action in accordance with KRS 227.495 to resolve or correct the matter.

Section 8. Suspension and Revocation of Certification. The commissioner shall revoke, suspend, or refuse to renew the certificate of an electrical inspector who is determined, by the commissioner after having afforded the opportunity for a KRS Chapter 13B administrative hearing, to have:

(1) Engaged in an activity that constitutes a conflict of interest, including:

(a) Work as an electrical contractor, master electrician, or electrician;

(b) Involvement in an activity in the electrical industry; or

(c) Having a pecuniary or associational interest in a business or other venture involved in an activity in the electrical industry.

(2) Engaged in fraud, deceit, or misrepresentation in obtaining certification;

(3) Demonstrated negligence, incompetence, or misconduct in the field of electrical inspection;

(4) Affixed or caused to be affixed a seal of approval or issued a certificate of approval for an electrical installation subject to inspection if he or she has not personally inspected the installation and found it to be satisfactory in accordance with the <u>National</u> <u>Electrical Code</u>, NFPA 70 incorporated by reference in 815 KAR 7:120 and 815 KAR 7:125[eode];

(5) Operated as an electrical inspector in a locality in conflict

with state or local laws, ordinances, or regulations;

(6) Knowingly overruled the proper findings of another electrical inspector or attempted to supplant, overrule, or otherwise invalidate the judgment of another electrical inspector without first obtaining express written consent from the designated electrical inspector;

(7) Failed to maintain accurate and adequate recordkeeping as required by Section 6 of this administrative regulation;

(8) Violated KRS 211.350(8); or

(9) Violated any provision of KRS 227.491 or this administrative regulation.

Section 9. Incorporation by Reference. (1) Form EL-11, "Application for Electrical Inspector Certification", August 2018 is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department of Housing, Buildings and Construction, <u>500 Mero Street, Frankfort, Kentucky</u> <u>40601[Electrical Section, 101 Sea Hero Road, Suite 100, Frankfort, Kentucky 40601-5412]</u>, Monday through Friday, 8 a.m. to 4:30 p.m. and is available online at <u>dhbc.ky.gov[http://dhbc.ky.gov/pages/default.aspx]</u>.

KERRY B. HARVEY, Secretary

RICK RAND, Commissioner

APPROVED BY AGENCY: October 9, 2020

FILED WITH LRC: October 9, 2020 at 4:06 p.m. PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on December 27, 2020 at 10:00 a.m., EDT, in the Department of Housing, Buildings and Construction, 500 Mero Street, First Floor, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by five working days prior to the hearing of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. The hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through December 31, 2020 at 11:59 p.m., EDT. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation by the above date to the

contact person: CONTACT PERSON: Benjamin Siegel, General Counsel, Department of Housing, Buildings and Construction, 500 Mero Street, 1st Floor, Frankfort, Kentucky 40601, phone (502) 782-0604, fax (502) 573-1057, email benjamin.siegel@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Benjamin Siegel

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the procedures for obtaining and maintaining a certification as an electrical inspector.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish the criteria for obtaining and maintaining a certification as an electrical inspector.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 227.489 requires the commissioner of the Department of Housing, Buildings and Construction to require that electrical inspectors be certified based on the standards of the National Electrical Code. This administrative regulation conforms to the authorizing statute by providing the requirements needed to become and remain a certified electrical inspector.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes the application process for an individual to follow to become a certified electrical inspector. This administrative regulation also establishes the processes a certified electrical inspector must follow to maintain his or her certification.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment clarifies that a master electrician actively engaged in the electrical trade in that capacity immediately preceding their application for electrical inspector certification must have taken an exam to obtain their master electrician's license to satisfy the requirements of Subsections 1(a) and 1(b) of Section 2 and not take an additional exam. This amendment also fixes grammatical and technical errors.

(b) The necessity of the amendment to this administrative regulation: This amendment clarifies the certification process for electrical inspectors.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment is authorized by the grant of authority in KRS 227.489 to require the certification of electrical inspectors in the Commonwealth.

(d) How the amendment will assist in the effective administration of the statutes: This amendment clarifies the electrical inspector certification process.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: All current and potential electrical inspectors in the Commonwealth and Department of Housing, Buildings and Construction personnel will be affected.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including;

(a) List the actions that each of the regulated entities identified in question (3) will have to comply with this administrative regulation or amendment: Potential electrical inspectors who did not pass an examination to receive their master electrician's license will have to pass an examination in order to obtain electrical inspector certification.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Other than the cost of an examination, this amendment will not impose any additional costs on any of the regulated entities identified in question (3).

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The requirements for certification will be made clear to potential electrical inspectors.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: There are no anticipated initial additional costs to administer this regulatory amendment.

(b) On a continuing basis: There are no anticipated additional costs to administer this regulatory amendment on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Implementation of this amendment is anticipated to result in no additional costs to the agency. Any agency costs resulting from this administrative amendment will be met with existing agency funds.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: This amendment will not necessitate an increase in fees or require funding to the Department for implementation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: There are no fees directly or indirectly increased by this administrative regulation amendment.

(9) TIERING: Is tiering applied? Tiering is not applied as all electrical inspectors will be subject to the amended requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will

be impacted by this administrative regulation? The Department of Housing, Buildings and Construction, Licensing Branch will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. The amendments are authorized by KRS 227.489.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This amendment is not anticipated to generate additional revenue for state or local government for the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This amendment is not anticipated to generate additional revenue for state or local government for subsequent years.

(c) How much will it cost to administer this program for the first year? There are no anticipated additional costs to administer this regulatory amendment for the first year.

(d) How much will it cost to administer this program for subsequent years? There are no anticipated additional costs to administer this regulatory amendment for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Neutral Expenditures (+/-): Neutral Other Explanation: None

CABINET FOR HEALTH AND FAMILY SERVICES Office of Inspector General Division of Health Care (Amendment)

902 KAR 20:160. Chemical dependency treatment services and facility specifications.

RELATES TO: KRS 198B.260, 202A.241, 210.005, 216B.010, 216B.015, 216B.105, 216B.990, <u>218A.202</u>, 309.080, <u>309.0831</u>, 309.130, <u>310.021</u>, 311.560, 311.571, 311.840 - 311.862, 314.011(8), 314.042, 319.050, 319.056, 319.064, 319C.010, 320.210(2), 335.080, 335.100, 335.300, 335.500, 42 C.F.R. Part 2, 45 C.F.R. 160, 164, 20 U.S.C. 1400, 29 U.S.C. 701, 42 U.S.C. 290ee-3, 1320d-2 - 1320d-8

STATUTORY AUTHORITY: KRS [216B.010,] 216B.042(1), 216B.105

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 and 216B.105 require the Cabinet for Health and Family Services to regulate health facilities and health services. This administrative regulation establishes licensure requirements for the operation, services, and facility specifications of chemical dependency treatment programs, including programs that [which] elect to provide outpatient behavioral health services for individuals with a substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis.

Section 1. Definitions. (1) "Aftercare" means the process of providing continued services following primary chemical dependency treatment to support and increase gains made during treatment.

(2) "Behavioral health professional" means:

(a) A psychiatrist licensed under the laws of Kentucky to practice medicine or osteopathy, or a medical officer of the government of the United States while engaged in the performance of official duties, who is certified or eligible to apply for certification by the American Board of Psychiatry and Neurology, Inc. or the American Osteopathic Board of Neurology and Psychiatry;

(b) A physician licensed in Kentucky to practice medicine or

osteopathy in accordance with KRS 311.571;

(c) A psychologist licensed and practicing in accordance with KRS 319.050;

(d) A certified psychologist with autonomous functioning or licensed psychological practitioner practicing in accordance with KRS 319.056;

(e) A clinical social worker licensed and practicing in accordance with KRS 335.100;

(f) An advanced practice registered nurse licensed and practicing in accordance with KRS 314.042;

(g) A physician assistant <u>as defined by KRS</u> <u>311.840(3)[licensed under KRS 311.840 to 311.862];</u>

(h) A licensed marriage and family therapist as defined by [licensed and practicing in accordance with] KRS 335.300(2);

(i) A licensed professional clinical counselor as defined by [licensed and practicing in accordance with] KRS 335.500(3); or

(j) A licensed professional art therapist as defined by KRS 309.130(2).

(3) "Behavioral health professional under clinical supervision" means a:

(a) Psychologist certified and practicing in accordance with KRS 319.056;

(b) Licensed psychological associate licensed and practicing in accordance with KRS 319.064;

(c) Marriage and family <u>therapy[therapist]</u> associate as defined by KRS 335.300(3);

(d) Social worker certified and practicing in accordance with KRS 335.080;

(e) Licensed professional counselor associate as defined by KRS 335.500(4); or

(f) Licensed professional art therapist associate as defined by KRS 309.130(3).

(4) "Certified alcohol and drug counselor" is defined by KRS 309.080(2).

(5) "Governing authority" means the individual, agency, partnership, or corporation that directs and establishes policy concerning the management and operation of a chemical dependency treatment program.

(6) "Interdisciplinary team" means a group of at least four (4) professionals, including a physician, registered nurse, certified chemical dependency counselor, and a person with a master's degree in psychology, social work, or counseling.

(7) "Licensed clinical alcohol and drug counselor" is defined by KRS 309.080(4).

(8) "Licensed clinical alcohol and drug counselor associate" is defined by KRS 309.080(5).

(9) "Peer support specialist" means a paraprofessional who:

(a) Is a registered alcohol and drug peer support specialist in accordance with KRS 309.0831; or

(b)1. Meets the application, training, examination, and supervision requirements of 908 KAR 2:220, 908 KAR 2:230, or 908 KAR 2:240; and

2. Works under the supervision of one (1) of the following:

a. Physician;

b. Psychiatrist;

c. Licensed psychologist;

d. Licensed psychological practitioner;

e. Licensed psychological associate;

f. Licensed clinical social worker;

g. Licensed marriage and family therapist;

h. Licensed professional clinical counselor;

i. Certified social worker;

i. Licensed marriage and family therapy associate;

k. Licensed professional counselor associate;

I. Licensed professional art therapist;

m. Licensed professional art therapist associate;

n. Advanced practice registered nurse;

o. Physician assistant;

p. Certified alcohol and drug counselor; or

g. Licensed clinical alcohol and drug counselor.

(10) "Restraint" means a physical or mechanical device used to restrict the movement of the patient or a portion of the patient's body.

(11) "Substance use disorder" is defined by KRS 222.005(12)[means a cluster of cognitive, behavioral, and physiological symptoms resulting from use of a substance which the individual continues to take despite experiencing substance-related problems as a result, including:

(a) Intoxication;

(b) Withdrawal; or

(c) A substance induced mental health disorder].

(12) "Targeted case manager" means an individual who meets the requirements for a targeted case manager established by 908 KAR 2:260.

Section 2. Scope of Operation and Services. (1) A chemical dependency treatment service shall have a structured inpatient program to provide medical, social, diagnostic, and treatment services to individuals with substance use disorder.

(2) Chemical dependency treatment services shall:

(a) Have a duration of less than thirty (30) days;

(b) Be hospital based or freestanding;

(c) Have eight (8) or more patient beds;

(d) Be under the medical direction of a physician; and

(e) Provide continuous nursing services.

(3) If a chemical dependency treatment program provides outpatient behavioral health services, as <u>established[described]</u> in Section 5 of this administrative regulation, for individuals with a substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis:

(a) The outpatient behavioral health services shall be provided:

1. On a separate floor, in a separate wing, or in a separate building on the campus of the chemical dependency treatment program's inpatient facility; or

2. At an extension off the campus of the chemical dependency treatment program's inpatient facility;

(b) The chemical dependency treatment program shall pay a fee in the amount of \$250 per off-campus extension providing outpatient behavioral health services, submitted to the Office of Inspector General at the time of:

1. Initial licensure, if applicable;

2. The addition of a new extension to the chemical dependency treatment program's license; and

3. Renewal;

(c) Each off-campus extension or on-campus program of outpatient behavioral health services shall be listed on the chemical dependency treatment program's license;

(d) An off-campus extension or a separate building on the campus of the chemical dependency treatment program's inpatient facility where outpatient behavioral health services are provided shall comply with the physical environment requirements of Section 8 of this administrative regulation and be approved by the State Fire Marshal's office prior to:

1. Initial licensure;

2. The addition of the extension or on-campus program of outpatient behavioral health services in a separate building; or

3. A change of location;

(e) The program shall employ directly or by contract a sufficient number of personnel to provide outpatient behavioral health services;

(f) The outpatient behavioral health services program shall have a program director who:

1. May also serve as the chemical dependency treatment program's treatment director described in Section 3(10) of this administrative regulation; and

2. Shall be a:

a. Psychiatrist;

b. Physician;

c. [Certified or] Licensed psychologist or certified psychologist with autonomous functioning;

d. Licensed psychological practitioner;

e. Psychiatric nurse;

f. Advanced practice registered nurse;

g. Licensed professional clinical counselor;

h. Licensed marriage and family therapist;

i. Licensed professional art therapist;

j. Licensed [board certified] behavioral analyst; or

k. Licensed clinical social worker; and

(g) Unless an extension of time is granted pursuant to subsection (4) of this section, the outpatient program shall become accredited by one (1) of the following within one (1) year of adding outpatient behavioral health services to the chemical dependency treatment program's license:

1. The Joint Commission;

2. The Commission on Accreditation of Rehabilitation Facilities;

3. The Council on Accreditation; or

4. A nationally recognized accreditation organization.

(4)(a) If a chemical dependency treatment services outpatient program has not obtained accreditation within the one (1) year timeframe required by subsection (3)(g) of this section, the program may request a one (1) time only extension to complete the accreditation process.

(b) A request for extension shall:

1. Be submitted in writing to the Office of Inspector General at least sixty (60) days prior to expiration of the one (1) year deadline described in subsection (3)(g) of this section;

2. Include evidence that the program initiated the process of becoming accredited within sixty (60) days of adding outpatient behavioral health services to the program's license and is continuing its efforts to obtain accreditation; and

3. Include an estimated timeframe by which approval of accreditation is anticipated.

(5) A program shall cease providing outpatient behavioral health services if the program fails to:

(a) Become accredited in accordance with subsection (3)(g) of this section;

(b) Request an extension in accordance with subsection (4) of this section, if accreditation has not been obtained; or

(c) Maintain accreditation.

(6) Proof of accreditation shall be provided to the Office of Inspector General upon receiving accreditation and at the time of annual renewal.

Section 3. Administration and Operation. (1) The licensee shall be responsible for compliance with federal, state, and local laws and administrative regulations pertaining to the operation of chemical dependency treatment programs.

(2)(a) The governing authority shall appoint a program administrator who shall have a:

1. Bachelor's degree in a health or human services field;

2. Bachelor's degree in another field supplemented with one

year of work experience in the field of chemical dependency; or
 High school diploma and four (4) years of experience in the field of chemical dependency.

(b) The governing authority shall establish, in writing:

1. Program goals and objectives; and

2. An evaluation plan for annual assessment of the attainment of the goals and objectives.

(3) Program administrator.

(a) The program administrator shall:

1. Be responsible for the daily management of the facility; and

2. Serve as the liaison between the governing authority and staff members.

(b) The program administrator shall keep the governing authority informed of the operations of the facility through reports and attendance at meetings of the governing authority.

(4) Administrative records and reports.

(a) A medication error, drug reaction, accident, or other incident involving a patient, visitor, or staff member[7] shall be documented in writing, signed by the program administrator and any witness to the event, and placed in an incident file.

(b) Licensure inspection reports, plans of correction, and program evaluations shall be available to the public, upon request, at the facility.

(5) Policies.

(a) Administrative policies. The program shall have a written administrative policy to cover each aspect of the facility's operation, <u>including[as follows]</u>:

1. A description of the organizational structure, staffing, and

allocation of responsibility and accountability;

2. A description of referral linkages with other facilities and providers;

3. A description of the services included in the program, including outpatient behavioral health services if provided;

4. An expense and revenue accounting system following generally accepted accounting procedures;

5. A volunteer program; and

6. Program evaluation and quality assurance review.

(b) Patient care policy. A written patient care policy shall be developed and shall include a description of:

 Actions to be taken <u>if[when]</u> a patient is lost, unaccounted for, or otherwise absent without authorization;

2. Provisions for patient visitation and use of telephones;

3. Provision of emergency medical services; and

4. Patient admission and discharge criteria, including the categories of individuals accepted and not accepted by the program.

(c) Patient rights policy. A written policy shall be developed and maintained to enhance patient dignity and to protect human rights. The policy shall assure that each patient or client receiving outpatient behavioral health services shall be[is]:

1. Informed of rules and regulations governing patient conduct and responsibilities, including the procedure for handling grievances;

2. Informed, prior to admission for rehabilitation or receipt of outpatient behavioral health services, of services available and charges for treatment, including charges not covered under Medicare, Medicaid, or other third-party payor;

3. Encouraged and assisted to:

a. Understand and exercise patient rights;

b. Voice grievances; and

c. Recommend changes in policies and services. Upon request by a patient, a grievance or recommendation shall be conveyed to that body within the organization with authority to take corrective action;

4. Presented with the opportunity to participate in the planning of his or her treatment;

5. Informed of the right to refuse to participate in experimental research;

6. Assured confidential treatment of records and presented with the opportunity to approve or refuse release of records to any individual not involved in his or her care, except as required by Kentucky law or third party payment contract; and

7. Treated with consideration, respect, and recognition of personal dignity and individuality, including privacy in treatment and personal health needs.

(6) Personnel.

(a) The governing authority shall:

1. Establish a personnel policy; and

2. Review the personnel policy at least one (1) time annually and update the policy as needed.

(b) There shall be a personnel record for each person employed by the chemical dependency treatment inpatient facility and, if applicable, the outpatient behavioral health services program, which shall include <u>evidence[the following]</u>:

1. [Evidence] Of the results of a tuberculosis test, performed either prior to or within the first week of employment and annually thereafter;

2. [Evidence] Of education, training, and experience, and a copy of current license or certification credentials, if applicable;

3. [Evidence] That the employee received orientation to the facility's written policies within the first week of employment; and

4. [Evidence] Of regular in-service training that[which] corresponds with job duties and includes a list of training and dates completed.

(7) Staffing requirements.

(a) The chemical dependency treatment program shall have personnel sufficient to meet patient needs at the inpatient facility on a twenty-four (24) hour basis.

(b) The number and classification of personnel required shall be based on the number of patients and the individual treatment plans.

(8) Medical director. The chemical dependency treatment program's inpatient facility shall have a medical director who shall:

(a) Be a physician licensed in accordance with KRS 311.571;[+]

(b) Be responsible for the medical aspect of the program; and (c) Have duties <u>that[which]</u> shall include:

1. Patient admission;

2. Approval of patient treatment plans;

3. Participation in the quality assurance review; and

4. Provision of medical services, personally or by a designated physician, either in-house or on-call, on a twenty-four (24) hour basis.

(9) Interdisciplinary team. The chemical dependency treatment program shall have an interdisciplinary team responsible for:

(a) Developing individual treatment plans;

(b) Developing aftercare plans; and

(c) Conducting quality assurance reviews.

(10) Treatment director. The chemical dependency treatment program shall have a full time treatment director responsible for:

(a) Coordinating the interdisciplinary team in developing individual treatment plans;

(b) Initiating a periodic review of each patient's treatment plan;

(c) Supervising the maintenance of patient records; and

(d) Coordinating the interdisciplinary team in developing an aftercare plan for each patient to provide continuity of care.

(11) Nursing services within the chemical dependency treatment program's inpatient facility.

(a) Nursing services shall be available on a twenty-four (24) hour basis.

(b) The program shall have at least one (1) full-time registered nurse.

(c) If a registered nurse is not on duty, a licensed practical nurse shall be responsible for the nursing care of patients and a registered nurse shall be on call.

(12) Medical supervision. A physician, or registered nurse under the direction of a physician, shall supervise:

(a) Implementation of the medical aspects of the treatment plan; and

(b) All staff directly involved in patient medical care.

(13) In-service training.

(a) All personnel of the chemical dependency treatment program's inpatient facility or, if applicable, the outpatient behavioral health services program[,] shall participate in ongoing in-service training specific to the employee's job activities.

(b) Training shall include:

1. Thorough job orientation for new personnel; and

2. Regular in-service training emphasizing professional competence and the human relationship necessary for effective health care.

(14) Patient records of the chemical dependency treatment program's inpatient facility.

(a)1. An individual record shall be maintained for each patient.

2. Each entry shall be signed and dated by the person making the entry.

(b) At the time of admission, the following information shall be entered into the patient's record:

1. Name, date of admission, birth date and place, marital status, and Social Security number;

2. Person to contact in case of emergency;

3. Next of kin; and

4. Type and place of employment.

(c) The record shall contain documentation of medical services provided during detoxification and rehabilitation, including the results of physical examinations.

(d)1. The record shall contain the patient's treatment plan <u>establishing[outlining]</u> goals and objectives for the individual during treatment.

2. The record shall also contain documentation of how the plan was implemented and of patient progress in meeting the goals and objectives <u>established[outlined]</u> in the treatment plan.

(e) The record shall contain notation of medication administered, stating the date, time, dosage, and frequency of administration and the name of the person administering each dose. (f) The record shall contain a discharge summary and a plan for aftercare.

(g) The discharge summary shall be entered in the patient's record within seven (7) days after discharge and shall include:

1. The course and progress of the patient with regard to the individual treatment plan;

2. General observations of the patient's condition initially, during treatment, and at discharge; and

3. The recommendations and arrangements for further treatment, including prescribed medications and aftercare.

(h) If the patient is referred to another service provider after discharge, and if the patient executes a written release, a copy of the discharge summary shall be [with the patient's permission] sent to the provider with the patient's permission.

(i) After a patient's death or discharge, the completed record shall be placed in an inactive file and <u>be retained for at least the longer of</u>:

1. [Retained for] Six (6) years; or

2. If a minor, three (3) years after the patient reaches the age of majority <u>pursuant to KRS 2.015[under state law, whichever is longest]</u>.

(15) Confidentiality and Security: Use and Disclosure.

(a) The chemical dependency treatment program shall maintain the confidentiality and security of medical records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 <u>through[te]</u> 1320d-8, and 45 C.F.R. Parts 160 and 164[, as amended], including the security requirements mandated by [subparts A and C of] 45 C.F.R. Part 164, <u>Subparts A and C</u>, or as provided by applicable federal or state law, including 42 U.S.C. 290ee-3, and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

(b) The chemical dependency treatment program may use and disclose medical records. Use and disclosure shall be as established or required by:

1. HIPAA, 42 U.S.C. 1320d-2 <u>through</u>[te] 1320d-8, and 45 C.F.R. Parts 160 and 164; or

2. 42 U.S.C. 290ee-3, and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

(c) This administrative regulation shall not be construed to <u>prohibit[forbid]</u> the chemical dependency treatment program from establishing higher levels of confidentiality and security than required by HIPAA, 42 U.S.C. 1320d-2 <u>through[te]</u> 1320d-8, and 45 C.F.R. Parts 160 and 164, or 42 U.S.C. 290ee-3, and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

(16) Linkage agreements.

(a) The program shall have linkages through written agreements with providers of other levels of care <u>that could[which may]</u> be medically indicated to supplement the services available in the program.

(b) Linkages shall include a hospital and an emergency medical transportation service in the area.

(17) Quality assurance. The program shall have a quality assurance program that includes an effective mechanism for reviewing and evaluating patient care on a regular basis by the interdisciplinary team.

(18) Medications.

(a) A prescription or nonprescription medication administered to a patient shall be noted in the patient's records with the date, time, and dosage, and signed by the person administering the medication.

(b) Each prescription medication shall be plainly labeled with the:

- 1. Patient's name;
- 2. Name of the drug;
- 3. Strength;
- 4. Name of pharmacy;
- 5. Date;
- 6. Physician name;
- 7. Caution statement; and
- 8. Directions for use.

(c)1. A prescription or nonprescription medication shall not be administered to a patient except on the written order of a physician or other practitioner acting within his or her statutory scope of practice.

2. A medication shall be administered by licensed personnel.

(d)1. Medication shall be kept in a locked storage area, which shall be well lighted and of sufficient size to permit storage without crowding.

2. Medication requiring refrigeration shall be kept in a separate locked box in a refrigerator.

3. Medication for external use shall be stored separately from medication administered by mouth or injection.

(e) A medication error or drug reaction shall be reported immediately to the medical director and treatment coordinator and an entry shall be made in the patient's record.

(f) An emergency medical kit, with contents approved by a physician, shall be:

1. Maintained at the facility; and

2. Inspected after use or at least monthly to remove deteriorated and outdated drugs and to ensure completeness of content.

(19) Restraints. Requirements for the use of restraints shall be met pursuant to KRS 202A.241 and 908 KAR 3:010, Section 9.

(20) Activities schedule. A daily schedule of program activities shall be posted in the chemical dependency treatment program's inpatient facility.

Section 4. Provision of Services. (1) <u>Withdrawal management</u> <u>services</u> [Detoxification]. A chemical dependency treatment program's inpatient facility shall provide <u>medically monitored</u> <u>intensive inpatient</u> [medical detoxification] services pursuant to the requirements of 902 KAR 20:111 directly or through another licensed provider for a patient who <u>meets the:</u>

(a) Diagnostic criteria for substance intoxication or withdrawal disorder as established by the most recent version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) for alcohol, tobacco, and other drug use; and

(b) Dimensional criteria for medically monitored intensive inpatient services in accordance with the most recent version of The American Society of Addiction Medicine (ASAM) Criteria [requires detoxification].

(2) Rehabilitation. A chemical dependency treatment program's inpatient facility shall provide:

(a) Medical services as needed, under the supervision of a physician;

(b) Scheduled individual, group, and family counseling;

(c) Psychological testing and evaluation as needed;

(d) Education of the patient on the subject of chemical dependency and related lifestyle issues, including nutrition and communication skills;

(e) Recreational activities with facilities and equipment, consistent with the patient's needs and the therapeutic program;

(f) Referral to other rehabilitative or community service agencies providing services not available through the program, and

(g) Aftercare services provided directly or through arrangement with another agency.

(3) Physical examinations. Within ten (10) days prior to, or three (3) days after, admission to the chemical dependency treatment program's inpatient facility for rehabilitation, a patient shall have a physical examination with tests ordered by a physician.

(4) Psychosocial history.

(a) A patient in a chemical dependency treatment program's inpatient facility shall have a psychosocial history and assessment interview within seventy-two (72) hours after admission for rehabilitation.

(b) The following data shall be collected and recorded in the patient record:

1. History of alcohol and drug use;

2. A determination of current emotional state;

3. Vocational history;

4. Familial relationships; and

5. Educational background.

(5) Treatment plan.

(a) The interdisciplinary team, with the participation of the

patient, shall develop an individual treatment plan within four (4) days after admission to the chemical dependency treatment program's inpatient facility for rehabilitation, based on the patient's medical evaluation and psychosocial history and assessment.

(b) The treatment plan shall:

1. Specify the services required for meeting the patient's needs;

2. Identify goals necessary for the patient to achieve, maintain, or reestablish physical health and adaptive capabilities;

3. Establish goals with both long-term and short-term objectives and the anticipated time expected to meet these goals; and

4. Identify the location and frequency of treatment procedures, including referrals for a required service not provided by the program.

(6) The treatment plan shall be reviewed and updated at least weekly for the duration of the inpatient treatment.

(7)(a) The patient's family or significant others shall be involved in the treatment process, if approved by the patient.

(b) An attempt to involve family members or significant others shall be reported in the patient's medical record.

(8) Aftercare plan.

(a)1. A written aftercare plan shall be developed prior to completion of treatment in the chemical dependency treatment program's inpatient facility by the:

a. Interdisciplinary team;

b. Patient; and

c. With the patient's permission, [the] patient's family or significant others.

2. The aftercare plan shall be designed to establish continued contact for the support of the patient.

(b) The aftercare plan shall include methods and procedures to meet patient needs through direct contact or with assistance from other community human services organizations.

(c) If aftercare services are provided directly, review and update of the aftercare plan shall be conducted with the frequency of review determined by the:

1. Interdisciplinary team;

2. Patient; and

3. With the patient's permission, [the] patient's family or significant others.

(d) If the patient is referred to another agency for aftercare services, follow-up shall be conducted to determine if services are being provided.

Section 5. Provision of Outpatient Behavioral Health Services, Plan of Care, and Client Records. (1) Pursuant to Section 2(3) of this administrative regulation, a chemical dependency treatment program may provide one (1) or more of the following outpatient behavioral health services for individuals with a substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis:

(a) Screening, which shall be provided <u>face-to-face or via</u> <u>telehealth</u> by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate to determine the:

1. Likelihood that an individual has a substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis; and

2. Need for an assessment;

(b) Assessment, which shall:

1. Be provided <u>face-to-face or via telehealth</u> by a behavioral health professional, behavioral health professional under clinical supervision, a certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate who gathers information and engages in a process with the client, thereby enabling the professional to:

a. Establish the presence or absence of a substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis;

b. Determine the client's readiness for change;

c. Identify the client's strengths or problem areas that

<u>could[which may]</u> affect the treatment and recovery processes; and d. Engage the client in developing an appropriate treatment relationship:

 Establish or rule out the existence of a clinical disorder or service need;

3. Include working with the client to develop a plan of care if a clinical disorder or service need is assessed; and

4. Not include psychological or psychiatric evaluations or assessments;

(c) Psychological testing, which shall:

1. Be performed <u>face-to-face or via telehealth</u> by a licensed psychologist, licensed psychological associate, or licensed psychological practitioner; and

2. Include a psychodiagnostic assessment of personality, psychopathology, emotionality, or intellectual disabilities, and interpretation and written report of testing results;

(d) Crisis intervention, which:

1. Shall be a therapeutic intervention for the purpose of immediately reducing or eliminating the risk of physical or emotional harm to the client or another individual;

2. Shall consist of clinical intervention and support services necessary to provide integrated crisis response, crisis stabilization interventions, or crisis prevention activities;

3. Shall be provided:

a. [On-site at the chemical dependency treatment program's facility;

 $\ensuremath{\textbf{b}}\xspace{-}$] As an immediate relief to the presenting problem or threat; and

<u>b.[e.]</u> In a face-to-face, one (1) on one (1) encounter or as a comparable service provided via telehealth;

4. [May include verbal de-escalation, risk assessment, or cognitive therapy;

5.] Shall be provided by a:

a. Behavioral health professional;

b. Behavioral health professional under clinical supervision;

c. Certified alcohol and drug counselor;

d. Licensed clinical alcohol and drug counselor; or

e. Licensed clinical alcohol and drug counselor associate;

 $\underline{5.[6.]}$ Shall be followed by a referral to noncrisis services, if applicable; and

6.[7.] May include:

a. Further service prevention planning, including:

(i) Lethal means reduction for suicide risk; or

(ii) Substance use disorder relapse prevention; or

b. Verbal de-escalation, risk assessment, or cognitive therapy;

(e) Mobile crisis services, which shall:

1. Be available twenty-four (24) hours a day, seven (7) days a week, every day of the year;

2. Be provided for a duration of less than twenty-four (24) hours;

3. Not be an overnight service;

4. Be a multi-disciplinary team based intervention that ensures access to acute substance use services and supports to:

a. Reduce symptoms or harm; or

b. Safely transition an individual in an acute crisis to appropriate, least restrictive level of care;

5. Involve all services and supports necessary to provide:

a. Integrated crisis prevention;

b. Assessment and disposition;

c. Intervention;

d. Continuity of care recommendations; and

e. Follow-up services;

6. Be provided in a home or community setting by a:

a. Behavioral health professional;

b. Behavioral health professional under clinical supervision;

c. Certified alcohol and drug counselor;

d. Licensed clinical alcohol and drug counselor; or

e. Licensed clinical alcohol and drug counselor associate; and

7. Ensure access to a board certified or board-eligible psychiatrist twenty-four (24) hours a day, seven (7) days a week,

every day of the year;

(f) Day treatment, which shall:

1. Be a nonresidential, intensive treatment program designed

for children who:

a. Have a substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis;

b. Are under twenty-one (21) years of age; and

c. Are at high risk of out-of-home placement due to a behavioral health issue;

2. Consist of an organized, behavioral health program of treatment and rehabilitative services for substance use disorder or co-occurring disorder in which substance use disorder is the primary diagnosis;

3. Have unified policies and procedures that address the organization's philosophy, admission and discharge criteria, admission and discharge process, staff training, and integrated case planning;

4. Include [the following]:

a. Individual outpatient therapy, family outpatient therapy, or group outpatient therapy;

b. Behavior management and social skill training;

c. Independent living skills that correlate to the age and development stage of the client; and

d. Services designed to explore and link with community resources before discharge and to assist the client and family with transition to community services after discharge;

5. Be provided [as follows]:

a. In collaboration with the education services of the local education authority including those provided through 20 U.S.C. 1400 et seq. (Individuals with Disabilities Education Act) or 29 U.S.C. 701 et seq. (Section 504 of the Rehabilitation Act);

b. On school days and during scheduled breaks;

c. In coordination with the child's individual educational plan or Section 504 plan if the child has an individual educational plan or Section 504 plan;

d. By personnel that includes a behavioral health professional, a behavioral health professional under clinical supervision, a certified alcohol and drug counselor, a licensed clinical alcohol and drug counselor, a licensed clinical alcohol and drug counselor associate, or a peer support specialist; and

e. According to a linkage agreement with the local education authority that specifies the responsibilities of the local education authority and the day treatment provider; and

6. Not include a therapeutic clinical service that is included in a child's individualized education plan;

(g) Peer support, which shall:

1. Be provided by a peer support specialist;

2. Be structured and scheduled nonclinical therapeutic activity with a client or group of clients;

3. Promote socialization, recovery, self-advocacy, preservation, and enhancement of community living skills; and

4. Be identified in the client's plan of care <u>developed through a</u> person-centered planning process;

(h) Intensive outpatient program services, which shall:

1. Offer a multi-modal, multi-disciplinary structured outpatient treatment program that is more intensive than individual outpatient therapy, group outpatient therapy, or family outpatient therapy;

2. Be provided at least:

 $\underline{a.}$ Three (3) hours per day at least three (3) days per week \underline{for} $\underline{adults};$ \underline{or}

b. Six (6) hours per week for adolescents;

3. Include [the following]:

a. Individual outpatient therapy;

b. Group outpatient therapy;

c. Family outpatient therapy unless contraindicated;

d. Crisis intervention; or

e. Psycho-education during which the client or client's family member shall be:

(i) Provided with knowledge regarding the client's diagnosis, the causes of the condition, and the reasons why a particular treatment might be effective for reducing symptoms; and

(ii) Taught how to cope with the client's diagnosis or condition in a successful manner;

4. Include a treatment plan, which shall:

a. Be individualized; and

b. Focus on stabilization and transition to a lower level of care;

5. Be provided by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate;

6. Include access to a board-certified or board-eligible psychiatrist for consultation;

7. Include access to a psychiatrist, other physician, or advanced practice registered nurse for medication prescribing and monitoring; and

8. Be provided in a setting with a minimum client-to-staff ratio of ten (10) clients to one (1) staff person;

(i) Individual outpatient therapy, which shall:

1. Be provided to promote the:

a. Health and wellbeing of the client; or

b. Recovery from a substance related disorder;

2. Consist of:

a. A face-to-face encounter or telehealth consultation with the client; and

b. A behavioral health therapeutic intervention provided in accordance with the client's plan of care;

3. Be aimed at:

a. Reducing adverse symptoms;

b. Reducing or eliminating the presenting problem of the client; and

c. Improving functioning;

4. Not exceed three (3) hours per day <u>alone or in combination</u> with any other outpatient therapy unless additional time with the client is medically necessary in accordance with 907 KAR 3:130; and

5. Be provided by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate;

(j) Group outpatient therapy, which shall:

1. Be provided to promote the:

a. Health and wellbeing of the client; or

b. Recovery from a substance related disorder;

2. Consist of a face-to-face behavioral health therapeutic intervention provided in accordance with the client's plan of care;

3. Excluding multi-family group therapy, be provided in a group setting of nonrelated individuals, not to exceed twelve (12) individuals in size. For group outpatient therapy, a nonrelated individual means any individual who is not a spouse, significant other, parent or person with custodial control, child, sibling, stepparent, stepchild, step-brother, step-sister, father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, sister-inlaw, grandparent, or grandchild;

4. Focus on the psychological needs of the client as evidenced in the client's plan of care;

5. Center on goals including building and maintaining healthy relationships, personal goals setting, and the exercise of personal judgment;

6. Not include physical exercise, a recreational activity, an educational activity, or a social activity;

7. Not exceed three (3) hours per day <u>alone or in combination</u> <u>with any other outpatient therapy</u> [per client] unless additional time is medically necessary in accordance with 907 KAR 3:130;

8. Ensure that the group has a deliberate focus and defined course of treatment;

9. Ensure that the subject of group outpatient therapy shall be related to each client participating in the group; and

10. Be provided by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate who shall maintain individual notes regarding each client within the group in the client's record;

(k) Family outpatient therapy, which shall:

1. Consist of a [face-to-face] behavioral health therapeutic intervention provided <u>face-to-face</u> or via <u>telehealth</u> through scheduled therapeutic visits between the therapist, at least one (1) member of the client's family, and the client unless the client's presence is not required in his or her plan of care;

2. Address issues interfering with the relational functioning of the family;

3. Seek to improve interpersonal relationships within the client's home environment;

4. Be provided to promote the health and wellbeing of the client or recovery from a substance use disorder;

5. Not exceed three (3) hours per day <u>alone or in combination</u> <u>with any other outpatient therapy</u> [per client] unless additional time is medically necessary in accordance with 907 KAR 3:130; and

6. Be provided by a behavioral health professional, a behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor associate;

(I) Collateral outpatient therapy, which shall consist of a faceto-face <u>or telehealth</u> behavioral health consultation:

1. With a parent, caregiver, or person who has custodial control of a client under the age of twenty-one (21), household member, legal representative, school personnel, or treating professional;

2. Provided by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor associate; and

3. Provided upon the written consent of a parent, caregiver, or person who has custodial control of a client under the age of twenty-one (21). Documentation of written consent shall be signed and maintained in the client's record;

(m) Screening, brief intervention, and referral to treatment for substance use disorders, which shall:

1. Be provided face-to-face or via telehealth;

<u>2.</u> Be an evidence-based early intervention approach for an individual with non-dependent substance use prior to the need for more extensive or specialized treatment;

3.[2.] Consist of:

a. Using a standardized screening tool to assess the individual for risky substance use behavior;

b. Engaging a client who demonstrates risky substance use behavior in a short conversation, providing feedback and advice; and

c. Referring the client to therapy or other services that address substance use if the client is determined to need additional services; and

<u>4.[3-]</u> Be provided by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor associate; [er]

(n) Targeted case management services, which shall:

1. Include services to an:

a. Adult or a child with substance use disorder; or

b. Adult or child with co-occurring mental health or substance use disorder and chronic or complex physical health issues;

2. Be provided by a <u>targeted</u> case manager [as described in subsection (2) or (3) of this section]; and

3. Include the following assistance:

a. Comprehensive assessment and reassessment of client needs to determine the need for medical, educational, social, or other services. The reassessment shall be conducted annually or more often if needed based on changes in the client's condition;

b. Development of a specific care plan <u>that[which]</u> shall be based on information collected during the assessment and revised if needed upon reassessment;

c. Referral and related activities, which may include:

(i) Scheduling appointments for the client to help the individual obtain needed services; or

(ii) Activities that help link the client with medical, social, educational providers, or other programs and services <u>that[which]</u> address identified needs and achieve goals specified in the care plan;

d. Monitoring, which shall be face-to-face and occur no less than once every three (3) months to determine that:

(i) Services are furnished according to the client's care plan;

(ii) Services in the care plan are adequate; and

(iii) Changes in the needs or status of the client are reflected in the care plan; and

e. Contacts with the client, family members, service providers, or others are conducted as frequently as needed to help the client:

(i) Access services;(ii) Identify needs and supports to assist the client in obtaining

services; and

(iii) Identify changes in the client's needs;

(o) Service planning, which shall be provided face-to-face by a behavioral health professional, behavioral health professional under clinical supervision, certified alcohol and drug counselor, licensed clinical alcohol and drug counselor, or licensed clinical alcohol and drug counselor, any of which shall be of the client's choosing to:

<u>1. Assist the client in creating an individualized plan for</u> services and developing measurable goals and objectives needed for maximum reduction of the effects of a substance use disorder or co-occurring disorder:

2. Restore the client's functional level to the client's best possible functional level; and

3. Develop a service plan, which:

a. Shall be directed and signed by the client; and

b. May include:

(i) A mental health advance directive being filed with a local hospital;

(ii) A crisis plan; or

(iii) A relapse prevention strategy or plan; or

(p) Medication assisted treatment with behavioral health therapy, which shall:

<u>1. Exclude methadone-based treatment restricted to licensure</u> in accordance with 908 KAR 1:370 and 908 KAR 1:374;

2. Require an advanced practice registered nurse, a physician, or a physician assistant who prescribes FDA-approved drugs for the treatment of opioid addiction in adult patients to:

a. Document in the patient's record whether or not the patient is compliant with prescribed dosing as evidenced by the results of:

(i) A KASPER report released to the practitioner pursuant to KRS 218A.202(7)(e); and

(ii) Drug testing; and

b. Comply with the prescribing and dispensing standards in 201 KAR 9:270 or 201 KAR 20:065 for FDA-approved drugs used for the treatment of opioid addiction; and

<u>3. Include individual and group outpatient therapy as a service</u> and document monitoring of compliance with recommended nonmedication therapies.

(2) [A case manager who provides targeted case management services to clients with a substance use disorder shall:

(a) Be a certified alcohol and drug counselor, meet the grandfather requirements of 907 KAR 15:040, Section 4(1)(a)3, or have a bachelor's degree in a human services field, including:

1. Psychology;

- 2. Sociology;
- 3. Social work;

4. Family studies;

- 5. Human services;
- 6. Counseling;
- 7. Nursing;
- 8. Behavioral analysis;
- 9. Public health;
- 10. Special education;
- 11. Gerontology;
- 12. Recreational therapy;

13. Education;

14. Occupational therapy;

- 15. Physical therapy;
- 16. Speech-language pathology;
- 17. Rehabilitation counseling; or

18. Faith-based education;

(b)1. Have a minimum of one (1) year of full-time employment working directly with adolescents or adults in a human service setting after completion of the requirements described in paragraph (a) of this subsection; or 2. Have a master's degree in a human services field as described in paragraph (a) of this subsection;

(c)1. Have successfully completed case management training in accordance with 908 KAR 2:260; and

2. Successfully complete continuing education requirements in accordance with 908 KAR 2:260; and

(d) Be supervised by a behavioral health professional who:

1. Has completed case management training in accordance with 908 KAR 2:260; and

2. Has supervisory contact at least two (2) times per month with at least one (1) of the contacts on an individual in person basis.

(3) A case manager who provides targeted case management services to clients with a mental health or substance use disorder and chronic or complex physical health issues shall:

(a) Meet the requirements of subsection (2)(a) of this section;

(b)1. After completion of a bachelor's degree, have a minimum of five (5) years of experience providing service coordination or referring clients with complex behavioral health needs and cooccurring disorders or multi-agency involvement to community based services; or

2. After completion of a master's degree in a human services field as described in subsection (2)(a) of this section, have a minimum of two (2) years of experience providing service coordination or referring clients with complex behavioral health needs and co-occurring disorders or multi-agency involvement to community based services;

(c)1. Have successfully completed case management training in accordance with 908 KAR 2:260; and

2. Successfully complete continuing education requirements in accordance with 908 KAR 2:260; and

(d) For a bachelor's level case manager, be supervised by a behavioral health professional who:

1. Has completed case management training in accordance with 908 KAR 2:260; and

2. Has supervisory contact at least three (3) times per month with at least two (2) of the contacts on an individual in person basis.

(4)] Plan of care.

(a) Each client receiving outpatient behavioral health services from a chemical dependency treatment program shall have an individual plan of care signed by a behavioral health professional.

(b) A plan of care shall:

1. Describe the services to be provided to the client, including the frequency of services;

2. Contain measurable goals for the client to achieve, including the expected date of achievement for each goal;

3. Describe the client's functional abilities and limitations or diagnosis listed in the current edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders;

4. Specify each staff member assigned to work with the client;

5. Identify methods of involving the client's family or significant others if indicated;

6. <u>Establish[Specify]</u> criteria to be met for termination of treatment;

7. Include any referrals necessary for services not provided directly by the chemical dependency treatment program; and

8. State the date scheduled for review of the plan.

(c) The client shall participate to the maximum extent feasible in the development of his or her plan of care, and the participation shall be documented in the client's record.

(d)1. The initial plan of care shall be developed through multidisciplinary team conferences at least thirty (30) days following the first ten (10) days of treatment.

2. The plan of care for individuals receiving intensive outpatient program services shall be reviewed every thirty (30) days thereafter and updated every sixty (60) days or earlier if clinically indicated.

3. Except for intensive outpatient program services, the plan of care for individuals receiving any other outpatient behavioral health service <u>established[described]</u> in subsection (1) of this section shall be reviewed and updated every six (6) months or earlier if clinically indicated.

4. The plan of care and each review and update shall be signed by the participants in the multidisciplinary team conference that developed it.

(3)[(5)] Client Records.

(a) A client record shall be maintained for each individual receiving outpatient behavioral health services.

(b) Each entry shall be current, dated, signed, and indexed according to the service received.

(c) Each client record shall contain:

1. An identification sheet, including the client's name, address, age, gender, marital status, expected source of payment, and referral source;

2. Information on the purpose for seeking a service;

3. If applicable, consent of appropriate family members or guardians for admission, evaluation, and treatment;

4. Screening information pertaining to the mental health or substance use disorder;

5. If applicable, a psychosocial history;

6. If applicable, staff notes on services provided;

7. If applicable, the client's plan of care,

8. If applicable, disposition;

9. If applicable, assigned status;

10. If applicable, assigned therapists, and

11. If applicable, a termination study <u>restating[recapitulating]</u> findings and events during treatment, clinical impressions, and condition on termination.

Section 6. Compliance with Building Codes, Ordinances, and Regulations; Chemical Dependency Treatment Program's Inpatient Facility. (1) The provisions of this administrative regulation shall not relieve the licensee from compliance with building codes, ordinances, and administrative regulations <u>that[which]</u> are enforced by city, county, or state jurisdictions.

(2) The following shall apply:

(a) Requirements for safety pursuant to the National Fire Protection Association 101, Life Safety Code adopted by the Kentucky Department of Housing, Buildings and Construction;

(b) Requirements for plumbing pursuant to 815 KAR 20:010 through <u>815 KAR 20:195[20:191];</u> and

(c) Requirements for making buildings and facilities accessible to and usable by persons with disabilities.

(3) The facility shall be approved by the Fire Marshal's Office before a license or license renewal is granted.

(4) The facility shall receive necessary approval from appropriate agencies prior to occupancy and licensure.

(5) Physical and sanitary environment.

(a) The physical plant and overall facility environment shall be maintained to protect the safety and well-being of patients, personnel, and visitors.

(b) A person shall be designated responsible for services and for the establishment of practices and procedures <u>for[in each of the following areas]</u>:

1. Plant maintenance;

2. Laundry operations either on site or off site; and

3. Housekeeping.

(c) The facility buildings, equipment, and surroundings shall be kept in good repair, neat, clean, free from accumulation of dirt and rubbish, and free from foul, stale, or musty odors.

1. An adequate number of housekeeping and maintenance personnel shall be provided.

2. Written housekeeping procedures shall be established for each area, and copies shall be available to personnel.

3. Equipment and supplies shall be provided for cleaning surfaces. The equipment shall be maintained in a safe, sanitary condition.

4. A hazardous cleaning solution, compound, or substance shall be labeled, stored in an approved container, and kept separate from nonhazardous cleaning materials.

5. The facility shall be free from insects, rodents, and their harborage.

6. Garbage and trash shall be stored in closed containers in an area separate from an area used for the preparation or storage of food.

7. The garbage and trash area shall be cleaned regularly and shall be in good repair.

(d) The facility shall have available at all times a quantity of linen essential to the proper care and comfort of residents.

1. Clean linen and clothing shall be stored in clean, dry, dustfree areas designated exclusively for this purpose.

2. Soiled linen and clothing shall be placed in suitable bags or closed containers and stored in a separate area ventilated to the exterior of the building.

Section 7. Chemical Dependency Treatment Program's Inpatient Facility Requirements and Special Conditions. (1) Patient rooms. Each patient room shall meet the [following] requirements established in this subsection.[:]

(a) The maximum room capacity shall be six (6) patients.

(b) The minimum room area, exclusive of toilet room, closet, locker, wardrobe, or vestibule, shall be:

1. 100 square feet for a one (1) bed room; and

2. Eighty (80) square feet per bed for multibed rooms.

(c)1. Partitions, cubicle curtains, or placement of furniture shall be used to provide privacy in a multiperson room.

2. Ample closet and drawer space shall be provided for the storage of each patient's personal property.

(d) The placement of a patient in a multibed room shall be appropriate to the age and program needs of the patient.

(2) Lavatory.

(a) In a single or multibed room with a private toilet room, the lavatory may be located in the toilet room.

(b) If two (2) or more patients share a common toilet<u></u> a lavatory shall be provided in each patient room.

(3) Centralized toilet area.

(a) If a centralized toilet area is used, the facility shall provide, for each gender on each floor, <u>at least</u> one (1) toilet for each eight (8) residents or a major fraction thereof.

(b) Toilets shall be separated by a permanent partition and at least one (1) toilet for each gender shall be designed for wheelchair use.

(4) Patient baths.

(a) There shall be $\underline{at \ least}$ one (1) shower stall or one (1) bathtub for each fifteen (15) patients not individually served.

(b) Each bathtub or shower shall provide space for the private use of the fixture and for dressing.

(5) The patient shall be encouraged to take responsibility for maintaining his or her own living quarters and for other day-to-day housekeeping activities of the program, as appropriate to his or her clinical status.

(6) Dietary service.

(a) The facility shall have a dietary department, organized, directed, and staffed to provide quality food service and optimal nutritional care.

1. The dietary service shall be directed on a full-time basis by an individual who, by education or specialized training and experience, is knowledgeable in food service management.

2. The dietary service shall have at least one (1) dietician licensed pursuant to KRS 310.021 to supervise the nutritional aspects of patient care and to approve menus on at least a consultative basis.

3. If food service personnel are assigned a duty outside the dietary department, the duty shall not interfere with the sanitation, safety, or time required for regular dietary assignments.

(b)1. A menu shall be planned, written, and rotated to avoid repetition.

2. Nutritional needs shall be met in accordance with:

a. Recommended dietary allowances of the Food and Nutrition Board of the National Research Council of the National Academy of Sciences; and

b. Physician orders, if applicable.

(c)1. A meal served shall correspond with the posted menu.

2. If a change in the menu is necessary;

a. Substitution shall provide equal nutritive value; and

b. The change shall be recorded on the menu.

3. A menu shall be kept on file for <u>at least</u> thirty (30) days.

(d) Food shall be:

1. Prepared by methods that conserve nutritive value, flavor, and appearance; and

2. Served at the proper temperature.

(e)1. At least three (3) meals shall be served daily with not more than a fifteen (15) hour span between a substantial evening meal and breakfast.

2. Each meal shall be served at a regular time and a nourishing between-meal or bedtime snack <u>shall be</u> offered.

(f) Food services shall be provided in accordance with 902 KAR 45:005.

Section 8. Physical environment of an off-campus extension or separate building on the campus of the chemical dependency treatment program's inpatient facility where outpatient behavioral health services are provided. (1) Accessibility. The off-campus extension or separate building on the campus of the chemical dependency treatment program's inpatient facility shall meet requirements for making buildings and facilities accessible to and usable by individuals with physical disabilities pursuant to KRS 198B.260 and 815 KAR 7:120.

(2) Physical location and overall environment.

(a) The program shall:

1. Comply with building codes, ordinances, and administrative regulations <u>that[which]</u> are enforced by city, county, or state jurisdictions;

2. Display a sign that can be viewed by the public that contains the facility name, hours of operation, and a street address;

3. Have a publicly listed telephone number and a dedicated phone number to send and receive faxes with a fax machine that shall be operational twenty-four (24) hours per day;

4. Have a reception and waiting area;

5. Provide a restroom; and

6. Have an administrative area.

(b) The condition of the physical location and the overall environment shall be maintained in a manner that assures the safety and well-being of clients, personnel, and visitors.

(3) Prior to occupancy, the facility shall have final approval from appropriate agencies.

ADAM D. MATHER, Inspector General

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 2, 2020

FILED WITH LRC: October 13, 2020 at 12:30 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on December 21, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky, 40621. Individuals interested in attending this hearing shall notify this agency in writing by December 14, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until December 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. In accordance with KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact persons: Kara Daniel or Donna Little (1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes minimum licensure requirements for the operation of chemical dependency treatment programs, including programs that elect to provide outpatient behavioral health services for individuals with a substance use disorder (SUD) or co-occurring disorder in which SUD is the primary diagnosis.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with KRS 216B.042(1), which requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, including licensure standards and procedures to ensure safe, adequate, and efficient health services. Additionally, this administrative regulation is necessary to comply with KRS 216B.105, which, unless otherwise exempt, prohibits the operation of a health facility without a Cabinet-issued license.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216B.042 by establishing minimum licensure requirements for the operation of chemical dependency treatment programs.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing standards for licensed chemical dependency treatment programs.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment is being filed concurrently with the Department for Medicaid Services administrative regulation, 907 KAR 15:080, Coverage provisions and requirements regarding chemical dependency treatment center services. Key changes to this administrative regulation, 902 KAR 20:160, are as follows:

Amends Section 1(1)(a) to clarify that a psychiatrist, as included under the definition of "behavioral health professional", may be certified or eligible to apply for certification by the American Osteopathic Board of Neurology;

Updates the definition of "peer support specialist" to include a registered alcohol and drug peer support specialist, and adds clarifying language related to the supervision of peer support specialists;

Adds "targeted case manager" to Section 1, Definitions, and amends Section 5(2) and (3) to delete unnecessarily duplicative language related to case managers because the training requirements and qualifications for targeted case managers are established in 908 KAR 2:260;

Replaces the "detoxification" with "medically monitored intensive inpatient services" and requires the patient to meet the diagnostic criteria for substance intoxication or withdrawal disorder as established by the most recent version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) for alcohol, tobacco, and other drug use, and also meet the dimensional criteria for medically monitored intensive inpatient services in accordance with the most recent version of The American Society of Addiction Medicine (ASAM) Criteria;

Allows for screening, assessment, psychological testing, crisis intervention, individual outpatient therapy, family outpatient therapy, collateral outpatient therapy, and screening, brief intervention, and referral to treatment for SUD to be provided via telehealth;

Removes the requirement for crisis intervention to be provided on-site at the program's facility;

Clarifies the number of hours per week that intensive outpatient services may be provided to adolescents; and

Adds service planning and medication assisted treatment as services that may be provided by a chemical dependency treatment program.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to align with the proposed changes to 907 KAR 15:080 and otherwise address necessary housekeeping changes.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of KRS 216B.042 because it establishes minimum licensure requirements for the operation of chemical dependency treatment centers.

(d) How the amendment will assist in the effective administration of the statutes: This amendment assists in the effective administration of the statutes by establishing standards for licensed chemical dependency treatment centers.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects the three (3) currently licensed chemical dependency treatment centers.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Entities licensed in accordance with this administrative regulation are required to comply with the standards established by this administrative regulation, including the following:

Must operate a structured inpatient program to provide medical, social, diagnostic, and treatment services to individuals with SUD;

Must ensure that inpatient services are provided under the medical direction of a physician;

Must provide continuous nursing services;

May provide one (1) or more of the following outpatient behavioral health services: screening, assessment, psychological testing, crisis intervention, mobile crisis services, day treatment, peer support, intensive outpatient program services, individual outpatient therapy, group outpatient therapy, family outpatient therapy, collateral outpatient therapy, screening, brief intervention, and referral to treatment for SUD, targeted case management, service planning, or medication assisted treatment;

Must be in compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the chemical dependency treatment program;

Must have a governing authority;

Must have a program administrator, interdisciplinary team, and treatment director;

Must maintain administrative policies, including patient care, patient rights, and personnel policies;

Must have a program for in-service training;

Must maintain client records in accordance with federal privacy and confidentiality rules;

Must have a process for quality assurance;

Must comply with requirements for administration and storage of medications;

Must post a daily schedule of activities;

Must comply with the requirements for providing medically monitored intensive inpatient services, rehabilitation services, physical examination of the patient, psychosocial history, and development of that patient's treatment plan and aftercare plan;

Must maintain compliance with applicable state and local laws relating to construction, plumbing, safety, and sanitation; and

Must maintain compliance with basic facility requirements for patient rooms, bathrooms, meal service, and overall physical environment.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no additional costs to chemical dependency treatment centers to comply with this amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Licensed chemical dependency treatment centers may enroll in the Kentucky Medicaid Program for reimbursement of covered services provided to Medicaid recipients in need of medically monitored intensive inpatient services, or outpatient services for the treatment of substance use disorder (SUD) or co-occurring disorder in which SUD is the primary diagnosis.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional costs to the cabinet for implementation of this administrative regulation.

(b) On a continuing basis: There are no additional costs to the cabinet for implementation of this administrative regulation on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State general funds and agency monies are used to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish or increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applicable as compliance with this administrative regulation applies equally to all individuals or entities who elect to be regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts the Cabinet for Health and Family Services, Office of Inspector General, and licensed chemical dependency treatment centers.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.042 and 216B.105

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? In accordance with 902 KAR 20:008, Section 3(2), the Cabinet collects a fee of \$1,000 + \$25 per bed from each chemical dependency treatment program. In accordance with this administrative regulation, the Cabinet collects \$250 for each outpatient extension site. These fees are existing provisions and have not been amended in this amendment.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? In accordance with 902 KAR 20:008, Section 3(2), the Cabinet collects a fee of \$1,000 + \$25 per bed from each chemical dependency treatment program. In accordance with this administrative regulation, the Cabinet collects \$250 for each outpatient extension site. These fees are existing provisions and have not been amended in this amendment.

(c) How much will it cost to administer this program for the first year? This amendment imposes no additional costs on the administrative body.

(d) How much will it cost to administer this program for subsequent years? This amendment imposes no additional costs on the administrative body.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): See response above.

Expenditures (+/-): This administrative regulation is anticipated to have minimal fiscal impact to the cabinet. Other Explanation:

. . . .

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 42 C.F.R. Part 2, 45 C.F.R. Parts 160, 164, 42 U.S.C. 1320d-2 - 1320d-8, 42 U.S.C. 209ee-3, 20 U.S.C. 1400, 29 U.S.C. 701

2. State compliance standards. KRS 216B.042, 216B.105

3. Minimum or uniform standards contained in the federal mandate. 42 C.F.R. Part 2 prohibits programs from disclosing any information that would identify a person as having or having had substance use disorder, unless that person provides written consent. 45 C.F.R. 160, 164, and 42 U.S.C. 1320d-2 – 1320d-8 establish the HIPAA privacy rules to protect individuals' medical records and other personal health information. 42 U.S.C. 209ee-3 pertains to the confidentiality of patient records. 20 U.S.C. 1400 is the Individuals with Disabilities Education Act. 29 U.S.C. 701 is Section 504 of the Rehabilitation Act.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation does not impose requirements that are more strict than federal laws or regulations.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Not applicable.

CABINET FOR HEALTH AND FAMILY SERVICES Office of Inspector General Division of Health Care (Amendment)

902 KAR 20:440. Facilities specifications, operation and services; residential crisis stabilization units.

RELATES TO: KRS <u>17.500</u>, 200.503(2), 210.005, <u>216B.050</u>, <u>216B.105(2)</u>, <u>309.080(4)</u>, <u>309.0831</u>, <u>309.130(2)</u>, <u>311.571</u>, <u>311.840</u> - <u>311.862</u>, <u>314.042</u>, <u>319.050</u>, <u>319.056</u>, <u>319.064</u>, <u>319C.010</u>, <u>335.080</u>, <u>335.100</u>, <u>335.300</u>, <u>335.500</u>, <u>439.3401</u>, 45 C.F.R. Parts 160, 164, 42 U.S.C. <u>1320d-2</u> – <u>1320d-8</u>, 42 U.S.C. <u>209ee-3</u>, 42 C.F.R. Part 2

STATUTORY AUTHORITY: KRS 216B.042

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, which includes establishing licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. This administrative regulation establishes minimum licensure requirements for the operation of residential crisis stabilization units that[which] serve at-risk children or children with severe emotional disabilities, at-risk adults or adults with severe mental illness, or individuals with substance use disorder or co-occurring disorders.

Section 1. Definitions. (1) "Behavioral health professional" means:

(a) A psychiatrist licensed under the laws of Kentucky to practice medicine or osteopathy, or a medical officer of the government of the United States while engaged in the performance of official duties, who is certified or eligible to apply for certification by the American Board of Psychiatry and Neurology, Inc. or the American Osteopathic Board of Neurology and Psychiatry;

(b) A physician licensed in Kentucky to practice medicine or osteopathy in accordance with KRS 311.571;

(c) A psychologist licensed and practicing in accordance with KRS 319.050;

(d) A certified psychologist with autonomous functioning or licensed psychological practitioner practicing in accordance with KRS 319.056;

(e) A clinical social worker licensed and practicing in accordance with KRS 335.100;

(f) An advanced practice registered nurse licensed and practicing in accordance with KRS 314.042;

(g) A physician assistant <u>as defined by KRS</u> <u>311.840(3)[licensed under KRS 311.840 to 311.862];</u>

(h) A <u>licensed</u> marriage and family therapist <u>as defined by</u> [licensed and practicing in accordance with] KRS 335.300(<u>2</u>);

(i) A <u>licensed</u> professional clinical counselor <u>as defined by</u> [licensed and practicing in accordance with] KRS 335.500(3); or

(j) A licensed professional art therapist as defined by KRS 309.130(2).

(2) "Behavioral health professional under clinical supervision" means a:

(a) Psychologist certified and practicing in accordance with KRS 319.056;

(b) Licensed psychological associate licensed and practicing in accordance with KRS 319.064;

(c) Marriage and family <u>therapy[therapist]</u> associate as defined by KRS 335.300(3);

(d) Social worker certified and practicing in accordance with KRS 335.080;

(e) Licensed professional counselor associate as defined by KRS 335.500(4); or

(f) Licensed professional art therapist associate as defined by KRS 309.130(3).

(3) "Cabinet" means the Cabinet for Health and Family Services.

(4) "Certified alcohol and drug counselor" is defined by KRS 309.080(2).

(5) "Chemical restraint" means the use of a drug that:

(a) Is administered to manage a resident's behavior in a way that reduces the [safety] risk to the resident or others;

(b) Has the temporary effect of restricting the resident's freedom of movement; and

(c) Is not a standard treatment for the resident's medical or psychiatric condition.

(6) "Child with a severe emotional disability" is defined by KRS 200.503(3).

(7) "Crisis stabilization unit" means a community-based facility that is not part of an inpatient unit and <u>that[which]</u> provides crisis services to no more than <u>sixteen (16)</u> [twelve (12)] clients who require overnight stays.

(8) <u>"Licensed clinical alcohol and drug counselor" is defined by</u> KRS 309.080(4);

(9) "Mechanical restraint" means any device attached or adjacent to a resident's body that he or she cannot easily remove that restricts freedom of movement or normal access to his or her body.

(10) [(9)] "Peer support specialist" means a paraprofessional who:

(a) <u>Is a registered alcohol and drug peer support specialist in</u> accordance with KRS 309.0831; or

(b)1. Meets the application, training, examination, and supervision requirements of 908 KAR 2:220, 908 KAR 2:230, or 908 KAR 2:240; and

2.[(b)] Works under the supervision of one (1) of the following:

a.[1.] Physician;

b.[2.] Psychiatrist;

c.[3.] Licensed psychologist;

d.[4.] Licensed psychological practitioner;

e.[5.] Licensed psychological associate;

f.[6-] Licensed clinical social worker;

g.[7-] Licensed marriage and family therapist;

h.[8-] Licensed professional clinical counselor;

i.[9.] Certified social worker;

[[[40.]] Licensed marriage and family <u>therapy[therapist]</u> associate;

k.[11.] Licensed professional counselor associate;

I.[12.] Licensed professional art therapist;

m.[13.] Licensed professional art therapist associate;

n.[14.] Advanced practice registered nurse;

o.[15.] Physician assistant; [or]

p.[16.] Certified alcohol and drug counselor; or

g. Licensed clinical alcohol and drug counselor.

(11) [(10)] "Personal restraint" means the application of physical force without the use of any device for the purpose of

restraining the free movement of a resident's body and does not include briefly holding without undue force a resident in order to calm or comfort him or her or holding a resident's hand to safely escort him or her from one (1) area to another.

(12) [(11)] "Seclusion" means the involuntary confinement of a resident alone in a room or in an area from which the resident is physically prevented from leaving.

(13) [(12)] (12) "Serious mental illness", "severe mental illness", or "SMI" means a diagnosis of a major mental disorder as included in the current edition of the Diagnostic and Statistical Manual of Mental Disorders under:

(a) Schizophrenia spectrum and other psychotic disorders;

(b) Bipolar and related disorders;

(c) Depressive disorders; or

(d) Post-traumatic stress disorders (under trauma and stressor related disorders) ["Severe mental illness" means the conditions defined by KRS 210.005(2) and (3)].

(14) [(13)] "Substance use disorder" is defined by KRS 222.005(12)[means a cluster of cognitive, behavioral, and physiological symptoms resulting from use of a substance which the individual continues to take despite experiencing substancerelated problems as a result, including:

(a) Intoxication;

(b) Withdrawal; or

(c) A substance induced mental health disorder].

(15) [(14)] "Time out" means the restriction of a resident for a period of time to a designated area from which the resident is not physically prevented from leaving, for the purpose of providing the resident an opportunity to regain self-control.

Section 2. Licensure Application and Fees. (1) An applicant for initial licensure as a residential crisis stabilization unit shall submit to the Office of Inspector General:

(a) A completed Application for License to Operate a Residential Crisis Stabilization Unit; and

(b) An accompanying initial licensure fee in the amount of \$750, made payable to the Kentucky State Treasurer.

(2) At least sixty (60) calendar days prior to the date of annual renewal, a residential crisis stabilization unit shall submit to the Office of Inspector General:

(a) A completed Application for License to Operate a Residential Crisis Stabilization Unit; and

(b) An annual renewal fee of \$500, made payable to the Kentucky State Treasurer.

(3)(a) Name change. A residential crisis stabilization unit shall:

1. Notify the Office of Inspector General in writing within ten (10) calendar days of the effective date of a change in the unit's name; and

2. Submit a processing fee of twenty-five (25) dollars.

(b) Change of location. A residential crisis stabilization unit shall not change the location where the unit is <u>operating[operated]</u> until an Application for License to Operate a Residential Crisis Stabilization Unit accompanied by a fee of \$100 is filed with the Office of Inspector General.

(c) Change of ownership.

1. The new owner of a residential crisis stabilization unit shall submit to the Office of Inspector General an Application for License to Operate a Residential Crisis Stabilization Unit accompanied by a fee of \$750 within ten (10) calendar days of the effective date of the ownership change.

2. A change of ownership for a license shall be deemed to occur in accordance with the criteria of 902 KAR 20:008, Section 2(16)[if more than twenty-five (25) percent of an existing residential crisis stabilization unit or capital stock or voting rights of a corporation is purchased, leased, or otherwise acquired by one (1) person from another].

(4) To obtain approval of initial licensure or renew a license to operate a residential crisis stabilization unit, the <u>applicant or</u> licensee shall be in compliance with this administrative regulation and federal, state, and local laws and <u>administrative</u> regulations pertaining to the operation of the unit.

Section 3. [Location. If an alcohol and other drug abuse

treatment program licensed pursuant to 908 KAR 1:370 obtains separate licensure under this administrative regulation to operate a residential crisis stabilization unit, the unit shall be located off the campus of any residential treatment program licensed pursuant to 908 KAR 1:370.

Section 4.] Accreditation. (1) Unless an extension is granted pursuant to subsection (2) of this section, an entity licensed under this administrative regulation to operate a residential crisis stabilization unit shall become accredited within one (1) year of initial licensure by [one (1) of the following]:

(a) The Joint Commission;

(b) <u>The</u> Commission on Accreditation of Rehabilitation Facilities;

(c) The Council on Accreditation; or

(d) A nationally recognized accreditation organization.

(2)(a) If a residential crisis stabilization unit has not obtained accreditation in accordance with subsection (1) of this section within one (1) year of initial licensure, the facility may request a one (1) time only extension to complete the accreditation process.

(b) A request for extension shall:

1. Be submitted in writing to the Office of Inspector General at least sixty (60) days prior to the date of annual renewal;

2. Include evidence that the facility initiated the process of becoming accredited within sixty (60) days of initial licensure and is continuing its efforts to obtain accreditation; and

3. Include an estimated timeframe by which approval of accreditation is anticipated.

(3) The cabinet shall revoke the license if the residential crisis stabilization unit fails to[meet one (1) of the following requirements]:

(a)<u>1.</u> Become accredited in accordance with subsection (1) of this section; or

<u>2.a.[(b)]</u> Request an extension in accordance with subsection (2) of this section if accreditation <u>will not be[has not been]</u> obtained within one (1) year of initial licensure; <u>and</u>

b. Become accredited during the extension granted in accordance with subsection (2) of this section; or

(b)[(c)] Maintain accreditation.

(4) Proof of accreditation shall be provided to the Office of Inspector General upon receiving accreditation within one (1) year of initial licensure and at the time of annual renewal <u>established[described]</u> in Section 2(2) of this administrative regulation.

Section <u>4.[5-]</u> Administration and Operation. (1) The licensee shall be legally responsible for:

(a) The residential crisis stabilization unit;

(b) The establishment of administrative policy; and

(c) Ensuring compliance with federal, state, and local laws and <u>administrative</u> regulations pertaining to the operation of the residential crisis stabilization unit.

(2) Executive director. The licensee shall establish lines of authority and designate an executive director who:

(a) May serve in a dual role as the residential crisis stabilization unit's program director <u>established[described]</u> in subsection (5) of this section;

(b) May serve in a dual role as the executive director of a behavioral health services organization (BHSO) <u>or alcohol and other drug treatment entity (AODE)</u> if:

1. The residential crisis stabilization unit and the BHSO or AODE are owned by the same entity; and

2. The residential crisis stabilization unit has a linkage with the BHSO <u>or AODE</u> to assist with continuity of care if needed after discharge from the <u>residential</u> crisis stabilization unit;

(c) Shall be responsible for the administrative management of the residential crisis stabilization unit, including:

1. The total program of the unit in accordance with the unit's written policies; and

2. Evaluation of the unit as it relates to the needs of each resident; and

(d) Shall have a master's degree in business administration or a human services field, or a bachelor's degree in a human services field, including:

- 1. Social work;
- 2. Sociology;
- 3. Psychology;
- 4. Guidance and counseling;
- 5. Education;
- 6. Religion;
- 7. Business administration;
- 8. Criminal justice;
- 9. Public administration;
- 10. Child care administration;
- 11. Christian education;
- 12. Divinity;
- 13. Pastoral counseling;
- 14. Nursing;
- 15. Public health; or

16. Another human service field related to working with children with severe emotional disabilities or clients with severe mental illness.

(3) An executive director with a master's degree shall have a minimum of two (2) years of prior supervisory experience in a human services program.

(4) An executive director with a bachelor's degree shall have a minimum of two (2) years of prior experience in a human services program plus two (2) years of prior supervisory experience in a human services program.

(5) A residential crisis stabilization unit shall have a program director who:

(a) May serve in a dual role as the program director of a BHSO or AODE if:

1. The residential crisis stabilization unit and the BHSO or <u>AODE</u> are owned by the same entity; and

2. The residential crisis stabilization unit has a linkage with the BHSO <u>or AODE</u> to assist with continuity of care if needed after discharge from the <u>residential</u> crisis stabilization unit; and

(b) Shall be a:

- 1. Psychiatrist;
- 2. Physician;

 [Certified or] Licensed psychologist or certified psychologist with autonomous functioning;

4. Licensed psychological practitioner;

5. Advanced practice registered nurse;

6. Licensed professional clinical counselor;

7. Licensed marriage and family therapist;

8. Licensed professional art therapist;

9. Licensed [board certified] behavior analyst; or

10. Licensed clinical social worker.

Section <u>5.[6.]</u> License Procedures. An entity licensed under this administrative regulation to operate a residential crisis stabilization unit shall be subject to the provisions of 902 KAR 20:008, Sections 1, 2, 5, 6, and 7.

Section <u>6.[7-]</u> Background Checks and Personnel Records. (1) All personnel of a residential crisis stabilization unit shall:

(a) Have a criminal record check performed upon initial hire and every two (2) years through the Administrative Office of the Courts or the Kentucky State Police;

(b) Not have a criminal conviction, or plea of guilty, to a:

1. Sex crime as defined by[specified in] KRS 17.500(8);

2. Violent crime as established[specified] in KRS 439.3401;

3. Criminal offense against a minor as established[specified] in

KRS 17.500; or

4. Class A felony; and

(c) Not be listed on the [following]:

1. Central registry established by 922 KAR 1:470;

2. Nurse aide or home health aide abuse registry established by 906 KAR 1:100; or

3. Caregiver misconduct registry established by [922 KAR 5:120E and] 922 KAR 5:120.

(2)[(a)] Prior to initial hire, an out-of-state criminal background information check shall be obtained for any applicant recommended for employment in a residential crisis stabilization

unit who has resided or resides outside of the Commonwealth.[

(b) A residential crisis stabilization unit may use Kentucky's national background check system established by 906 KAR 1:190 to satisfy the background check requirements of subsections (1) and (2)(a) of this section.]

(3) A residential crisis stabilization unit shall perform annual criminal record and registry checks as <u>established[described]</u> in subsection (1) of this section on a random sample of at least twenty-five (25) percent of all personnel.

(4) A personnel record shall be kept on each staff member and shall contain[the following items]:

(a) Name and address;

(b) Verification of all training and experience, including licensure, certification, registration, or renewals;

(c) Verification of submission to the background check requirements of subsections (1), (2), and (3) of this section;

(d) Performance appraisals conducted no less than annually; and

(e) Employee incident reports.

Section <u>7.[8-]</u> Quality Assurance and Utilization Review. (1) The residential crisis stabilization unit shall have a quality assurance and utilization review program designed to:

(a) Enhance treatment and care through the ongoing objective assessment of services provided, including the correction of identified problems; and

(b) Provide an effective mechanism for review and evaluation of the service needs of each client.

(2) The need for continuing services shall be evaluated immediately upon a change in a client's service needs or a change in the client's condition to ensure that proper arrangements have been made for:

(a) Discharge;

(b) Transfer; or

(c) Referral to another service provider, if appropriate.

Section <u>8.[9.]</u> Client Grievance Policy. The residential crisis stabilization unit shall have written policies and procedures governing client grievances, which shall include[the following]:

(1) A process for filing a written client grievance;

(2) An appeals process with time frames for filing and responding to a grievance in writing;

(3) Protection for a client from interference, coercion, discrimination, or reprisal; and

(4) Conspicuous posting of the grievance procedures in a public area to inform a client of:

(a) His or her right to file a grievance;

(b) The process for filing a grievance; and

(c) The address and telephone number of the cabinet's ombudsman.

Section <u>9.[10.]</u> Services and Staffing. (1) An entity licensed under this administrative regulation to operate a residential crisis stabilization unit shall provide[the following services]:

(a) Screening <u>as established by 907 KAR 15:070, Section</u> 3(2)(a);

(b) Assessment <u>as established by 907 KAR 15:070, Section</u> <u>3(2)(b);</u>

(c) Treatment planning <u>as established by 907 KAR 15:070.</u> Section 3(2)(e);

(d) Individual [outpatient] therapy as established by 907 KAR 15:070, Section 3(2)(c);

(e) Group [outpatient] therapy as established by 907 KAR 15:070, Section 3(2)(d); and

(f) Psychiatric services.

(2) An entity licensed under this administrative regulation to operate a residential crisis stabilization unit may provide:

(a) Family therapy <u>as established by 907 KAR 15:070, Section</u> <u>3(2)(f)</u>; or

(b) Peer support by a peer support specialist <u>as established by</u> 907 KAR 15:070, Section 3(2)(g).

(3)(a) Except as provided by paragraph (b) of this subsection, the services identified in subsection (1) and (2)(a) of this section

shall be delivered by a behavioral health professional or a behavioral health professional under clinical supervision.

(b) In addition to the professionals identified in paragraph (a) of this subsection, the services identified in subsection (1)(a), (b), (d), and (e) and subsection (2)(a) of this section may be provided by a certified alcohol and drug counselor <u>or licensed clinical alcohol and drug counselor</u>.

(c)1. A residential crisis stabilization unit shall have access to a board-certified or board-eligible psychiatrist twenty-four (24) hours per day, seven (7) days per week.

2. The psychiatrist may serve more than one (1) residential crisis stabilization unit and be available through telehealth consultation.

(d) The psychiatrist shall be available to evaluate, provide treatment, and participate in treatment planning.

(4) If a crisis stabilization program serves adults with a severe mental illness or substance use disorder and children with severe emotional disabilities:

(a) The programs shall not be located on the same campus; and

(b) The children's program shall serve clients:

1. Under the age of eighteen (18); or

2. Up to the age of twenty-one (21) if developmentally appropriate for the client.

(5) A residential crisis stabilization unit shall:

(a) Provide treatment for acute withdrawal <u>as established by</u> <u>907 KAR 15:070, Section 3(2)(h)</u>, if appropriate;

(b) Complete a mental status evaluation and physical health questionnaire of the client upon admission;

(c) Have written policies and procedures for:

1. Crisis intervention; and

2. Discharge planning, which shall begin at the time of admission and aftercare planning processes;

(d) Make referrals for physical health services to include diagnosis, treatment, and consultation for acute or chronic illnesses occurring during the client's stay in the residential crisis stabilization unit or identified during the admission assessment;

(e) Have a description of linkages with behavioral health services organizations licensed under 902 KAR 20:430 or other programs, including entities licensed as an AODE, that [which]:

1. Address identified needs and achieve goals specified in the treatment plan; and

2. Help promote continuity of care after discharge;

(f) Have at least one (1) direct-care staff member assigned direct-care responsibility for:

1. Every four (4) clients during normal waking hours; and

2. Every six (6) clients during normal sleeping hours;

(g) Ensure that administrative management of the unit is provided by the unit's executive director;

(h) Provide a training program for direct-care staff pertaining to:

1. The care of clients in a <u>residential</u> crisis stabilization unit;

2. Detection and reporting of abuse, neglect, or exploitation;

3. Emergency and safety procedures;

4. Behavior management, including de-escalation training;

5. Physical management procedures and techniques;

6. Suicide prevention and care; and

7. Trauma informed care; and

(i) Assure that each client shall be:

1. In need of short-term behavior management and at risk of placement in a higher level of care;

2. Able to take care of his or her own personal needs, if an adult;

3. Medically able to participate in services; and

4. Served in the least restrictive environment available in the community.

Section <u>10.[11.]</u> Client Records. (1) A client record shall be maintained for each individual receiving services.

(2) Each entry shall be current, dated, signed, and indexed according to the service received.

(3) Each client record shall contain:

(a) An identification sheet, including the client's name, address, date of birth, gender, marital status, expected source of payment,

and referral source;

(b) Information on the purpose for seeking a service;

(c) If applicable, consent via signature of <u>an</u> appropriate family <u>member or guardian[members or guardians]</u> for admission, evaluation, and treatment;

(d) Mental status evaluation and physical health questionnaire of the client taken upon admission;

(e) Staff notes for all services provided;

(f) Documentation of treatment planning, including diagnosis and all services to be provided; and

(g) Documentation of medication prescribing and monitoring used in treatment.

(4) Ownership.

(a) Client records shall be the property of the residential crisis stabilization unit.

(b) The original client record shall not be removed from the unit except by court order or subpoena.

(c) Copies of a client record or portions of the record may be used and disclosed. Use and disclosure shall be as established by subsection (6) of this section.

(5) Retention of records. After a client's death or discharge, the completed client record shall be placed in an inactive file and <u>be</u> retained for at least the longer of:

(a) [Retained for] Six (6) years; or

(b) If a minor, three (3) years after the client reaches the age of majority <u>pursuant to KRS 2.015[under state law, whichever is the longest]</u>.

(6) Confidentiality and Security: Use and Disclosure.

(a) The residential crisis stabilization unit shall maintain the confidentiality and security of client records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 <u>through[te]</u> 1320d-8, and 45 C.F.R. Parts 160 and 164, [as <u>amended</u>,] including the security requirements mandated by [subparts A and C of] 45 C.F.R. Part 164, <u>Subparts A and C</u>, or as provided by applicable federal or state law, including 42 U.S.C. 290ee-3, and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

(b) The residential crisis stabilization unit may use and disclose client records. Use and disclosure shall be as established or required by:

1. HIPAA, 42 U.S.C. 1320d-2 <u>through[te]</u> 1320d-8, and 45 C.F.R. Parts 160 and 164; or

2. 42 U.S.C. 290ee-3, and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

(c) A residential crisis stabilization unit may establish higher levels of confidentiality and security than required by HIPAA, 42 U.S.C. 1320d-2 <u>through[te]</u> 1320d-8, and 45 C.F.R. Parts 160 and 164, or 42 U.S.C. 290ee-3, and the Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2.

Section <u>11.[42.]</u> Client Rights. (1) A residential crisis stabilization unit shall have written policies and procedures to ensure that the rights of a client are protected, including a statement of rights and responsibilities, which shall be:

(a) Provided at the time of admission:

1. To the client; or

2. If the client is a minor or incapacitated, to the client, client's parent, guardian, or other legal representative;

(b) Read to the client or client's parent, guardian, or other legal representative if requested or if either cannot read;

(c) Written in language that is understandable to the client;

(d) Conspicuously posted in a public area of the facility; and

(e) Cover the [following]:

1. [The] Right to treatment, regardless of race, religion, or ethnicity;

2. [The] Right to recognition and respect of personal dignity in the provision of all treatment and care;

3. [The] Right to be provided treatment and care in the least restrictive environment possible;

4. [The] Right to an individualized plan of care;

5. [The] Right of the client, including the client's <u>parent</u>, <u>guardian</u>, <u>or other legal representative[parents or guardian]</u> if the client is a minor <u>or incapacitated</u>, to participate in treatment planning;

6. [The] Nature of care, procedures, and treatment provided;

7. [The] Right to an explanation of risks, side effects, and benefits of all medications and treatment procedures used;

8. [The] Right to be free from verbal, sexual, physical, or mental abuse; and

9. [The] Right, to the extent permitted by law, to refuse the specific medications or treatment procedures and the responsibility of the facility if the client refuses treatment, to seek appropriate legal alternatives or orders of involuntary treatment, or in accordance with professional standards, to terminate the relationship with the client upon reasonable notice.

(2) A residential crisis stabilization unit's written policies and procedures concerning client rights shall assure and protect the client's personal privacy within the constraints of his or her plan of care, including:

(a) Visitation by family or significant others in a suitable area of the facility; and

(b) Telephone communications with family or significant others at a reasonable frequency.

(3)(a) If a privacy right is limited, a full explanation shall be given to the client or the client's parent. [or] guardian, or other legal representative if the client is a minor or incapacitated.

(b) Documentation shall be included in the client's record of any privacy limitation.

(4) Information shall be provided to the client, or the client's parent. [er] guardian, or other legal representative if the client is a minor or incapacitated, regarding the use and disposition of special observation and audio visual techniques, which may include [the following]:

(a) One (1) way vision mirror;

(b) Audio recording;

(c) Video tape recording;

(d) Television;

(e) Movie; or

(f) Photographs.

(5)(a) If the residential crisis stabilization unit serves children as <u>established[described]</u> in Section <u>9[10](4)(b)</u> of this administrative regulation, written policy and procedures shall be developed in consultation with professional and direct-care staff to provide for behavior management of residents, including the use of a time-out room.

(b)1. Behavior management techniques:

a. Shall be explained fully to each client and, if the client is a minor or incapacitated, the client's parent, guardian, or other legal representative; and

b. May include time out or personal restraint.

2. Prone holds, chemical restraint, and mechanical restraint shall be prohibited in a residential crisis stabilization unit.

(c) The unit shall prohibit cruel and unusual disciplinary measures including [the following]:

1. Corporal punishment;

2. Forced physical exercise;

3. Forced fixed body positions;

4. Group punishment for individual actions;

5. Verbal abuse, ridicule, or humiliation;

6. Denial of three (3) balanced nutritional meals per day;

7. Denial of clothing, shelter, bedding, or personal hygiene needs:

8. Denial of access to educational services;

Denial of visitation, mail, or phone privileges for punishment;
 Exclusion of the resident from entry to his or her assigned

living unit; and 11. Personal restraint or seclusion as a punishment or

employed for the convenience of staff. (d) Written policy shall prohibit residents from administering

disciplinary measures upon one another and shall prohibit persons other than professional or direct-care staff from administering disciplinary measures to residents.

(6) If personal restraint is used as a safe behavioral management technique, the residential crisis stabilization unit shall have a policy <u>that[which]</u> shall:

(a) Establish[Describe] criteria for appropriate use of personal

restraint;

(b) Establish[Describe] documentation requirements; and

(c) Ensure that staff who implement the use of personal restraint shall:

1. Have documented training in the proper use of the procedure used;

2. Be certified in physical management by a nationallyrecognized training program in which certification is obtained through skilled-out testing; and

3. Receive annual training and recertification in crisis intervention and behavior management.

Section <u>12.[13.]</u> Reports of Abuse, Neglect, or Exploitation. (1) A residential crisis stabilization unit shall have written policies <u>that[which]</u> assure:

(a) The reporting of cases of abuse, neglect, or exploitation of adults and children to the cabinet pursuant to KRS Chapters 209 and 620; and

(b) That a resident may file a complaint with the cabinet concerning resident abuse, neglect, or exploitation.

(2) The unit shall have evidence that all allegations of abuse, neglect, or exploitation are thoroughly investigated internally[$_{-}$] and shall prevent further potential abuse while the investigation is in progress.

Section <u>13.[14.]</u> Medication Prescribing and Monitoring in a Residential Crisis Stabilization Unit. (1) Medication prescribing and monitoring shall be under the direction of a licensed psychiatrist, a licensed physician supervised by a psychiatrist, or an APRN certified in psychiatric-mental health nursing practice who meets the requirements established in 201 KAR 20:057.

(2) Prescriptions concerning medication shall not exceed an order for more than five (5) refills.

(3) Medication prescribing and monitoring used in treatment shall be recorded in the staff notes and on a special medications chart in the client record.

(4) A copy of the prescription shall be kept in the client record.

(5) A blood or other laboratory test or examination shall be performed in accordance with accepted medical practice on each client receiving medication prescribed or administered by the residential crisis stabilization unit staff.

(6) Drug supplies shall be stored under proper sanitary, temperature, light, and moisture conditions.

(7) Medication kept by the unit shall be properly labeled.

(8) A medication shall be stored in the originally received container unless transferred to another container by a pharmacist or another person licensed to transfer the medication.

(9) Medication kept in the unit shall be kept in a locked cabinet.(10) A controlled substance shall be kept under double lock

(for example, in a locked box in a locked cabinet). (11) There shall be a controlled substances record, in which is

recorded:

(a) The name of the client;

(b) The date, time, dosage, balance remaining, and method of administration of each controlled substance;

(c) The name of the prescribing physician or other ordering practitioner acting within the scope of his or her license to practice; and

(d) The name of the nurse who administered $it[_{7}]$ or staff who supervised the self-administration.

(12) Access to the locked cabinet shall be restricted to a designated medication nurse or other authorized personnel.

(13) Medication to be self-administered shall be made available to the client at the time of administration.

Section <u>14.[15.]</u> Facility Requirements. (1) Living Unit. A living unit shall be located within a single building in which there is at least 120 square feet of space for each resident in the facility.

(2) Bedrooms.

(a) More than four (4) clients shall not sleep in the same[a] bedroom.

(b) A bedroom shall be equipped with a bed for each client.

(c) A bed shall:

1. Be at least thirty-six (36) inches wide and at least five (5) feet in length;

2. Be long and wide enough to accommodate the client's size; 3. Have a mattress cover, two (2) sheets, a pillow, and bed

covering to keep the client comfortable;

4. Be equipped with a support mechanism and a clean mattress; and

5. Be placed so that a client shall not experience discomfort because of proximity to a radiator or heat outlet, or exposure to a draft.

(d) There shall be separate sleeping quarters for males and females.

(e) A client shall not be housed in a room, a detached building, or other enclosure that has not previously been inspected and approved for residential use by the Office of Inspector General and the Department of Housing, Buildings and Construction.

(3) Bathrooms.

(a) For every eight (8) residents, each residential crisis stabilization unit shall have at least one (1):

1. Wash basin with hot and cold water;

2. Bath or shower with hot and cold water; and

3. Flush toilet.

(b) If separate toilet and bathing facilities are not provided, males and females shall not be permitted to use those facilities at the same time.

(4) Living area.

(a) The living area shall provide comfortable seating for all clients housed within the residential crisis stabilization unit.

(b) Each living unit shall be equipped with a:

1. Working sink; and

2. Stove and refrigerator, unless a kitchen is directly available within the same building as the living unit.

(5) There shall be adequate lighting, heating, heated water, and ventilation.

(6) There shall be space for a client to store personal belongings, including a receptacle where personal property may be stored and locked.

(7) The residential crisis stabilization unit shall be kept in good repair, neat, clean, free from accumulations of dirt and rubbish, and free from foul, stale, and musty odors.

(8) The residential crisis stabilization unit shall be kept free from insects and rodents with their harborages eliminated.

(9) The residential crisis stabilization unit shall establish an infection control system <u>that[which]</u> includes training personnel on proper hygiene related to infections prevalent among alcohol and other drug abusers.

(10) Services shall be provided in an area where clients are ensured privacy and confidentiality.

Section <u>15.[16.]</u> Facility Specifications. (1) A residential crisis stabilization unit shall:

(a) Be of safe and substantial construction;

(b) Be in compliance with applicable state and local laws relating to zoning, construction, plumbing, safety, and sanitation;

(c) Be approved by the State Fire Marshal's office prior to initial licensure or if the unit changes location; and

(d) Meet requirements for making buildings and facilities accessible to and usable by individuals with physical disabilities pursuant to KRS 198B.260 and 815 KAR 7:120.

(2) A residential crisis stabilization unit shall:

(a) Have a written emergency plan and procedures for meeting potential disasters such as fires or severe weather;

(b) Post the emergency plan conspicuously in a public area of the unit and provide a copy to all personnel;

(c) Provide training for all personnel on how to report a fire, extinguish a small fire, and evacuate a building; and

(d) Practice fire drills monthly, with a written record kept of all practiced fire drills, detailing the date, time, and residents who participated.

Section <u>16.[17.]</u> Denial and Revocation. (1) The cabinet shall deny an Application for License to Operate a Residential Crisis Stabilization Unit if:

(a) Any person with ownership interest in the <u>residential</u> crisis stabilization unit has had previous ownership interest in a health care facility that had its license revoked or voluntarily relinquished its license as the result of an investigation or pending disciplinary action;

(b) Any person with ownership interest in the <u>residential</u> crisis stabilization unit has been discontinued from participation in the Medicaid Program due to fraud or abuse of the program; or

(c) The applicant fails after the initial inspection to submit an acceptable plan of correction or fails to submit an acceptable amended plan of correction within the timeframes required by 902 KAR 20:008, Section $2(\underline{13})[(\underline{5})]$.

(2) The cabinet shall revoke a license if it finds that:

(a) In accordance with KRS 216B.105(2), there has been a substantial failure by the residential crisis stabilization unit to comply with the provisions of this administrative regulation;

(b) The residential crisis stabilization unit fails to submit an acceptable plan of correction or fails to submit an acceptable amended plan of correction within the timeframes required by 902 KAR 20:008, Section 2(13)[(5)]; or

(c) The residential crisis stabilization unit is terminated from participation in the Medicaid Program pursuant to 907 KAR 1:671.

(3) The denial or revocation of a residential crisis stabilization unit's license shall be mailed to the applicant or licensee, by certified mail, return receipt requested, or by personal service. Notice of the denial or revocation shall <u>state[set forth]</u> the particular reasons for the action.

(4) The denial or revocation shall become final and conclusive thirty (30) days after notice is given, unless the applicant or licensee, within the thirty (30) day period, files a request in writing for a hearing with the cabinet.

(5) Urgent action to suspend a license.

(a) The cabinet shall take urgent action to suspend a residential crisis stabilization unit's license if the cabinet has probable cause to believe that the continued operation of the unit would constitute an immediate danger to the health, welfare, or safety of its residents.

(b)1. The residential crisis stabilization unit shall be served with notice of the hearing on the urgent suspension to be held no sooner than twenty (20) days from the delivery of the notice.

2. Notice of the urgent suspension shall <u>state[set_forth]</u> the particular reasons for the action.

(6) Notice of a hearing on an urgent suspension shall be served on the residential crisis stabilization unit by certified mail, return receipt requested, or by personal service.

(7)(a) Within five (5) working days of completion of the hearing, the cabinet's hearing officer shall render a written decision affirming, modifying, or revoking the urgent suspension.

(b) The urgent suspension shall be affirmed if there is substantial evidence of an immediate danger to the health, safety, or welfare of the residents.

(8) The decision rendered under subsection (7) of this section shall be a final order of the agency on the matter, and any party aggrieved by the decision may appeal to circuit court.

(9) If the cabinet issues an urgent suspension, the cabinet shall take action to revoke the residential crisis stabilization unit's license pursuant to subsection (3) of this section if:

(a) The facility fails to attend the expedited hearing; or

(b) The decision rendered under subsection (7) of this section affirms that there is substantial evidence of an immediate danger to the health, safety, or welfare of the residents.

(10) Pursuant to KRS 216B.050, the cabinet may compel obedience to its lawful orders.

Section <u>17.[48-]</u> Incorporation by Reference. (1) The OIG 20:440, "Application for License to Operate a Residential Crisis Stabilization Unit", October 2014 edition, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of Inspector General, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

ADAM D. MATHER, Inspector General ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 2, 2020 FILED WITH LRC: October 13, 2020 at 12:30 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on December 21, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by December 14, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until December 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. In accordance with KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact: persons: Kara L. Daniel or Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes minimum licensure requirements for the operation of residential crisis stabilization units that serve at-risk children or children with severe emotional disabilities, at-risk adults or adults with severe mental illness, or individuals with substance use disorder or co-occurring disorders.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with KRS 216B.042(1), which requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, including licensure standards and procedures to ensure safe, adequate, and efficient health services.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of KRS 216B.042 by establishing minimum licensure requirements for the operation of residential crisis stabilization units.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing standards for licensed residential crisis stabilization units.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment is being filed concurrently with the Department for Medicaid Services administrative regulation, 907 KAR 15:070, Coverage provisions and requirements regarding services provided by residential crisis stabilization units. Key changes to this administrative regulation, 902 KAR 20:440, are as follows:

Amends Section 1(1)(a) to clarify that a psychiatrist, as included under the definition of "behavioral health professional", may be certified or eligible to apply for certification by the American Osteopathic Board of Neurology;

Amends Section 1(7) to allow a crisis stabilization unit to serve sixteen (16) clients rather than twelve (12) clients who require overnight stays;

Adds a definition for "licensed clinical alcohol and drug counselor";

Updates the definition of "peer support specialist" to include a registered alcohol and drug peer support specialist, and allow for peer support specialists to work under the supervision of a licensed clinical alcohol and drug counselor;

Deletes the prohibition against co-locating a residential alcohol and other drug treatment entity (AODE) and a residential crisis stabilization program on the same campus;

Adds language to allow the executive director to serve in a dual role as the executive director of a residential crisis stabilization unit and an AODE if both facilities are owned by the same entity and meet other criteria;

Adds language to allow the program director to serve in a dual role as the program director of a residential crisis stabilization unit and an AODE if both facilities are owned by the same entity and meet other criteria;

Removes language allowing residential crisis stabilization units to use the Kentucky National Background Check Program (NBCP) to satisfy the State-level criminal record check requirements. Use of the NBCP was originally included in this administrative regulation by error, prior to receiving additional information from the Federal Bureau of Investigation, which clarified that the Kentucky State Police relies upon a federal statute, Section 6201 of the Affordable Care Act (ACA), for the submission of fingerprints to the FBI for direct patient access employees in voluntarily participating long-term care settings. Because residential crisis stabilization units are not included in the statutory definition of a "long-term care facility" or otherwise covered under Section 6201 of the ACA, residential crisis stabilization units cannot voluntarily participate in the Kentucky NBCP;

Adds a cross-reference to applicable sections in 907 KAR 15:070 as it relates to the following services provided by residential crisis stabilization units: screening, assessment, treatment planning, individual therapy, group therapy, family therapy, and peer support;

Allows a licensed clinical alcohol and drug counselor to provide screening, assessment, treatment planning, individual therapy, group therapy, and family therapy;

Adds a cross-reference to 907 KAR 15:070, Section 3, if a residential crisis stabilization unit provides treatment for acute withdrawal; and

Adds licensed AODE programs as one of the programs with which residential crisis stabilization units may have a linkage to help promote continuity of care after discharge.

(b) The necessity of the amendment to this administrative regulation: This amendment is necessary to align with the proposed changes to 907 KAR 15:070.

(c) How the amendment conforms to the content of the authorizing statutes: This amendment conforms to the content of KRS 216B.042 because it establishes minimum licensure requirements for the operation of residential crisis stabilization units.

(d) How the amendment will assist in the effective administration of the statutes: This amendment assists in the effective administration of the statutes by establishing standards for licensed residential crisis stabilization units.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This administrative regulation affects the four (4) currently licensed residential crisis stabilization units.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Entities licensed in accordance with this administrative regulation are required to comply with the standards established by this administrative regulation, including:

State Fire Marshal approval of the facility's location prior to initial licensure or a change of location;

Accreditation within one (1) year of initial licensure, unless an extension is granted;

Compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the residential crisis stabilization unit;

Designation of an executive director who may also serve as the residential crisis stabilization unit's program director if the individual is a behavioral health professional as defined by Section 1 of this administrative regulation;

Compliance with abuse registry and criminal background check requirements;

Implementation of a process for quality assurance and utilization review;

Implementation of a process for responding to client grievances;

Mandatory delivery of screening, assessment, treatment planning, individual therapy, group therapy, and psychiatric services;

Optional delivery of family therapy and peer support services;

Treatment for acute withdrawal, if appropriate;

Retention of client records;

Implementation of administrative and personnel policies as well as policies that ensure that the rights of clients are protected;

Medication prescribing and monitoring;

Compliance with basic facility requirements for bedrooms, bathrooms, living areas, infection control, and cleanliness; and

Compliance with applicable state and local laws relating to zoning, construction, plumbing, safety, and sanitation as well as emergency plans in the effect of a disaster or severe weather.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no additional costs to residential crisis stabilization units to comply with this amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Licensed residential crisis stabilization units may enroll in the Kentucky Medicaid Program for reimbursement of covered services provided to Medicaid recipients in need of short-term crisis services.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional costs to the cabinet for implementation of this administrative regulation.

(b) On a continuing basis: There are no additional costs to the cabinet for implementation of this administrative regulation on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State general funds and agency monies are used to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish or increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applicable as compliance with this administrative regulation applies equally to all individuals or entities who elect to be regulated by it.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts the Cabinet for Health and Family Services, Office of Inspector General, and licensed residential crisis stabilization units.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 216B.042

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency

(including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The Cabinet collects an initial fee of \$750 and annual renewal fee of \$500 from each licensed residential crisis stabilization unit. These fees are existing requirements and are not being amended by this amendment.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will generate an initial licensure fee of \$750 and annual licensing fee of \$500 for each entity licensed as a residential crisis stabilization unit. These fees are existing requirements and are not being amended by this amendment.

(c) How much will it cost to administer this program for the first year? This amendment imposes no additional costs on the administrative body.

(d) How much will it cost to administer this program for subsequent years? This amendment imposes no additional costs on the administrative body.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): See response above.

Expenditures (+/-): This administrative regulation is anticipated to have minimal fiscal impact to the cabinet.

Other Explanation:

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 45 C.F.R. Parts 160, 164, 42 U.S.C. 1320d-2 - 1320d-8, 42 U.S.C. 209ee-3, 42 C.F.R. Part 2

2. State compliance standards. KRS 216B.042

3. Minimum or uniform standards contained in the federal mandate. 45 C.F.R. 160, 164, and 42 U.S.C. 1320d-2 – 1320d-8 establish the HIPAA privacy rules to protect individuals' medical records and other personal health information. 42 U.S.C. 209ee-3 pertains to the confidentiality of patient records. 42 C.F.R. Part 2 prohibits programs from disclosing any information that would identify a person as having or having had substance use disorder, unless that person provides written consent.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation does not impose requirements that are more strict than federal laws or regulations.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Not applicable.

CABINET FOR HEALTH AND FAMILY SERVICES Department for Medicaid Services Division of Policy and Operations (Amendment)

907 KAR 15:070. Coverage provisions and requirements regarding services provided by residential crisis stabilization units.

RELATES TO: KRS 205.520, <u>21 U.S.C. 823(g)(2)</u>, 42 U.S.C. 1396a(a)(10)(B), 42 U.S.C. 1396a(a)(23)

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3)

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has a responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed or opportunity presented by federal law to qualify for federal Medicaid funds. This administrative regulation establishes the coverage provisions and requirements regarding Medicaid Program behavioral health services provided by residential crisis stabilization units.

Section 1. General Coverage Requirements. (1) For the department to reimburse for a service covered under this administrative regulation, the service shall be:

(a) Medically necessary; and

(b) Provided:

1. To a recipient; and

2. By a residential crisis stabilization unit that meets the provider participation requirements established in Section 2 of this administrative regulation.

(2)(a) Direct contact between a practitioner and a recipient shall be required for each service.

(b) A service that does not meet the requirement in paragraph (a) of this subsection shall not be covered.

(3) A service shall be:

(a) Stated in the recipient's plan of care; and

(b) Provided in accordance with the recipient's plan of care.

(4) A residential crisis stabilization unit shall establish a plan of care for each recipient receiving services.

Section 2. Provider Participation. (1) To be eligible to provide services under this administrative regulation, a residential crisis stabilization unit shall:

(a) Be currently enrolled in the Kentucky Medicaid Program in accordance with 907 KAR 1:672;

(b) Except as established in subsection (3) of this section, be currently participating in the Kentucky Medicaid Program in accordance with 907 KAR 1:671;

(c) Be licensed as a residential crisis stabilization unit in accordance with 902 KAR 20:440;

(d) Comply with the requirements established in 902 KAR 20:440;

(e) Have:

1. For each service it provides, the capacity to provide the full range of the service as established in this administrative regulation;

2. Demonstrated experience in serving individuals with behavioral health disorders;

3. The administrative capacity to ensure quality of services;

4. A financial management system that provides documentation of services and costs; and

5. The capacity to document and maintain individual case records;

(f) Be a community-based, residential program that offers an array of services including:

1. Screening;

2. Assessment;

3. Treatment planning;

4. Individual [outpatient]-therapy;

5. Group [outpatient] therapy;

6. Psychiatric services;

7. Family [outpatient] therapy at the option of the residential crisis stabilization unit; [or]

8. Peer support at the option of the residential crisis stabilization unit;

9. Withdrawal management if treating substance use disorders; or

10. Medication assisted treatment if treating substance use disorders;

(g) Provide services in order to:

1. Stabilize a crisis and divert an individual from a higher level of care;

2. Stabilize an individual and provide treatment for acute withdrawal, if applicable; and

3. Re-integrate an individual into the individual's community or other appropriate setting in a timely fashion;

(h) Not be part of a hospital;

(i) Be used when an individual:

1. Is experiencing a behavioral health crisis that cannot be safely accommodated within the individual's community; and

2. Needs overnight care that is not hospitalization;

(j) Except as established in subsection (2)(a) of this section, not contain more than sixteen (16) beds;

(k) Except as established in subsection (2)(b) of this section, not be part of multiple units comprising one (1) facility with more than sixteen (16) beds in aggregate;

(I) Agree to provide services in compliance with federal and state laws regardless of age, sex, race, creed, religion, national origin, handicap, or disability;

(m) Comply with the Americans with Disabilities Act (42 U.S.C. 12101 et seq.) and any amendments to the Act;

(n) Have the capacity to employ staff authorized to provide treatment services in accordance with this section and to coordinate the provision of services among team members;

(o) Have the capacity to provide the full range of residential crisis stabilization services as stated in Section 3(2) of this administrative regulation and on a twenty-four (24) hour a day, seven (7) day a week, every day of the year basis;

(p) Have access to a board certified or board-eligible psychiatrist twenty-four (24) hours a day, seven (7) days a week, every day of the year; [and]

(q) Have knowledgeable staff regarding <u>mental health</u>, substance use, <u>or co-occurring disorders based on the population</u> being served; and

(r) For the treatment or stabilization of withdrawal management symptoms for substance use disorder or co-occurring disorders, have a planned and structured regimen of twenty-four (24) hour professionally directed evaluation, observation, medical monitoring, and addiction treatment[disorders].

(2) If every recipient receiving services in the:

(a) Single unit is under the age of twenty-one (21) years or over the age of sixty-five (65) years, the limit of sixteen (16) beds established in subsection (1)(j) of this section shall not apply; or

(b) Multiple units is under the age of twenty-one (21) years or over the age of sixty-five (65) years, the limit of sixteen (16) beds established in subsection (1)(k) of this section shall not apply.

(3) In accordance with 907 KAR 17:015, Section 3(3), a residential crisis stabilization unit <u>that[which]</u> provides a service to an enrollee shall not be required to be currently participating in the fee-for-service Medicaid Program.

Section 3. Covered Services. (1)(a) Except as specified in the requirements stated for a given service, the services covered may be provided for:

1. A mental health disorder;

2. A substance use disorder; or

3. Co-occurring mental health and substance use disorders.

(b) Residential crisis stabilization services shall be provided in a residential crisis stabilization unit.

(2) Residential crisis stabilization services shall include the services established in this subsection.[-

(a) A screening provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A licensed clinical social worker;

4. A licensed professional clinical counselor;

5. A licensed professional art therapist;

6. A licensed marriage and family therapist;

A physician;

8. A psychiatrist;

9. An advanced practice registered nurse; or

10. A behavioral health practitioner under supervision except

for a licensed assistant behavior analyst; (b) An assessment provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A licensed clinical social worker;

4. A licensed professional clinical counselor:

5. A licensed professional art therapist;

6. A licensed marriage and family therapist;

7. A physician;

8. A psychiatrist;

9. An advanced practice registered nurse;

10. A licensed behavior analyst; or

11. A behavioral health practitioner under supervision;

- (c) Individual outpatient therapy or group outpatient therapy provided by:
 - 1. A licensed psychologist;
 - 2. A licensed psychological practitioner;
 - 3. A licensed clinical social worker;
 - 4. A licensed professional clinical counselor;
 - 5. A licensed professional art therapist;
 - 6. A licensed marriage and family therapist;
 - 7. A physician;
 - 8. A psychiatrist;
 - 9. An advanced practice registered nurse;
 - 10. A licensed behavior analyst; or
 - 11. A behavioral health practitioner under supervision;
 - (d) Treatment planning provided by:
 - 1. A licensed psychologist;
 - 2. A licensed psychological practitioner;
 - 3. A licensed clinical social worker;
 - 4. A licensed professional clinical counselor;
 - 5. A licensed professional art therapist;
 - 6. A licensed marriage and family therapist;
 - 7. A physician;
 - 8. A psychiatrist;
 - 9. An advanced practice registered nurse:
 - 10. A licensed behavior analyst; or
- 11. A behavioral health practitioner under supervision except for a certified alcohol and drug counselor;
 - (e) Psychiatric services provided by:

1. A psychiatrist; or

- 2. An APRN: or
- () At the ending of the
- (f) At the option of the residential crisis stabilization unit:
- 1. Family outpatient therapy provided by:
- a. A licensed psychologist;
- b. A licensed psychological practitioner;
- c. A licensed clinical social worker;
- d. A licensed professional clinical counselor;
- e. A licensed professional art therapist;
- f. A licensed marriage and family therapist;
- g. A physician;
- h. A psychiatrist;
- i. An advanced practice registered nurse; or
- i. A behavioral health practitioner under supervision except for
- a licensed assistant behavior analyst; or
- 2. Peer support provided by a peer support specialist working under the supervision of:
 - a. An approved behavioral health service provider; or
 - b. A certified alcohol and drug counselor.
 - (3)](a) A screening shall:
- 1. Establish the need for a level of care evaluation to determine the most appropriate and least restrictive service to maintain the safety of the individual who may have a mental health disorder, substance use disorder, or co-occurring disorders;
 - 2. Not establish the presence or specific type of disorder; [and]
- 3. Establish the need for an in-depth assessment of the number and duration of risk factors including:
 - a. Imminent danger and availability of lethal weapons;
 - b. Verbalization of suicidal or homicidal risk;
- c. Need of immediate medical attention, including withdrawal management needs;
 - d. Positive and negative coping strategies;
 - e. Lack of family or social supports;
 - f. Active psychiatric diagnosis; or
 - g. Current drug and alcohol use;
- 4. Be provided face-to-face or via telehealth as appropriate pursuant to 907 KAR 3:170; and
 - 5. Be provided by:
 - a. An approved behavioral health practitioner; or
- b. An approved behavioral health practitioner under supervision.
 - (b) An assessment shall:
- 1. Include gathering information and engaging in a process with the individual that enables the practitioner to:
 - a. Establish the presence or absence of a mental health

- disorder, a substance use disorder, or co-occurring disorders;
 - b. Determine the individual's readiness for change;
- c. Identify the individual's strengths or problem areas that may affect the treatment and recovery processes; and
- d. Engage the individual in developing an appropriate treatment relationship;
- Establish or rule out the existence of a clinical disorder or service need;
- 3. Include working with the individual to develop a treatment and service plan; [and]
- Not include psychological or psychiatric evaluations or assessments;
- 5. If being made for the treatment of a substance use disorder, utilize a multi-dimensional assessment that complies with The ASAM Criteria; and
 - Be provided by:
 - a. An approved behavioral health practitioner; or
- b. An approved behavioral health practitioner under supervision.
 - (c) Individual [outpatient] therapy shall:
 - Be provided to promote the:
 - a. Health and wellbeing of the individual; or
- b. Restoration of a recipient to their best possible functional level[Recovery] from a substance use disorder, a mental health disorder, or co-occurring disorders;
 - 2. Consist of:
- a. A face-to-face, one (1) on one (1) encounter between the provider and recipient; and
- b. A behavioral health therapeutic intervention provided in accordance with the recipient's identified crisis treatment plan;
 - Be aimed at:
 - a. Reducing adverse symptoms;
- b. Reducing or eliminating the presenting problem of the recipient; and
 - c. Improving functioning; [and]
- 4. Not exceed three (3) hours per day unless additional time is medically necessary; and
 - 5. Be provided by:
 - a. An approved behavioral health practitioner; or
- b. An approved behavioral health practitioner under supervision.
 - (d)1. Group [outpatient] therapy shall:
- a. Be a behavioral health therapeutic intervention provided in accordance with a recipient's identified crisis treatment plan;
 - b. Be provided to promote the:
 - (i) Health and wellbeing of the individual; or
- (ii) <u>Restoration of a recipient to their best possible functional</u> <u>level[Recovery]</u> from a substance use disorder, a mental health disorder, or co-occurring disorders;
- c. Consist of a face-to-face behavioral health therapeutic intervention provided in accordance with the recipient's identified crisis treatment plan;
 - d. Be provided to a recipient in a group setting:
 - (i) Of nonrelated individuals; and

educational activity, or a social activity; and

additional time is medically necessary. 2. The group shall have a:

b. Defined course of treatment.

5. The group shall be provided by:

a. Deliberate focus; and

recipient participating in the group.

judgment;

1123

- (ii) Not to exceed twelve (12) individuals in size;
- e. Focus on the psychological needs of the recipients as evidenced in each recipient's crisis treatment plan;

relationships, personal goals setting, and the exercise of personal

f. Center on goals including building and maintaining healthy

g. Not include physical exercise, a recreational activity, an

h. Not exceed three (3) hours per day per recipient unless

3. The subject of group outpatient therapy shall relate to each

4. The provider shall keep individual notes regarding each

recipient within the group and within each recipient's health record.

a. An approved behavioral health practitioner; or

b. An approved behavioral health practitioner under supervision.

(e)1. Treatment planning shall:

a. Involve assisting a recipient in creating an individualized plan for services needed;

b. Involve restoring a recipient's functional level to the recipient's best possible functional level; and

c. Be performed using a person-centered planning process.

2. A service plan:

a. Shall be directed by the recipient;

b. Shall include practitioners of the recipient's choosing; and

c. May include:

(i) A mental health advance directive being filed with a local hospital;

(ii) A crisis plan; or

(iii) A relapse prevention strategy or plan.

3. A service plan shall be completed by:

a. An approved behavioral health practitioner; or

<u>b. An approved behavioral health practitioner under supervision.</u>

(f)[1.] Family [outpatient] therapy shall:

<u>1.</u> Consist of a face-to-face behavioral health therapeutic intervention provided:

a. Through scheduled therapeutic visits between the therapist and the recipient and at least one (1) member of the recipient's family; and

b. To address issues interfering with the relational functioning of the family and to improve interpersonal relationships within the recipient's home environment: [-]

2. [Family outpatient therapy shall:]

a. Be provided to promote:

(i) The health and wellbeing of the individual; or

(ii) <u>Restoration of a recipient to their best possible functional</u> <u>level[Recovery]</u> from a substance use disorder, a mental health disorder, or co-occurring disorders; and

b. Not exceed three (3) hours per day per individual unless additional time is medically necessary; and

3. Be provided by:

a. An approved behavioral health practitioner; or

b. An approved behavioral health practitioner under supervision.

(g)1. Peer support services <u>provided by a peer support</u> <u>specialist working under the supervision of an approved behavioral</u> <u>health practitioner</u> shall:

a. Be social and emotional support that is provided by an individual who is experiencing a mental health disorder, a substance use disorder, or co-occurring mental health and substance use disorders to a recipient by sharing a similar mental health disorder, substance use disorder, or co-occurring mental health and substance use disorders in order to bring about a desired social or personal change;

b. Be an evidence-based practice;

c. Be structured and scheduled non-clinical therapeutic activities with an individual recipient or a group of recipients;

d. Be provided by a self-identified consumer, parent, or family member:

(i) Of a child consumer of mental health disorder services, substance use disorder services, or co-occurring mental health disorder services and substance use disorder services; and

(ii) Who has been trained and certified in accordance with 908 KAR 2:220, 908 KAR 2:230, or 908 KAR 2:240;

e. Promote socialization, recovery, self-advocacy, preservation, and enhancement of community living skills for the recipient;

f. Be coordinated within the context of a comprehensive, individualized treatment plan developed through a person-centered planning process;

g. Be identified in each recipient's treatment plan; and

h. Be designed to directly contribute to the recipient's individualized goals as specified in the recipient's treatment plan.

2. To provide peer support services, a residential crisis stabilization unit shall:

a. Employ peer support specialists who are qualified to provide

peer support services in accordance with 908 KAR 2:220, 908 2:230, or 908 2:240;

b. [Use an approved behavioral health services provider or certified alcohol and drug counselor to supervise peer support specialists;

e-]Have the capacity to coordinate the provision of services among team members; [and]

<u>c.[d.]</u> Have the capacity to provide on-going continuing education and technical assistance to peer support specialists.

d. Require individuals providing peer support services to recipients to provide no more than thirty (30) hours per week of direct recipient contact; and

e. Require peer support services provided to recipients in a group setting to not exceed eight (8) individuals within any group at one (1) time.

(h)1. Withdrawal management services for substance use disorder shall:

 a. Meet the service criteria for medically monitored intensive inpatient services for adults and medically monitored high-intensity inpatient services for adolescents in accordance with The ASAM Criteria; and

b. Comply with services pursuant to the requirements of 902 KAR 20:111.

2. A recipient who is receiving withdrawal management services shall:

a. Meet the current dimensional admissions criteria for withdrawal management level of care as found in The ASAM Criteria; and

<u>b. Not require the full resources of an acute care hospital or a</u> medically managed inpatient treatment program.

3. Withdrawal management services shall be provided by:

a. A physician or psychiatrist;

b. A physician assistant;

c. An advanced practice registered nurse; or

<u>d.</u> Any other approved behavioral health practitioner or nurse with oversight by a physician, advanced practice registered nurse, or a physician assistant.

(i)1. Medication assisted treatment shall be available per patient choice for the treatment of a substance use disorder or cooccurring disorders.

2. Medication assisted treatment shall be provided by a provider who:

<u>a. ls:</u>

(i) A physician licensed to practice medicine under KRS Chapter 311;

(ii) An advanced practice registered nurse (APRN); or

(iii) A physician assistant who has appropriately updated department provider enrollment information;

b. Meets standards in accordance with 201 KAR 9:270 or 201 KAR 20:065;

c. Maintains a current waiver under 21 U.S.C 823(g)(2) to prescribe buprenorphine products; and

d. Has experience and knowledge in addiction medicine.

(3) For those recipients being treated for a substance use disorder, care coordination shall include at minimum:

(a) Referring the recipient to appropriate community services: (b) Facilitating medical and behavioral health follow-ups;

(c) Linking to appropriate levels of substance use treatment

within the continuum in order to provide on-going support; and

(d) Facilitating medication assisted treatment as necessary, per patient choice, if the medication is not offered on-site.

(4) The extent and type of a screening shall depend upon the problem of the individual seeking or being referred for services.

(5) A diagnosis or clinical impression shall be made using terminology established in the most current edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders.

(6) <u>After July 1, 2021, if treating substance use disorders, the</u> <u>facility</u> <u>shall</u> <u>possess</u> an <u>appropriate</u> ASAM level of <u>care</u> <u>certification in accordance with The ASAM Criteria.</u>

(7) The department shall not reimburse for a service billed by or on behalf of an entity or individual who is not a billing provider.

Section 4. Additional Limits and Non-covered Services or Activities. (1) The following services or activities shall not be covered under this administrative regulation:

(a) A service provided to:

1. A resident of:

a. A nursing facility; or

b. An intermediate care facility for individuals with an intellectual disability;

2. An inmate of a federal, local, or state:

a. Jail;

b. Detention center; or

c. Prison; or

3. An individual with an intellectual disability without documentation of an additional psychiatric diagnosis;

(b) Psychiatric or psychological testing for another agency, including a court or school, that does not result in the individual receiving psychiatric intervention or behavioral health therapy from the residential crisis stabilization unit:

(c) A consultation or educational service provided to a recipient or to others;

(d) A telephone call, an email, a text message, or other electronic contact that does not meet the requirements stated in the definition of "face-to-face";

(e) Travel time;

(f) A field trip;

(g) A recreational activity;

(h) A social activity; or

(i) A physical exercise activity group.

(2) Residential crisis stabilization services shall not include:

(a) Room and board;

(b) Educational services;

(c) Vocational services;

(d) Job training services;

(e) Habilitation services;

(f) Services to an inmate in a public institution pursuant to 42 C.F.R. 435.1010;

(g) Services to an individual residing in an institution for mental diseases pursuant to 42 C.F.R. 435.1010;

(h) Recreational activities;

(i) Social activities; or

(j) Services required to be covered elsewhere in the state plan.
 (3)(a) A consultation by one (1) provider or professional with

another shall not be covered under this administrative regulation. (b) A third party contract shall not be covered under this administrative regulation.

Section 5. No Duplication of Service. (1) The department shall not reimburse for a service provided to a recipient by more than one (1) provider, of any program in which the service is covered, during the same time period.

(2) For example, if a recipient is receiving a residential crisis stabilization service from a community mental health center, the department shall not reimburse for the same service provided to the same recipient during the same time period by a residential crisis stabilization unit.

Section 6. Records Maintenance, Documentation, Protection, and Security. A residential crisis stabilization unit shall maintain a current health record for each recipient in accordance with 902 KAR 20:440.

Section 7. Medicaid Program Participation Compliance. (1) A residential crisis stabilization unit shall comply with:

(a) 907 KAR 1:671;

(b) 907 KAR 1:672; and

(c) All applicable state and federal laws.

(2)(a) If a residential crisis stabilization unit receives any duplicate payment or overpayment from the department, regardless of reason, the residential crisis stabilization unit shall return the payment to the department.

(b) Failure to return a payment to the department in accordance with paragraph (a) of this subsection may be:

1. Interpreted to be fraud or abuse; and

 $\ensuremath{\text{2. Prosecuted}}$ in accordance with applicable federal or state law.

(3)(a) When the department makes payment for a covered service and the residential crisis stabilization unit accepts the payment:

1. The payment shall be considered payment in full;

2. A bill for the same service shall not be given to the recipient; and

3. Payment from the recipient for the same service shall not be accepted by the residential crisis stabilization unit.

(b)1. A residential crisis stabilization unit may bill a recipient for a service that is not covered by the Kentucky Medicaid Program if the:

a. Recipient requests the service; and

b. Residential crisis stabilization unit makes the recipient aware in advance of providing the service that the:

(i) Recipient is liable for the payment; and

(ii) Department is not covering the service.

2. If a recipient makes payment for a service in accordance with subparagraph 1. of this paragraph, the:

a. Residential crisis stabilization unit shall not bill the department for the service; and

b. Department shall not:

(i) Be liable for any part of the payment associated with the service; and

(ii) Make any payment to the residential crisis stabilization unit regarding the service.

(4)(a) The signature of the residential crisis stabilization unit's staff or representative shall indicate that the residential crisis stabilization unit attests that any claim associated with a service is valid and submitted in good faith.

(b) Any claim and substantiating record associated with a service shall be subject to audit by the:

1. Department or its designee;

2. Cabinet for Health and Family Services, Office of Inspector General or its designee;

3. Kentucky Office of Attorney General or its designee;

4. Kentucky Office of the Auditor for Public Accounts or its designee; or

5. United States General Accounting Office or its designee.

(c) If a residential crisis stabilization unit receives a request from the department or its designee to provide a claim, related information, related documentation, or record for auditing purposes, the residential crisis stabilization unit shall provide the requested information to the department within the timeframe requested by the department.

(d)1. All services provided shall be subject to review for recipient or provider <u>fraud or</u> abuse; <u>and compliance with this</u> <u>administrative regulation and state and federal law</u>.

2. Willful abuse by a residential crisis stabilization unit shall result in the suspension or termination of the residential crisis stabilization unit from Medicaid Program participation.

Section 8. Third Party Liability. A residential crisis stabilization unit shall comply with KRS 205.622.

Section 9. Use of Electronic Signatures. (1) The creation, transmission, storage, and other use of electronic signatures and documents shall comply with the requirements established in KRS 369.101 to 369.120.

(2) A residential crisis stabilization unit that chooses to use electronic signatures shall:

(a) Develop and implement a written security policy that shall:

1. Be adhered to by each of the residential crisis stabilization unit's employees, officers, agents, or contractors;

2. Identify each electronic signature for which an individual has access; and

3. Ensure that each electronic signature is created, transmitted, and stored in a secure fashion;

(b) Develop a consent form that shall:

1. Be completed and executed by each individual using an electronic signature;

2. Attest to the signature's authenticity; and

3. Include a statement indicating that the individual has been notified of his or her responsibility in allowing the use of the electronic signature; and

(c) Provide the department, immediately upon request, with:

1. A copy of the residential crisis stabilization unit's electronic signature policy;

2. The signed consent form; and

3. The original filed signature.

Section 10. Auditing Authority. The department shall have the authority to audit any:

(1) Claim;

(2) Medical record; or

(3) Documentation associated with any claim or medical record.

Section 11. Federal Approval and Federal Financial Participation. The department's coverage of services pursuant to this administrative regulation shall be contingent upon:

(1) Receipt of federal financial participation for the coverage; and

(2) Centers for Medicare and Medicaid Services' approval for the coverage.

Section 12. Appeals. (1) An appeal of an adverse action by the department regarding a service and a recipient who is not enrolled with a managed care organization shall be in accordance with 907 KAR 1:563.

(2) An appeal of an adverse action by a managed care organization regarding a service and an enrollee shall be in accordance with 907 KAR 17:010.

LISA LEE, Commissioner

ERIC FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 2, 2020 FILED WITH LRC: October 13, 2020 at 12:40 p.m. PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A

public hearing on this administrative regulation shall, if requested, be held on December 21, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by December 14, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until December 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. In accordance with KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Persons: Jonathan Scott and Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the coverage provisions and requirements regarding Medicaid Program behavioral health services provided by residential crisis stabilization units (RCSUs).

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with federal mandates. Section 1302(b)(1)(E) of the Affordable Care Act

mandates that "essential health benefits" for Medicaid programs include "mental health and substance use disorder services, including behavioral health treatment" for all recipients. 42 U.S.C. 1396a(a)(23) is known as the freedom of choice of provider mandate. This federal law requires the Medicaid Program to "provide that (A) any individual eligible for medical assistance (including drugs) may obtain such assistance from any institution, agency, community pharmacy or person, qualified to perform the service or services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services." 42 U.S.C. 1396a(a)(10)(B) requires the Medicaid Program to ensure that services are available to Medicaid recipients in the same amount, duration, and scope.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by complying with federal mandates and enhancing and ensuring Medicaid recipients' access to behavioral health services.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will assist in the effective administration of the authorizing statutes by complying with federal mandates and enhancing and ensuring Medicaid recipients' access to behavioral health services.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments to this administrative regulation combine a previously separate description of who may perform a service and a description of the service itself. In addition, the amendments implement additional requirements relating to withdrawal management and medication assisted treatment, including a requirement that the services be conducted in accordance with the ASAM Criteria.

(b) The necessity of the amendment to this administrative regulation: These amendments are necessary to comply with existing OIG administrative regulations, implement an SUD 1115 waiver, and provide additional formatting improvements.

(c) How the amendment conforms to the content of the authorizing statutes: The amendments conform to the content of the authorizing statutes by implementing an SUD 1115 waiver.

(d) How the amendment will assist in the effective administration of the statutes: The amendments will assist in the effective administration of the statutes by providing additional clarity and requirements relating to residential crisis stabilization units.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: There are currently fifteen (15) entities that are providing residential crisis stabilization unit (RCSU) services under this administrative regulation. Medicaid recipients who qualify for behavioral health services provided by an RCSU will also be affected by this administrative regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment. Facilities and providers may need to comply with the ASAM Criteria in order to provide certain services.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). The entities referenced in paragraph (a) could experience administrative costs associated with enrolling with the Medicaid Program.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3). The entities referenced in paragraph (a) will benefit by receiving Medicaid Program reimbursement, and the benefit of providing additional services. Behavioral health professionals authorized to provide services in a residential crisis stabilization unit will benefit by having more

employment opportunities in Kentucky. Medicaid recipients in need of behavioral health services will benefit from an expanded base of providers from which to receive these services.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: DMS does not anticipate additional costs in implementing this administrative regulation.

(b) On a continuing basis: DMS does not anticipate additional costs in implementing this administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under the Social Security Act, Title XIX and matching funds of general fund appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment. Neither an increase in fees nor funding is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any fees.

(9) Tiering: Is tiering applied? Tiering is not applied as the policies apply equally to the regulated entities.

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 42 U.S.C. 1396a(a)(10)(B) and 42 U.S.C. 1396a(a)(30)(A).

2. State compliance standards. KRS 205.520(3) states: "Further, it is the policy of the Commonwealth to take advantage of all federal funds that may be available for medical assistance. To qualify for federal funds the secretary for health and family services may by regulation comply with any requirement that may be imposed or opportunity that may be presented by federal law. Nothing in KRS 205.510 to 205.630 is intended to limit the secretary's power in this respect."

KRS 205.6311 requires the Department for Medicaid Services to "promulgate administrative regulations. ... to expand the behavioral health network to allow providers to provide services within their licensure category."

3. Minimum or uniform standards contained in the federal mandate. 42 U.S.C. 1396a(a)(10)(B) requires the Medicaid Program to ensure that services are available to Medicaid recipients in the same amount, duration, and scope. Expanding the provider base will help ensure Medicaid recipient access to services statewide and reduce or prevent the lack of availability of services due to demand exceeding supply in any given area. Medicaid reimbursement for services is required to be consistent with efficiency, economy and quality of care and be sufficient to attract enough providers to assure access to services. 42 U.S.C. 1396a(a)(30)(A) requires Medicaid state plans to: "...provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1903(i)(4)) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.'

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? The administrative regulation does not impose stricter than federal requirements.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. The administrative regulation does not impose stricter than federal

requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services will be affected by the amendment to this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.010(1), 194A.030(2), 194A.050(1), 205.520(3), 205.6311, 42 U.S.C. 1396a(a)(10)(B), and 42 U.S.C. 1396a(a)(30)(A).

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The amendment is not expected to generate revenue for state or local government.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The amendment is not expected to generate revenue for state or local government.

(c) How much will it cost to administer this program for the first year? DMS does not expect any additional costs in administering these amendments during the first year.

(d) How much will it cost to administer this program for subsequent years? DMS does not expect any additional costs in administering these amendments during subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

CABINET FOR HEALTH AND FAMILY SERVICES Department for Medicaid Services Division of Policy and Operations (Amendment)

907 KAR 15:080. Coverage provisions and requirements regarding [outpatient] chemical dependency treatment center services.

RELATES TO: KRS 205.520, <u>205.622</u>, <u>309.0831</u>, <u>21 U.S.C.</u> <u>823(g)(2)</u>, 42 U.S.C. 1396a(a)(10)(B), 1396a(a)(23), <u>42 C.F.R.</u> 435.10<u>10</u>

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3)

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has a responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed or opportunity presented by federal law to qualify for federal Medicaid funds. This administrative regulation establishes the coverage provisions and requirements regarding Medicaid Program outpatient <u>and inpatient</u> chemical dependency treatment center services.

Section 1. General Coverage Requirements. (1) For the department to reimburse for a service covered under this administrative regulation, the service shall be:

(a) Medically necessary; and

(b) Provided:

1. To a recipient; and

2. By a chemical dependency treatment center that meets the provider participation requirements established in Section 2 of this administrative regulation.

(2)(a) <u>Direct[Face-to-face]</u> contact between a practitioner and a recipient shall be required for each service except for:

1. Collateral outpatient therapy for a recipient under the age of twenty-one (21) years if the collateral outpatient therapy is in the recipient's plan of care;

2. A family outpatient therapy service in which the corresponding current procedural terminology code establishes that the recipient is not present; or

3. A psychological testing service comprised of interpreting or explaining results of an examination or data to family members or others in which the corresponding current procedural terminology code establishes that the recipient is not present.

(b) A service that does not meet the requirement in paragraph (a) of this subsection shall not be covered.

(3) A billable unit of service shall be actual time spent delivering a service in <u>an[a face-to-face]</u> encounter.

(4) A service shall be:

(a) Stated in the recipient's plan of care; and

(b) Provided in accordance with the recipient's plan of care.

(5)(a) A chemical dependency treatment center shall establish a plan of care for each recipient receiving services from a chemical dependency treatment center.

(b) A plan of care shall meet the treatment plan requirements established in 902 KAR 20:160.

Section 2. Provider Participation. (1)(a) To be eligible to provide services under this administrative regulation, a chemical dependency treatment center shall:

1. Be currently enrolled as a provider in the Kentucky Medicaid Program in accordance with 907 KAR 1:672;

2. Except as established in subsection (2) of this section, be currently participating in the Kentucky Medicaid Program in accordance with 907 KAR 1:671;

3. Be licensed as a chemical dependency treatment center to provide outpatient <u>and inpatient</u> behavioral health services in accordance with 902 KAR 20:160; and

4. Have:

a. For each service it provides, the capacity to provide the full range of the service as established in this administrative regulation;

b. Documented experience in serving individuals with <u>mental</u> <u>health, substance use, or co-occurring[behavioral health]</u> disorders;

c. The administrative capacity to ensure quality of services;

d. A financial management system that provides documentation of services and costs; and

e. The capacity to document and maintain individual health records.

(b) The documentation referenced in paragraph (a)4.b. of this subsection shall be subject to audit by:

1. The department or its designee;

2. The Cabinet for Health and Family Services, Office of Inspector General;

3. A managed care organization, if the chemical dependency treatment center is enrolled in its network;

4. The Centers for Medicare and Medicaid Services;

5. The Kentucky Office of the Auditor of Public Accounts; or

6. The United States Department of Health and Human Services, Office of the Inspector General.

(2) In accordance with 907 KAR 17:015, Section 3(3), a chemical dependency treatment center <u>that[which]</u> provides a service to an enrollee shall not be required to be currently participating in the fee-for-service Medicaid Program.

(3) A chemical dependency treatment center shall:

(a) Agree to provide services in compliance with federal and state laws regardless of age, sex, race, creed, religion, national origin, handicap, or disability; and

(b) Comply with the Americans with Disabilities Act (42 U.S.C. 12101 et seq.) and any amendments to the act.

(4)(a) Except as provided by paragraph (b) of this subsection, a chemical dependency treatment center shall possess accreditation, within one (1) year of initial enrollment, by one (1) of the following:

1. The Joint Commission;

2. The Commission on Accreditation of Rehabilitation Facilities; 3. The Council on Accreditation; or

4. A nationally recognized accreditation organization.

(b) The department shall grant a one (1) time extension to a chemical dependency treatment center that requests a one (1) time extension to complete the accreditation process, if the request is submitted at least ninety (90) days prior to expiration of provider enrollment.

Section 3. Covered Services.

(1) <u>Reimbursement shall not be available for services</u> performed within a chemical dependency treatment program by a:

(a) Licensed behavior analyst;

(b) Licensed assistant behavior analyst;

(c) Registered behavior technician; or

(d) Community support associate.

(2) The services covered may be provided for a substance use disorder or co-occurring disorders.

(3)[(2)] The [following] services listed in this subsection shall be covered under this administrative regulation in accordance with the requirements established in this subsection.[-

(a) A screening, crisis intervention, or intensive outpatient program service provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A certified psychologist with autonomous functioning;

4. A licensed clinical social worker;

5. A licensed professional clinical counselor;

6. A licensed professional art therapist;

7. A licensed marriage and family therapist;

8. A physician;

9. A psychiatrist;

10. An advanced practice registered nurse;

11. A licensed psychological associate working under the supervision of a board-approved licensed psychologist:

12. A certified psychologist working under the supervision of a board-approved licensed psychologist:

13. A licensed clinical alcohol and drug counselor in accordance with Section 11 of this administrative regulation; or

14. A behavioral health practitioner under supervision, except for a licensed assistant behavior analyst;

a licensed assistant benavior analys (b) An assessment provided by:

(b) An assessment provided b 1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A certified psychologist with autonomous functioning;

4. A licensed clinical social worker:

5. A licensed professional clinical counselor;

6. A licensed professional art therapist;

7. A licensed marriage and family therapist;

8. A physician;

9. A psychiatrist;

10. An advanced practice registered nurse;

11. A licensed behavior analyst;

12. A licensed psychological associate working under the supervision of a board-approved licensed psychologist;

13. A certified psychologist working under the supervision of a board-approved licensed psychologist;

14. A licensed clinical alcohol and drug counselor in accordance with Section 11 of this administrative regulation; or

15. A behavioral health practitioner under supervision;

(c) Psychological testing provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A certified psychologist with autonomous functioning;

4. A licensed psychological associate working under the supervision of a board-approved licensed psychologist; or

5. A certified psychologist working under the supervision of a board-approved licensed psychologist;

(d) Day treatment or mobile crisis services provided by: 1. A licensed psychologist;

1. A licensed psychologi

2. A licensed psychological practitioner;

3. A certified psychologist with autonomous functioning;

4. A licensed clinical social worker:

5. A licensed professional clinical counselor;

6. A licensed professional art therapist;

7. A licensed marriage and family therapist;

8. A physician;

9. A psychiatrist;

10. An advanced practice registered nurse;

11. A licensed psychological associate working under the supervision of a board-approved licensed psychologist;

12. A certified psychologist working under the supervision of a board-approved licensed psychologist;

13. A licensed clinical alcohol and drug counselor in accordance with Section 11 of this administrative regulation;

14. A behavioral health practitioner under supervision, except for a licensed assistant behavior analyst; or

15. A peer support specialist working under the supervision of an approved behavioral health services provider;

(e) Peer support provided by a peer support specialist working under the supervision of an approved behavioral health services provider;

(f) Individual outpatient therapy, group outpatient therapy, or collateral outpatient therapy provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A certified psychologist with autonomous functioning;

4. A licensed clinical social worker;

5. A licensed professional clinical counselor;

6. A licensed professional art therapist;

7. A licensed marriage and family therapist;

8. A physician;

9. A psychiatrist;

10. An advanced practice registered nurse;

11. A licensed behavior analyst;

12. A licensed psychological associate working under the supervision of a board-approved licensed psychologist;

13. A certified psychologist working under the supervision of a board-approved licensed psychologist;

14. A licensed clinical alcohol and drug counselor in accordance with Section 11 of this administrative regulation; or

15. A behavioral health practitioner under supervision;

(g) Family outpatient therapy provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A certified psychologist with autonomous functioning;

4. A licensed clinical social worker;

5. A licensed professional clinical counselor;

6. A licensed professional art therapist:

7. A licensed marriage and family therapist;

8. A physician;

9. A psychiatrist;

10. An advanced practice registered nurse;

11. A licensed psychological associate working under the supervision of a board-approved licensed psychologist;

12. A certified psychologist working under the supervision of a board-approved licensed psychologist;

13. A licensed clinical alcohol and drug counselor in accordance with Section 11 of this administrative regulation; or

14. A behavioral health practitioner under supervision, except for a licensed assistant behavior analyst; or

(h) A screening, brief intervention, and referral to treatment for a substance use disorder or SBIRT provided by:

1. A licensed psychologist;

2. A licensed psychological practitioner;

3. A certified psychologist with autonomous functioning;

4. A licensed clinical social worker:

5. A licensed professional clinical counselor;

6. A licensed professional art therapist;

7. A licensed marriage and family therapist;

8. A physician;

9. A psychiatrist;

10. An advanced practice registered nurse;

11. A licensed psychological associate working under the supervision of a board-approved licensed psychologist;

12. A certified psychologist working under the supervision of a board-approved licensed psychologist;

13. A licensed clinical alcohol and drug counselor in accordance with Section 11 of this administrative regulation; or

14. A behavioral health practitioner under supervision, except for a licensed assistant behavior analyst.

(3)(a) A screening shall:

1. Determine the likelihood that an individual has a substance use disorder;

2. Not establish the presence or specific type of disorder; [and]

3. Establish the need for an in-depth assessment;

4. Be provided face-to-face or via telehealth as appropriate pursuant to 907 KAR 3:170; and

5. Be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(b) An assessment shall:

1. Include gathering information and engaging in a process with the individual that enables the practitioner to:

a. Establish the presence or absence of a substance use disorder;

b. Determine the individual's readiness for change;

c. Identify the individual's strengths or problem areas that may affect the treatment and recovery processes; and

d. Engage the individual in developing[the development of] an appropriate treatment relationship;

2. Establish or rule out the existence of a clinical disorder or service need;

3. Include working with the individual to develop a plan of care; [and]

4. Not include psychological or psychiatric evaluations or assessments:

5. Utilize a multidimensional assessment that complies with the most current edition of The ASAM Criteria to determine the most appropriate level of care;

6. Be provided face-to-face or via telehealth as appropriate pursuant to 907 KAR 3:170; and

7. Be provided by: a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(c) Psychological testing shall:

1. Include[:

а psychodiagnostic assessment of a.] personality, psychopathology, emotionality, or intellectual disabilities;

2. Include an[and b.] interpretation and a written report of testing results;

3. Be face-to-face or via telehealth as appropriate pursuant to 907 KAR 3:170; and

4. Be provided by:

a. A licensed psychologist;

b. A certified psychologist with autonomous functioning;

c. A licensed psychological practitioner;

d. A certified psychologist under supervision; or

e. A licensed psychological associate under supervision[and

2. Be performed by an individual who has met the requirements of KRS Chapter 319 related to the necessary credentials to perform psychological testing].

(d) Crisis intervention:

1. Shall be a therapeutic intervention for the purpose of immediately reducing or eliminating the risk of physical or emotional harm to:

a. The recipient; or

b. Another individual;

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2. Shall consist of clinical intervention and support services necessary to provide integrated crisis response, crisis stabilization interventions, or crisis prevention activities for individuals; 3. Shall be provided:

a. [On-site in the facility where the outpatient behavioral health services are provided;

 $\ensuremath{\textbf{b}}\xspace$]As an immediate relief to the presenting problem or threat; and

<u>b.[e.]</u> In a <u>one (1) on one (1)[face-to-face, one-on-one]</u> encounter between the provider and the recipient, <u>which is</u> <u>delivered either face-to-face or via telehealth if appropriate</u> <u>pursuant to 907 KAR 3:170;</u>

4. Shall be followed by a referral to non-crisis services if applicable; [and]

5. May include:

a. Further service prevention planning including[that includes]:

(i) Lethal means reduction for suicide risk; or

(ii) Substance use disorder relapse prevention; or

b. Verbal de-escalation, risk assessment, or cognitive therapy;

and

6. Shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(e) Mobile crisis services shall:

1. Be available twenty-four (24) hours per day, seven (7) days per week, every day of the year;

2. <u>Be provided for a duration of less than twenty-four (24)</u> hours:

3. Not be an overnight service;

<u>4.[Ensure access to a board-certified or board-eligible</u> psychiatrist twenty-four (24) hours per day, seven (7) days per week, every day of the year;

3. Be provided for a duration of less than twenty-four (24) hours;

4. Not be an overnight service;

5-] Be a <u>face-to-face</u>, multi-disciplinary team-based intervention in a home or community setting that ensures access to substance use disorder services and supports to:

a. Reduce symptoms or harm; or

b. Safely transition an individual in an acute crisis to the

appropriate least restrictive level of care;

5.[6-] Involve all services and supports necessary to provide:

a. Integrated crisis prevention;

b. Assessment and disposition;

c. Intervention;

d. Continuity of care recommendations; and

e. Follow-up services;

6. Include access to a board-certified or board-eligible psychiatrist twenty-four (24) hours a day, seven (7) days a week, every day of the year; and

7. Be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section;

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section; or

c. A peer support specialist who:

(i) Is under the supervision of an approved behavioral health practitioner, as limited by subsection (1) of this section; and

(ii) Provides support services for a mobile crisis service[faceto-face in a home or community setting].

(f)1. Day treatment shall be a non-residential, intensive treatment program for an individual under the age of twenty-one (21) years who has:

a. A substance use disorder; and

b. A high risk of out-of-home placement due to a behavioral health issue.

2. Day treatment shall:

a. Be face-to-face;

<u>b.</u> Consist of an organized, behavioral health program of treatment and rehabilitative services;

<u>c.[b-]</u> Include:

(i) Individual outpatient therapy, family outpatient therapy, or group outpatient therapy;

(ii) Behavior management and social skills training;

(iii) Independent living skills that correlate to the age and

developmental stage of the recipient; or

(iv) Services designed to explore and link with community resources before discharge and to assist the recipient and family with transition to community services after discharge; and

d.[c.] Be provided:

(i) In collaboration with the education services of the local education authority including those provided through 20 U.S.C. 1400 et seq. (Individuals with Disabilities Education Act) or 29 U.S.C. 701 et seq. (Section 504 of the Rehabilitation Act);

(ii) On school days and <u>during</u> [on non-instructional weekdays during the school year including]scheduled school breaks;

(iii) In coordination with the recipient's individualized educational plan or Section 504 plan if the recipient has an individualized educational plan or Section 504 plan; and

(iv) [Under the supervision of a licensed or certified approved behavioral health services provider or a behavioral health practitioner working under clinical supervision; and

(v)] With a linkage agreement with the local education authority that specifies the responsibilities of the local education authority and the day treatment provider.

3. To provide day treatment services, a chemical dependency treatment center shall have:

a. The capacity to employ staff authorized to provide day treatment services in accordance with this section and to coordinate the provision of services among team members; and

b. Knowledge of substance use disorders and co-occurring disorders.

4. Day treatment shall not include a therapeutic clinical service that is included in a child's individualized education program or Section 504 plan.

5. Day treatment shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section;

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section; or

c. A peer support specialist who:

(i) Is under the supervision of an approved behavioral health practitioner, as limited by subsection (1) of this section; and

(ii) Provides support services for a day treatment service.

(g)1. Peer support services shall:

a. Be emotional support that is provided by:

(i) An individual who has been trained and certified in accordance with 908 KAR 2:220 [or 907 KAR 2:240]and who is experiencing or has experienced a substance use disorder to a recipient by sharing a similar substance use disorder in order to bring about a desired social or personal change:

(ii) A parent <u>or other family member</u>, who has been trained and certified in accordance with 908 KAR 2:230, of a child having or who has had a substance use disorder to a parent or family member of a child sharing a similar substance use disorder in order to bring about a desired social or personal change;[er]

(iii) <u>An individual who has been trained and certified in</u> <u>accordance with 908 KAR 2:240 and identified as experiencing a</u> <u>substance use disorder</u> [A family member who has been trained and certified in accordance with 908 KAR 2:230 of a child having or who has had a substance use disorder to a parent or family member of a child sharing a similar substance use disorder in order to bring about a desired social or personal change]; <u>or</u>

(iv) A registered alcohol and drug peer support specialist who has been trained and certified in accordance with KRS 309.0831 and is a self-identified consumer of substance use disorder services who provides emotional support to others with substance use disorder to achieve a desired social or personal change;

b. Be an evidence-based practice;

c. Be structured and scheduled non-clinical therapeutic activities with an individual recipient or a group of recipients;

d. Be provided face-to-face;

e. Promote socialization, recovery, self-advocacy, preservation, and enhancement of community living skills for the recipient;

f. Except for the engagement into substance use disorder treatment through an emergency department bridge clinic, [e-] be coordinated within the context of a comprehensive, individualized

plan of care developed through a person-centered planning process;

g.[f.] Be identified in each recipient's plan of care; and

h.[g.] Be designed to contribute directly to the recipient's individualized goals as specified in the recipient's plan of care.

2. To provide peer support services, a chemical dependency treatment center shall:

a. Have demonstrated:

(i) The capacity to provide peer support services for the behavioral health population being served including the age range of the population being served; and

(ii) Experience in serving individuals with behavioral health disorders;

b. Employ peer support specialists who are qualified to provide peer support services in accordance with 908 KAR 2:220, 908 KAR 2:230,[er] 908 KAR 2:240, or KRS 309.0831;

c. Use an approved behavioral health practitioner[services provider] to supervise peer support specialists;

d. Have the capacity to coordinate the provision of services among team members; [and]

e. Have the capacity to provide on-going continuing education and technical assistance to peer support specialists;

f. Require individuals providing peer support services to recipients to provide no more than thirty (30) hours per week of direct recipient contact; and

g. Require peer support services provided to recipients in a group setting to not exceed eight (8) individuals within any group at one (1) time.

(h)1. Intensive outpatient program services shall:

a. Be an alternative to or transition from a higher level of care for a substance use disorder or co-occurring disorders[inpatient hospitalization or partial hospitalization for a substance use disorder].

b. Offer a multi-modal, multi-disciplinary structured outpatient treatment program that is significantly more intensive than individual outpatient therapy, group outpatient therapy, or family outpatient therapy;

c. Meet the service criteria, including the components for support systems, staffing, and therapies outlined in the most current edition of The ASAM Criteria for intensive outpatient level of care services;

d. Be provided face-to-face;

e. Be provided at least three (3) hours per day at least three (3) days per week for adults;

f. Be provided at least six (6) hours per week for adolescents; and

g.[d.] Include:

(i) Individual outpatient therapy, group outpatient therapy, or family outpatient therapy unless contraindicated;

(ii) Crisis intervention; or

(iii) Psycho-education related to identified goals in the recipient's treatment plan.

2. During psycho-education, the recipient or recipient's family member shall be:

a. Provided with knowledge regarding the recipient's diagnosis, the causes of the condition, and the reasons why a particular treatment might be effective for reducing symptoms; and

b. Taught how to cope with the recipient's diagnosis or condition in a successful manner.

3. An intensive outpatient program services treatment plan shall:

a. Be individualized; and

b. Focus on stabilization and transition to a lesser level of care.

4. To provide intensive outpatient program services, a chemical dependency treatment center shall have:

a. Access to a board-certified or board-eligible psychiatrist for consultation:

b. Access to a psychiatrist, physician, or advanced practice registered nurse for medication prescribing and monitoring;

c. Adequate staffing to ensure a minimum recipient-to-staff ratio of ten (10) recipients to one (1) staff person;

d. The capacity to provide services utilizing a recognized intervention protocol based on nationally accepted treatment principles; and

e. The capacity to employ staff authorized to provide intensive outpatient program services in accordance with this section and to coordinate the provision of services among team members.

5. Intensive outpatient program services shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

An approved behavioral health practitioner under b. supervision, as limited by subsection (1) of this section.

(i) Individual outpatient therapy shall:

1. Be provided to promote the:

a. Health and wellbeing of the recipient; and

b. Restoration of a recipient to their best possible functional level from substance use disorder or co-occurring disorders[Recipient's recovery from a substance use disorder];

2. Consist of:

a. A face-to-face encounter or via telehealth as appropriate pursuant to 907 KAR 3:170 that is a one (1) on one (1) encounter between the provider and recipient[, one-on-one encounter between the provider and recipient]; and

b. A behavioral health therapeutic intervention provided in accordance with the recipient's identified plan of care;

3. Be aimed at:

a. Reducing adverse symptoms;

b. Reducing or eliminating the presenting problem of the recipient; and

c. Improving functioning; [and]

4. Not exceed three (3) hours per day alone or in combination with any other outpatient therapy per recipient unless additional time is medically necessary; and

5. Be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

An approved behavioral health practitioner under b. supervision, as limited by subsection (1) of this section.

(j)1. Group outpatient therapy shall:

a. Be a behavioral health therapeutic intervention provided in accordance with a recipient's identified plan of care;

b. Be provided to promote the:

(i) Health and wellbeing of the individual[recipient]; and

(ii) Restoration of a recipient to their best possible functional level from a substance use disorder or co-occurring disorders[Recipient's recovery from a substance use disorder];

c. Consist of a face-to-face behavioral health therapeutic intervention provided in accordance with the recipient's identified plan of care;

d. Be provided to a recipient in a group setting:

(i) Of nonrelated individuals except for multi-family group therapy; and

(ii) Not to exceed twelve (12) individuals in size;

e. Focus on the psychological needs of the recipients as evidenced in each recipient's plan of care;

f. Center on goals, including building and maintaining healthy relationships, personal goals setting, and the exercise of personal iudament:

g. Not include physical exercise, a recreational activity, an educational activity, or a social activity; and

h. Not exceed three (3) hours per day alone or in combination with any other outpatient therapy per recipient unless additional time is medically necessary.

2. The group shall have a:

a. Deliberate focus; and

b. Defined course of treatment.

3. The subject of group outpatient therapy shall relate to each recipient participating in the group.

4. The provider shall keep individual notes regarding each recipient within[of] the group and within each recipient's health record.

5. Group outpatient therapy shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(k)1. Family outpatient therapy shall consist of a face-to-face <u>or</u> <u>appropriate telehealth</u>, <u>pursuant to 907 KAR 3:170</u>, behavioral health therapeutic intervention provided:

a. Through scheduled therapeutic visits between the therapist and the recipient and at least one (1) member of the recipient's family; and

b. To address issues interfering with the relational functioning of the family and to improve interpersonal relationships within the recipient's home environment.

2. A family outpatient therapy session shall be billed as one (1) service regardless of the number of individuals (including multiple members from one (1) family) who participate in the session.

3. Family outpatient therapy shall:

a. Be provided to promote the:

(i) Health and well-being of the individual[recipient]; or

(ii) <u>Restoration of a recipient to their best possible functional</u> <u>level</u> from a substance use disorder or co-occurring <u>disorder</u>[Recipient's recovery from a substance use disorder]; and

b. Not exceed three (3) hours per day <u>alone or in combination</u> with any other outpatient therapy per <u>recipient[individual]</u> unless additional time is medically necessary.

4. Family outpatient therapy shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(I)1. Collateral outpatient therapy shall:

a. Consist of a face-to-face or appropriate telehealth, provided pursuant to 907 KAR 3:170, behavioral health consultation:

(i) With a parent or caregiver of a recipient, household member of a recipient, <u>legal representative of a recipient[recipient's</u> representative], school <u>personnel[staff person]</u>, treating professional, or other person with custodial control or supervision of the recipient; and

(ii) That is provided in accordance with the recipient's plan of care; and

b. Not be reimbursable if the therapy is for a recipient who is at least twenty-one (21) years of age.

2. Written consent by a parent or custodial guardian to discuss a recipient's treatment with any person other than a parent or legal guardian shall be signed and filed in the recipient's health record[Consent given to discuss a recipient's treatment with any person other than a parent or legal guardian shall be signed by the recipient or recipient's representative and filed in the recipient's health record].

3. Collateral outpatient therapy shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(m)<u>1.</u> Screening, brief intervention, and referral to treatment for a substance use disorder shall:

<u>a. Be provided face-to-face or via telehealth as appropriate</u> according to 907 KAR 3:170;

<u>b.[1-]</u> Be an evidence-based early-intervention approach for an individual with non-dependent substance use [in order] to provide an effective strategy for intervention prior to the need for more extensive or specialized treatment; and

c.[2.] Consist of:

(i)[a.] Using a standardized screening tool to assess an individual for risky substance use behavior;

(ii)[b-] Engaging a recipient, who demonstrates risky substance use behavior, in a short conversation and providing feedback and advice[to the recipient]; and

(iii)[c.] Referring a recipient to additional substance use disorder services if the recipient is determined to need additional services to address [the recipient's] substance use.

2. A screening and brief intervention that does not meet criteria for referral to treatment may be subject to coverage by the department.

3. A screening, brief intervention, and referral to treatment for a substance use disorder shall be provided by:

a. An approved behavioral health practitioner, as limited by

subsection (1) of this section; or

<u>b.</u> An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(n)1. Service planning shall:

a. Be provided face-to-face;

<u>b.</u> Involve assisting a recipient in creating an individualized plan for services and developing measurable goals and objectives needed for maximum reduction of the effects of a substance use disorder or co-occurring disorders;

<u>c. Involve restoring a recipient's functional level to the</u> recipient's best possible functional level; and

d. Be performed using a person-centered planning process.

2. A service plan:

a. Shall be directed and signed by the recipient;

b. Shall include practitioners of the recipient's choosing; and

<u>c. May include:</u> (i) A mental health advance directive being filed with a local hospital:

(ii) A crisis plan; or

(iii) A relapse prevention strategy or plan.

3. Service planning shall be provided by:

a. An approved behavioral health practitioner, as limited by subsection (1) of this section; or

b. An approved behavioral health practitioner under supervision, as limited by subsection (1) of this section.

(o)1. Ambulatory withdrawal management services shall:

a. Be provided face-to-face for recipients with a substance use disorder or co-occurring disorders:

<u>b. Be incorporated into a recipient's care as appropriate</u> according to the continuum of care described in the most current version of The ASAM Criteria; and

<u>c. Be in accordance with the most current version of The</u> ASAM Criteria for ambulatory withdrawal management levels in an outpatient setting.

<u>2. A recipient who is receiving ambulatory withdrawal</u> management services shall:

a. Meet the most current edition of diagnostic criteria for substance withdrawal management found in the Diagnostic and Statistical Manual of Mental Disorders; and

b. Meet the current dimensional admissions criteria for withdrawal management level of care as found in The ASAM Criteria.

3. Ambulatory withdrawal management services shall be provided by:

a. A physician;

b. A psychiatrist;

c. A physician assistant;

d. An advanced practice registered nurse; or

e. Any other approved behavioral health practitioner with oversight by a physician, advanced practice registered nurse, or a physician assistant, as limited by subsection (1) of this section.

(p)1. Medication assisted treatment shall be provided by an authorized prescribing provider who:

<u>a. ls:</u>

(i) A physician licensed to practice medicine under KRS Chapter 311;

(ii) An advanced practice registered nurse (APRN); or

(iii) A physician assistant who has appropriately updated department provider enrollment information;

b. Meets standards in accordance with 201 KAR 9:270 or 201 KAR 20:065:

<u>c. Maintains a current waiver under 21 U.S.C. 823(g)(2) to</u> prescribe buprenorphine products; and

d. Has experience and knowledge in addiction medicine.

2. Medication assisted treatment with behavioral health therapies shall:

a. Be co-located within the same practicing site as the practitioner with a waiver pursuant to subparagraph 1.b. of this paragraph or be conducted via telehealth as appropriate according to 907 KAR 3:170; or

<u>b. Be conducted with agreements in place for linkage to</u> <u>appropriate behavioral health treatment providers who specialize in</u> <u>substance</u> use disorders and are knowledgeable in biopsychosocial dimensions of alcohol or other substance use disorder, such as:

(i) An approved behavioral health practitioner, as limited by subsection (1) of this section; or

(ii) A multi-specialty group or behavioral health provider group pursuant to 907 KAR 15:010.

3. A medication assisted treatment program shall:

a. Assess the need for treatment including:

(i) A full patient history to determine the severity of the patient's substance use disorder; and

(ii) Identifying and addressing any underlying or co-occurring diseases or conditions, as necessary;

b. Educate the patient about how the medication works, including:

(i) The associated risks and benefits; and

(ii) Overdose prevention;

c. Evaluate the need for medically managed withdrawal from substances;

d. Refer patients for higher levels of care if necessary; and

e. Obtain informed consent prior to integrating pharmacologic or nonpharmacologic therapies.

4. Medication assisted treatment shall be provided by:

a. A physician;

b. A psychiatrist;

c. An advanced practice registered nurse; or

d. An approved behavioral health practitioner, as limited pursuant to subsection (1) of this section, or approved behavioral health practitioner under supervision, as limited pursuant to subsection (1) of this section, to provide counseling, behavioral therapies, and other support components with experience and knowledge in addiction medicine.

(q)1. An inpatient chemical dependency treatment program shall:

a. Be a structured inpatient program to provide medical, social, diagnostic, and treatment services to individuals with substance use disorder or co-occurring disorders;

b. Be provided face-to-face, twenty-four (24) hours per day, seven (7) days per week, 365 days a year with continuous nursing services and under the medical direction of a physician;

c. Meet the service criteria for medically monitored intensive inpatient services using The ASAM Criteria; and

d. Include the following services:

(i) Screening;

(ii) Assessment;

(iii) Service planning;

(iv) Psychiatric services;

(v) Individual therapy;

(vi) Family therapy;

(vii) Group therapy;

(viii) Peer support;

(ix) Medication assisted treatment; or

(x) Medically monitored inpatient withdrawal management, as established pursuant to subparagraph 2. of this paragraph.

 Medically monitored inpatient withdrawal management services provided in an inpatient chemical dependency treatment center shall:

a. Meet the service criteria for medically monitored inpatient withdrawal management services using the current edition of The ASAM Criteria; and

b. Comply with services pursuant to the requirements of 902 KAR 20:111.

3. For a recipient in an inpatient chemical dependency treatment program, care coordination shall include at minimum:

a. Facilitating medication assisted treatment for recipients as necessary, per recipient choice;

b. Referral to appropriate community services;

c. Facilitation of medical and behavioral health follow ups; and d. Linking the recipient to the appropriate level of substance

use treatment within the continuum to provide ongoing supports.

4. Inpatient chemical dependency treatment services shall be provided in accordance with 902 KAR 20:160, Sections 4 and 7.

5. Length-of-stay for chemical dependency treatment services shall be person-centered and according to an individually designed plan of care that is consistent with this administrative regulation and the licensure of the facility and practitioner.

<u>6.a. Except as established in clause b. or c. of this</u> subparagraph, the physical structure in which inpatient chemical dependency treatment services is provided shall:

(i) Have between nine (9) and sixteen (16) beds; and

(ii) Not be part of multiple units comprising one (1) facility with more than sixteen (16) beds in aggregate.

b. If every recipient receiving services in the physical structure is under the age of twenty-one (21) years or over the age of sixtyfive (65) years, the limit of sixteen (16) beds established in clause a. of this subparagraph shall not apply.

c. The limit of sixteen (16) beds established in clause a. of this subparagraph shall not apply if the facility possesses the appropriate inpatient ASAM certification to provide chemical dependency treatment center services, with the exception that:

(i) Each currently enrolled chemical dependency treatment center shall be granted a one (1) time provisional certification that expires July 1, 2021, unless extended by the department; or

(ii) A federal waiver, or other change to controlling federal law that allows for the availability of federal financial participation, shall be available for this clause to be operational.

7. Inpatient chemical dependency treatment services shall not include:

a. Room and board;

b. Educational services;

c. Vocational services;

d. Job training services;

e. Habilitation services;

<u>f. Services to an inmate in a public institution pursuant to 42</u> C.F.R. 435.1010;

<u>g. Services to an individual residing in an institution for mental</u> <u>diseases pursuant to 42 C.F.R. 435.1010;</u>

h. Recreational activities;

i. Social activities; or

j. Services required to be covered elsewhere in the Medicaid state plan.

8. To provide inpatient chemical dependency treatment services, the program shall:

a. Have the capacity to employ staff authorized to provide services in accordance with this section and to coordinate the provision of services among team members:

b. Be licensed as a chemical dependency treatment services and facility in accordance with 902 KAR 20:160; and

c. After July 1, 2021, possess an appropriate ASAM Level of Care Certification for medically monitored intensive inpatient services in accordance with The ASAM Criteria.

<u>9.a. Inpatient chemical dependency treatment shall be</u> provided by:

(i) An approved behavioral health practitioner, except as provided pursuant to subsection (1) of this section; or

(ii) An approved behavioral health practitioner under supervision, except as provided pursuant to subsection (1) of this section.

b. Support services for inpatient chemical dependency shall be provided by a peer support specialist under the supervision of an approved behavioral health practitioner.

(4)[The extent and type of a screening shall depend upon the nature of the problem of the individual seeking or being referred for services.

(5) A diagnosis or clinical impression shall be made using terminology established in the most current edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental DisordersTM.

(6)] The department shall not reimburse for a service billed by or on behalf of an entity or individual who is not a billing provider.

Section 4. Additional Limits and Non-covered Services or Activities. (1)(a) Except as established in paragraph (b) of this subsection, unless a diagnosis is made and documented in the recipient's health record within three (3) visits, the service shall not be covered.

(b) The requirement established in paragraph (a) of this

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subsection shall not apply to:

1. Mobile crisis services;

2. Crisis intervention;

- 3. A screening; or
- 4. An assessment.

(2) The department shall not reimburse for both a screening and <u>a screening, brief intervention and referral to treatment</u> (SBIRT)[an SBIRT] provided to a recipient on the same date of service.

(3) The following services or activities shall not be covered under this administrative regulation:

(a) A service provided to:

1. A resident of:

a. A nursing facility; or

b. An intermediate care facility for individuals with an intellectual disability;

2. An inmate of a federal, local, or state:

a. Jail;

b. Detention center; or

c. Prison; or

3. An individual with an intellectual disability without documentation of an additional psychiatric diagnosis;

(b) A consultation or educational service provided to a recipient or to others;

(c) A telephone call, an email, a text message, or other electronic contact that does not meet the requirements stated in the definition of "face-to-face" established in 907 KAR 15:005, Section 1(21). Contact that is not reimbursable under this paragraph may be permissible if it is conducted in the course of a telehealth service permitted pursuant to 907 KAR 3:170 or this administrative regulation, as applicable[(14)];

(d) Travel time:

(e) A field trip;

(f) A recreational activity;

(g) A social activity; or

(h) A physical exercise activity group.

(4)(a) A consultation by one (1) provider or professional with another shall not be covered under this administrative regulation

except as established in Section 3(3)(1)1 of this administrative regulation.

(b) A third-party contract shall not be covered under this administrative regulation.

(5) A billing supervisor arrangement between a billing supervisor and <u>an approved[a]</u> behavioral health practitioner under supervision shall not:

(a) Violate the clinical supervision rules or policies of the respective professional licensure boards governing the billing supervisor and the <u>approved</u> behavioral health practitioner under supervision; or

(b) Substitute for the clinical supervision rules or policies of the respective professional licensure boards governing the billing supervisor and the <u>approved</u> behavioral health practitioner under supervision.

Section 5. No Duplication of Service. (1) The department shall not reimburse for a service provided to a recipient by more than one (1) provider, of any program in which the same service is covered, during the same time period.

(2) For example, if a recipient is receiving a behavioral health service from an independent behavioral health provider, the department shall not reimburse for the same service provided to the same recipient during the same time period by a chemical dependency treatment center.

Section 6. Records Maintenance, Documentation, Protection, and Security. (1) A chemical dependency treatment center shall maintain a current health record for each recipient.

(2) A health record shall document each service provided to the recipient including the date of the service and the signature of the individual who provided the service.

(3) A health record shall:

(a) Include:

1. An identification and intake record including:

- a. Name;
- b. Social Security number;
- c. Date of intake;
- d. Home (legal) address;

e. Health insurance or Medicaid participation information;

f. If applicable, the referral source's name and address;

g. Primary care physician's name and address;

h. The reason the individual is seeking help including the presenting problem and diagnosis;

i. Any physical health diagnosis, if a physical health diagnosis exists for the individual, and information regarding:

(i) Where the individual is receiving treatment for the physical health diagnosis; and

(ii) The physical health provider's name; and

j. The name of the informant and any other information deemed necessary by the chemical dependency treatment center in order to comply with the requirements of:

(i) This administrative regulation;

(ii) The chemical dependency treatment center's licensure board;

(iii) State law; or

(iv) Federal law;

2. Documentation of the:

a. Screening;

b. Assessment, if an assessment was performed; and

c. Disposition, if a disposition was performed;

3. A complete history including mental status and previous treatment;

4. An identification sheet;

5. A consent for treatment sheet that is accurately signed and dated; and

6. The individual's stated purpose for seeking services; and

(b) Be:

1. Maintained in an organized central file;

2. Furnished upon request:

a. To the Cabinet for Health and Family Services; or

b. For an enrollee, to the managed care organization in which the recipient is enrolled or has been enrolled in the past;

3. Made available for inspection and copying by:

a. Cabinet for Health and Family Services' personnel; or

b. Personnel of the managed care organization in which the recipient is enrolled if applicable;

4. Readily accessible; and

5. Adequate for the purpose of establishing the current treatment modality and progress of the recipient if the recipient received services beyond a screening.

(4) Documentation of a screening shall include:

(a) Information relative to the individual's stated request for services; and

(b) Other stated personal or health concerns if other concerns are stated.

(5)(a) A chemical dependency treatment center's <u>service</u> notes regarding a recipient shall:

1. Be made within forty-eight (48) hours of each service visit; [and]

2. Indicate if the service was provided face-to-face or via telehealth for outpatient services; and

3. Describe the:

a. Recipient's symptoms or behavior, reaction to treatment, and attitude;

b. Behavioral health practitioner's intervention;

c. Changes in the plan of care if changes are made; and

d. Need for continued treatment if deemed necessary.

(b)1. Any edit to notes shall:

a. Clearly display the changes; and

b. Be initialed and dated by the person who edited the notes.

2. Notes shall not be erased or illegibly marked out.

(c)1. Notes recorded by <u>an approved[a]</u> behavioral health practitioner [working] under supervision shall be co-signed and dated by the supervising professional within thirty (30) days.

2. If services are provided by <u>an approved[a]</u> behavioral health practitioner [working]under supervision, there shall be a monthly supervisory note recorded by the supervising professional

that[which] reflects consultations with the <u>approved</u> behavioral health practitioner working under supervision concerning the:

a. Case; and

b. Supervising professional's evaluation of the services being provided to the recipient.

(6) Immediately following a screening of a recipient, the practitioner shall perform a disposition related to:

(a) A provisional diagnosis;

(b) A referral for further consultation and disposition, if applicable; or

(c)1. If applicable, termination of services and referral to an outside source for further services; or

2. If applicable, termination of services without a referral to further services.

(7) Any change to a recipient's plan of care shall be documented, signed, and dated by the rendering practitioner and by the recipient or recipient's representative.

(8)(a) Notes regarding services to a recipient shall:

1. Be organized in chronological order;

2. Be dated;

3. Be titled to indicate the service rendered;

4. State a starting and ending time for the service; and

5. Be recorded and signed by the rendering practitioner and include the professional title (for example, licensed clinical social worker) of the provider.

(b) Initials, typed signatures, or stamped signatures shall not be accepted.

(c) Telephone contacts, family collateral contacts not covered under this administrative regulation, or other non-reimbursable contacts shall:

1. Be recorded in the notes; and

2. Not be reimbursable.

(9)(a) A termination summary shall:

1. Be required, upon termination of services, for each recipient who received at least three (3) service visits; and

2. Contain a summary of the significant findings and events during the course of treatment including the:

a. Final assessment regarding the progress of the individual toward reaching goals and objectives established in the individual's plan of care:

b. Final diagnosis of clinical impression; and

c. Individual's condition upon termination and disposition.

(b) A health record relating to an individual who has been terminated from receiving services shall be fully completed within ten (10) days following termination.

(10) If an individual's case is reopened within ninety (90) days of terminating services for the same or related issue, a reference to the prior case history with a note regarding the interval period shall be acceptable.

(11)(a) Except as established in paragraph (b) of this subsection, if a recipient is transferred or referred to a health care facility or other provider for care or treatment, the transferring chemical dependency treatment center shall, within ten (10) business days of awareness of the transfer or referral, transfer the recipient's records in a manner that complies with the records' use and disclosure requirements as established in or required by:

1.a. The Health Insurance Portability and Accountability Act;

b. 42 U.S.C. 1320d-2 to 1320d-8; and

c. 45 C.F.R. Parts 160 and 164; or

2.a. 42 U.S.C. 290ee-3; and

b. 42 C.F.R. Part 2.

(b) If a recipient is transferred or referred to a residential crisis stabilization unit, a psychiatric hospital, a psychiatric distinct part unit in an acute care hospital, a Level I psychiatric residential treatment facility, a Level II psychiatric residential treatment facility, or an acute care hospital for care or treatment, the transferring chemical dependency treatment center shall, within forty-eight (48) hours of the transfer or referral, transfer the recipient's records in a manner that complies with the records' use and disclosure requirements as established in or required by:

1.a. The Health Insurance Portability and Accountability Act;

b. 42 U.S.C. 1320d-2 to 1320d-8; and

c. 45 C.F.R. Parts 160 and 164; or

2.a. 42 U.S.C. 290ee-3; and

b. 42 C.F.R. Part 2.

(12)(a) If a chemical dependency treatment center's Medicaid Program participation status changes as a result of voluntarily terminating from the Medicaid Program, involuntarily terminating from the Medicaid Program, a licensure suspension, or death of an owner or deaths of owners, the health records of the chemical dependency treatment center shall:

1. Remain the property of the chemical dependency treatment center; and

2. Be subject to the retention requirements established in subsection (13) of this section.

(b) A chemical dependency treatment center shall have a written plan addressing how to maintain health records in the event of death of an owner or deaths of owners.

(13)(a) Except as established in paragraph (b) or (c) of this subsection, a chemical dependency treatment center shall maintain a health record regarding a recipient for at least six (6) years from the last date of the service or until any audit dispute or issue is resolved beyond six (6) years.

(b) After a recipient's death or discharge from services, a provider shall maintain the recipient's record for the longest of the following periods:

1. Six (6) years unless the recipient is a minor; or

2. If the recipient is a minor, three (3) years after the recipient reaches the age of majority under state law.

(c) If the Secretary of the United States Department of Health and Human Services requires a longer document retention period than the period referenced in paragraph (a) of this subsection, pursuant to 42 C.F.R. 431.17, the period established by the secretary shall be the required period.

(14)(a) A chemical dependency treatment center shall comply with 45 C.F.R. Part 164.

(b) All information contained in a health record shall:

1. Be treated as confidential;

2. Not be disclosed to an unauthorized individual; and

3. Be disclosed to an authorized representative of:

a. The department;

b. Federal government; or

c. For an enrollee, the managed care organization in which the enrollee is enrolled.

(c)1. Upon request, a chemical dependency treatment center shall provide to an authorized representative of the department, federal government, or managed care organization if applicable, information requested to substantiate:

a. Staff notes detailing a service that was rendered;

b. The professional who rendered a service; and

c. The type of service rendered and any other requested information necessary to determine, on an individual basis, whether the service is reimbursable by the department or the managed care organization, if applicable.

2. Failure to provide information referenced in subparagraph 1. of this paragraph shall result in denial of payment for any service associated with the requested information.

Section 7. Medicaid Program Participation Compliance. (1) A chemical dependency treatment center shall comply with:

(a) 907 KAR 1:671;

(b) 907 KAR 1:672; and

(c) All applicable state and federal laws.

(2)(a) If a chemical dependency treatment center receives any duplicate payment or overpayment from the department or a managed care organization, regardless of reason, the chemical dependency treatment center shall return the payment to the department or managed care organization in accordance with 907 KAR 1:671.

(b) Failure to return a payment to the department or managed care organization in accordance with paragraph (a) of this subsection may be:

1. Interpreted to be fraud or abuse; and

2. Prosecuted in accordance with applicable federal or state law.

(3)(a) When the department makes payment for a covered

service and the chemical dependency treatment center accepts the payment:

1. The payment shall be considered payment in full;

2. A bill for the same service shall not be given to the recipient; and

3. Payment from the recipient for the same service shall not be accepted by the chemical dependency treatment center.

(b)1. A chemical dependency treatment center may bill a recipient for a service that is not covered by the Kentucky Medicaid Program if the:

a. Recipient requests the service; and

b. Chemical dependency treatment center makes the recipient aware in writing in advance of providing the service that the:

(i) Recipient is liable for the payment; and

(ii) Department is not covering the service.

2. If a recipient makes payment for a service in accordance with subparagraph 1. of this paragraph, the:

a. Chemical dependency treatment center shall not bill the department for the service; and

b. Department shall not:

(i) Be liable for any part of the payment associated with the service; and

(ii) Make any payment to the chemical dependency treatment center regarding the service.

(4)(a) A chemical dependency treatment center shall attest by the chemical dependency treatment center's staff's or representative's signature that any claim associated with a service is valid and submitted in good faith.

(b) Any claim and substantiating record associated with a service shall be subject to audit by the:

1. Department or its designee;

2. Cabinet for Health and Family Services, Office of Inspector General, or its designee;

3. Kentucky Office of Attorney General or its designee;

Kentucky Office of the Auditor for Public Accounts or its designee;

5. United States General Accounting Office or its designee; or

6. For an enrollee, managed care organization in which the enrollee is enrolled.

(c)1. If a chemical dependency treatment center receives a request from the:

a. Department to provide a claim, related information, related documentation, or record for auditing purposes, the chemical dependency treatment center shall provide the requested information to the department within the timeframe requested by the department; or

b. Managed care organization in which an enrollee is enrolled to provide a claim, related information, related documentation, or record for auditing purposes, the chemical dependency treatment center shall provide the requested information to the managed care organization within the timeframe requested by the managed care organization.

2.a. The timeframe requested by the department or managed care organization for a chemical dependency treatment center to provide requested information shall be:

(i) A reasonable amount of time given the nature of the request and the circumstances surrounding the request; and

(ii) A minimum of one (1) business day.

b. A chemical dependency treatment center may request a longer timeframe to provide information to the department or a managed care organization if the chemical dependency treatment center justifies the need for a longer timeframe.

(d)1. All services provided shall be subject to review for recipient or provider <u>fraud or</u> abuse, <u>and compliance with this</u> <u>administrative regulation and state and federal law</u>.

2. Willful abuse by a chemical dependency treatment center shall result in the suspension or termination of the chemical dependency treatment center from Medicaid Program participation in accordance with 907 KAR 1:671.

Section 8. Third Party Liability. A chemical dependency treatment center shall comply with KRS 205.622.

Section 9. Use of Electronic Signatures. (1) The creation, transmission, storage, and other use of electronic signatures and documents shall comply with the requirements established in KRS 369.101 to 369.120.

(2) A chemical dependency treatment center that chooses to use electronic signatures shall:

(a) Develop and implement a written security policy that shall:

1. Be adhered to by each of the chemical dependency treatment center's employees, officers, agents, or contractors;

2. Identify each electronic signature for which an individual has access; and

3. Ensure that each electronic signature is created, transmitted, and stored in a secure fashion;

(b) Develop a consent form that shall:

1. Be completed and executed by each individual using an electronic signature;

2. Attest to the signature's authenticity; and

3. Include a statement indicating that the individual has been notified of his or her responsibility in allowing the use of the electronic signature; and

(c) Provide the department, immediately upon request, with:

1. A copy of the chemical dependency treatment center's electronic signature policy;

2. The signed consent form; and

3. The original filed signature.

Section 10. Auditing Authority. The department or managed care organization in which an enrollee is enrolled shall have the authority to audit any:

(1) Claim;

(2) Health record; or

(3) Documentation associated with any claim or health record.

Section 11. Federal Approval and Federal Financial Participation. (1) The department's reimbursement of services pursuant to this administrative regulation shall be contingent upon:

(a) Receipt of federal financial participation for the coverage;

.,

and

(b) Centers for Medicare and Medicaid Services' approval for the coverage.

(2) The reimbursement of services provided by a licensed clinical alcohol and drug counselor or licensed clinical alcohol and drug counselor associate shall be contingent and effective upon approval by the Centers for Medicare and Medicaid Services.

Section 12. Appeals. (1) An appeal of an adverse action by the department regarding a service and a recipient who is not enrolled with a managed care organization shall be in accordance with 907 KAR 1:563.

(2) An appeal of an adverse action by a managed care organization regarding a service and an enrollee shall be in accordance with 907 KAR 17:010.

LISA LEE, Commissioner

ERIC FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 2, 2020

FILED WITH LRC: October 13, 2020 at 12:40 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on December 21, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by December 14, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until December 31, 2020. Send written notification of intent to attend the public hearing or written comments on the

proposed administrative regulation to the contact person. In accordance with KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Persons: Jonathan Scott and Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the coverage provisions and requirements regarding Medicaid Program outpatient and inpatient chemical dependency treatment center (CDTC) services.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to comply with federal mandates. Section 1302(b)(1)(E) of the Affordable Care Act mandates that "essential health benefits" for Medicaid programs include "mental health and substance use disorder services, including behavioral health treatment" for all recipients.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by complying with federal mandates and enhancing and ensuring Medicaid recipients' access to behavioral health services.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will assist in the effective administration of the authorizing statutes by complying with federal mandates and enhancing and ensuring Medicaid recipients' access to behavioral health services.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendments to this administrative regulation combine a previously separate description of who may perform a service and a description of the service itself. This series of amendments also includes a reference to the defined terms "approved behavioral health practitioner" and "approved behavioral health practitioner under supervision" from 907 KAR 15:005 instead of a listing of each provider in each service. This provides for more transparency and compactness in the administrative regulation. The administrative regulation has also clarified the use of telehealth in several places. Additional requirements relating to mobile crisis services include requiring access to a board-certified or board eligible psychiatrist at all times, and allowing for the use of peer support specialists. Day treatment services include additional requirements relating to staff qualifications. Peer support specialist services are amended to further allow and enhance the use of emergency department bridge clinics. In addition, peer support specialist services are now required to only be 30 hours per week of direct recipient contact and group peer support services are not allowed to exceed 8 individuals within any group at one time. Intensive outpatient program services are required to comply with the most recent service criteria of the ASAM Criteria, and additional clarification is given about how the services are to be provided to adults and adolescents. The amendments also include new services and requirements relating to "service planning" "ambulatory withdrawal management", "medication assisted treatment", and "inpatient chemical dependency treatment".

(b) The necessity of the amendment to this administrative regulation: These amendments are necessary to comply with existing OIG administrative regulations, implement an SUD 1115 waiver, require compliance with the ASAM Criteria, and provide additional formatting improvements.

(c) How the amendment conforms to the content of the authorizing statutes: The amendments conform to the content of the authorizing statutes by implementing an SUD 1115 waiver.

(d) How the amendment will assist in the effective

administration of the statutes: The amendments will assist in the effective administration of the statutes by providing additional clarity and requirements relating to chemical dependency treatment centers.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: Entities licensed as chemical dependency treatment centers (CDTCs), behavioral health professionals authorized to provide services in CDTCs, and Medicaid recipients who receive services in CDTCs will be affected by the administrative regulation. Currently there are 3 CDTC licenses issued by the state.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment. Entities that qualify as chemical dependency treatment centers and who wish to provide services to Medicaid recipients will need to enroll with the Medicaid Program as prescribed in the Medicaid provider enrollment regulation (complete an application and submit it to DMS) and sign agreements with managed care organizations if the individual wishes to provide services to Medicaid recipients who are enrolled with a managed care organization.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). The entities referenced in paragraph (a) could experience administrative costs associated with enrolling with the Medicaid Program.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3). The entities referenced in paragraph (a) will benefit by receiving Medicaid Program reimbursement for providing behavioral health services to Medicaid recipients. Behavioral health professionals authorized to provide services in a chemical dependency treatment center will benefit by having more employment opportunities in Kentucky. Medicaid recipients in need of behavioral health services will benefit from an expanded base of providers from which to receive these services.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: DMS anticipates potential savings of more than \$4.6 million due to the availability of a level of care that is less expensive than hospitalization via the introduction of inpatient chemical dependency treatment centers.

(b) On a continuing basis: DMS anticipates potential savings of more than \$4.6 million due to the availability of a level of care that is less expensive than hospitalization via the introduction of inpatient chemical dependency treatment centers.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under the Social Security Act, Title XIX and matching funds of general fund appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment. Neither an increase in fees nor funding is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any fees.

(9) Tiering: Is tiering applied? Tiering is not applied as the policies apply equally to the regulated entities.

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. Section 1302(b)(1)(E) of the Affordable Care Act, 42 U.S.C. 1396a(a)(10)(B), and 42 U.S.C. 1396a(a)(23).

2. State compliance standards. KRS 205.520(3) states: "Further, it is the policy of the Commonwealth to take advantage of all federal funds that may be available for medical assistance. To qualify for federal funds the secretary for health and family services may by regulation comply with any requirement that may be imposed or opportunity that may be presented by federal law. Nothing in KRS 205.510 to 205.630 is intended to limit the secretary's power in this respect."

3. Minimum or uniform standards contained in the federal mandate. Substance use disorder services are federally mandated for Medicaid programs. Section 1302(b)(1)(E) of the Affordable Care Act mandates that "essential health benefits" for Medicaid programs include "mental health and substance use disorder services, including behavioral health treatment." 42 U.S.C. 1396a(a)(23) is known as the freedom of choice of provider mandate. This federal law requires the Medicaid Program to "provide that (A) any individual eligible for medical assistance (including drugs) may obtain such assistance from any institution, agency, community pharmacy or person, qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services." Medicaid recipients enrolled with a managed care organization may be restricted to providers within the managed care organization's provider network. The Centers for Medicare and Medicaid Services (CMS) - the federal agency that oversees and provides the federal funding for Kentucky's Medicaid Program has expressed to the Department for Medicaid Services (DMS) the need for DMS to expand its substance use disorder provider base to comport with the freedom of choice of provider requirement. 42 U.S.C. 1396a(a)(10)(B) requires the Medicaid Program to ensure that services are available to Medicaid recipients in the same amount, duration, and scope as available to other individuals (non-Medicaid). Expanding the provider base will help ensure Medicaid recipient access to services statewide and reduce or prevent the lack of availability of services due to demand exceeding supply in any given area.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? The administrative regulation does not impose stricter than federal requirements.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. The administrative regulation does not impose stricter than federal requirements.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services will be affected by the amendment to this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.030(2), 194A.050(1), 205.520(3).

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The amendment is not expected to generate revenue for state or local government.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The amendment is not expected to generate revenue for state or local government.

(c) How much will it cost to administer this program for the first year? DMS anticipates potential savings of more than \$4.6 million

due to the availability of a level of care that is less expensive than hospitalization via the introduction of inpatient chemical dependency treatment centers.

(d) How much will it cost to administer this program for subsequent years? DMS anticipates potential savings of more than \$4.6 million due to the availability of a level of care that is less expensive than hospitalization via the introduction of inpatient chemical dependency treatment centers.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

CABINET FOR HEALTH AND FAMILY SERVICES Department for Community Based Services Division of Family Support (Amendment)

921 KAR 3:020. Financial requirements.

RELATES TO: 7 C.F.R. <u>Part 273 [273.1, 273.2, 273.8, 273.9, 273.10, 273.11, 273.12]</u>, 7 U.S.C. 2014, [2017(d), 26 U.S.C. 3507,] 29 U.S.C. 2801-2931, 38 U.S.C. 1833, 42 U.S.C. 601-619, 1382a(b)(4)(B)(iv), 4951-4960, 9902(2), 12501-12604[, Pub.L. 110-246]

STATUTORY AUTHORITY: KRS 194A.010(2), 194A.050(1), 7 C.F.R. 271.4, 7 U.S.C. 2011-2029

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.010(2) requires the Cabinet for Health and Family Services to administer income-supplement programs that protect, develop, preserve, and maintain families and children in the Commonwealth. KRS 194A.050(1) requires the secretary to promulgate administrative regulations necessary to implement programs mandated by federal law or to qualify for the receipt of federal funds and necessary to cooperate with other state and federal agencies for the proper administration of the cabinet and its programs. 7 U.S.C. 2011 to 2029 and 7 C.F.R. 271.4 authorize [requires] the cabinet to administer a Supplemental Nutrition Assistance [the Food Stamp] Program (SNAP) within the state and prescribe the manner in which the program shall be implemented. This administrative regulation establishes the financial eligibility requirements used by the cabinet in the administration of SNAP [the Food

Stamp Program]. In addition, 7 U.S.C. 2014 allows states to exclude additional types of income and resources if these specific types of income and resources are not counted in the state's Temporary Assistance for Needy Families (TANF) or Medicaid Programs.

Section 1. Financial Eligibility Requirements. (1) As established in 7 C.F.R. <u>Part</u> 273, national uniform standards of financial eligibility for <u>SNAP</u> [the Food Stamp Program] shall be composed of the following criteria:

(a) Income limitations; and

(b) Resource limitations.

(2) [Participation in the program shall be limited to a household that is prevented from obtaining a more nutritious diet because of its income.

(3)] The income eligibility standards shall be:

(a) Derived from the federal income poverty guidelines as defined in 42 U.S.C. 9902(2) for the forty-eight (48) contiguous states; and

(b) Adjusted annually each October 1, as published in the Federal Register.

Section 2. Countable Income. All [nonexcluded] income not excluded by Section 3 of this administrative regulation shall be considered in determining eligibility, including the following:

(1) Wages earned by a household member, including wages received by a striker as established [defined] in 921 KAR 3:035,

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Section 5(10);

(2) The gross income of a self-employment enterprise, including the total gain from the sale of capital goods or equipment related to the business, excluding the cost of doing business;

(3) Training allowance from vocational and rehabilitative programs recognized by federal, state, or local governments, to the extent that the allowances are not reimbursements;

(4) Volunteers in Service to America[;] (VISTA) payments <u>pursuant to</u> [under] 42 U.S.C. 4951 to 4960, unless specifically excluded in accordance with 7 C.F.R. 273.9(c)(10)(iii);

(5) The earned or unearned income of an ineligible household member or nonhousehold member as <u>established</u> [described] in 921 KAR 3:035, Section 5(3) and (4);

(6) Assistance payments from federal or federally-aided public assistance including:

(a) Supplemental security income or "SSI";

(b) Kentucky Transitional Assistance Program or "K-TAP" in accordance with 921 KAR 2:016;

(c) General assistance programs;

(d) Other assistance programs based on need; or

(e) Kinship care in accordance with 922 KAR 1:130;

(7) Annuities;

(8) Pensions;

(9) Retirement, veteran's, or disability benefits;

(10) Worker's or unemployment compensation;

(11) Strike pay;

(12) Old-age survivors or Social Security benefits;

(13) Except as excluded in Section 3(16) of this administrative regulation, foster care payments for a child or adult;

(14) Gross income derived from rental property, minus the cost of doing business. This income shall be considered as earned income if the household member is actively engaged in the management of the property an average of twenty (20) hours or more per week;

(15) Wages earned by a household member that are garnished or diverted by an employer and paid to a third party for a household expense;

(16) Support or alimony payments made directly to the household from a nonhousehold member. This shall include any portion of a payment returned to the household by the cabinet;

(17) Wages received from a TANF funded work program in accordance with 42 U.S.C. 601-619;

(18) A payment from:

(a) A government sponsored program;

(b) A royalty; or

(c) Similar direct money payments from a source that may be construed as a gain or benefit;

(19) Money withdrawn from a trust fund;

(20) The amount of monthly income deemed to a sponsored immigrant [alion] as established in 921 KAR 3:035, Section 5(11);

(21) The portion of means tested assistance monies:

(a) From a:

1. Federal welfare program;

2. State welfare program; or

3. Local welfare program; and

(b) Withheld for the purpose of recouping an overpayment resulting from the household's intentional failure to comply with that program's requirements;

(22) Earnings of an individual who is participating in an on-thejob training program <u>pursuant to</u> [under] 29 U.S.C. 2801-2931 unless the individual is under:

(a) Nineteen (19) years of age; and

(b) The parental control of another adult member; and

(23) An assistance payment for child care or attendant care:

(a) Received from an outside source; and

(b) Paid to one (1) household member:

1. From another household member; or

2. On behalf of another household member.

Section 3. Income Exclusions. The following shall not be considered as income:

(1) Money:

(a) Withheld from:

1. An assistance payment;

2. Earned income; or

3. Another income source; and

(b) Voluntarily or involuntarily returned to repay a prior overpayment received from the same income source, except as established in Section 2(21) of this administrative regulation;

(2) [Child support income shall be considered as follows:]

(a) A child support payment [shall be excluded] if:

1. Received by a recipient of the K-TAP or Kinship Care Program; and

2. It is transferred to the Child Support Enforcement Program in the Department for Income Support to maintain eligibility in K-TAP or Kinship Care Program; and

(b) A portion of child support money returned to the household receiving K-TAP or Kinship Care Program benefits by the cabinet shall not be excluded <u>from income</u>;

(3) A gain or benefit that is not in the form of money payable directly to the household;

(4) A <u>monetary</u> [money] payment that is not legally obligated and otherwise payable directly to a household, but is paid to a third party for a household expense;

(5) Income:

(a) Received:

1. In the certification period; and

2. Too infrequently or irregularly to be reasonably anticipated; and

(b) Not in excess of thirty (30) dollars per quarter;

(6) Educational income including grants, loans, scholarships, and work study income except as defined Section 2(17) of this administrative regulation;

(7) A loan from a:

(a) Private individual; or

(b) Commercial institution;

(8) A reimbursement for a past or future expense, other than normal living expenses;

(9) Money received and used for the care and maintenance of a third-party beneficiary who is not a household member;

(10) The earned income of a child who is:

(a) A member of the household;

(b) An elementary or secondary school student; and

(c) Age seventeen (17) years or younger;

(11) Money received in the form of a nonrecurring lump-sum payment;

(12) The cost of producing self-employment income. If the cost of producing farm self-employment income exceeds the income derived from self-employment farming, the loss shall be offset against any other countable income in the household;

(13) Income specifically excluded by 7 U.S.C. 2014 from consideration as income for the purpose of determining <u>SNAP</u> [Food Stamp Program] eligibility;

(14) An energy assistance payment or allowance that is made:

(a) In accordance with any federal law, except 42 U.S.C. 601 to 619, including a utility reimbursement made by:

1. The Department of Housing and Urban Development; or [and]

2. Rural <u>Housing Service</u> [and Economic Community and Development]; or

(b) For the purpose of a one (1) time payment or allowance made as <u>established</u> [defined] in a federal or state law for the costs of:

1. Weatherization;

2. Emergency repair; or

3. Replacement of:

a. An unsafe or inoperative furnace; or

b. Other heating or cooling device;

(15) A cash donation based on need received from a nonprofit charitable organization, not to exceed \$300 in a federal fiscal year quarter;

(16) A foster care payment for a foster child if the household requests that the child be excluded from the household in determining eligibility;

(17) <u>Dividend</u> [Money received under 26 U.S.C. 3507 of the Internal Revenue code, as an advanced payment of earned income credit;

(18) Interest or dividend] income, in accordance with 7 U.S.C. 2014;

(18)[(19)] Additional wages received by a member of the military while deployed to a designated combat zone, in accordance with 7 U.S.C. 2014;

(19)[(20)] Veteran's benefits provided to children with identified birth defects born to female Vietnam veterans, in accordance with 38 U.S.C. 1833;

(20)[(21)] Income from AmeriCorps programs, except for Volunteers in Service to America, as specified in Section 2(4) of this administrative regulation, in accordance with 42 U.S.C. 12501-12604;

(21)[(22)] Income from a <u>YouthBuild</u> [Youthbuild] program, unless the income is from on-the-job training, as <u>established</u> [defined] in Section 2 of this administrative regulation, in accordance with 29 U.S.C. 2931; and

(22)[(23)] Income associated with the fulfillment of an approved Plan for Achieving Self-Support (PASS), in accordance with 42 U.S.C. 1382a(b)(4)(B)(iv).

Section 4. Income Eligibility Standards. Participation in <u>SNAP</u> [the Food Stamp Program] shall be limited to a household whose income falls at or below the applicable standards, as established by the Food and Nutrition Service in 7 C.F.R. <u>Part</u> 273 that are established in this section:

(1) A household that contains a member who is elderly or has a disability as defined in 921 KAR 3:010, Section 1(9) or (11) [1(11) or (13)], shall have the member's net income compared to 100 percent of the federal income poverty guidelines.

(2) A household in which a member receives or is authorized to receive cash, in-kind, or other benefits funded under TANF pursuant to 42 U.S.C. 601-619, shall be considered categorically eligible in accordance with 921 KAR 3:030, Section 6(4).

(3) A household in which all members are recipients of SSI shall be considered categorically eligible in accordance with 921 KAR 3:030, Section 6(3).

(4)(a) Other households shall have a:

1. Gross income compared to 130 percent of the federal income poverty guidelines; and

2. Net income compared to 100 percent of the federal income poverty guidelines.

(b) A household's gross income as calculated pursuant to paragraph (a) of this subsection shall be the household's total income:

1. After excluded income has been disregarded in accordance with Section 3 of this administrative regulation; and

2. Before any deductions in accordance with Section 5 of this administrative regulation have been made.

Section 5. Income Deductions. The following shall be allowable income deductions:

(1) A monthly standard deduction per household, based on household size, as established in 7 U.S.C. 2014, that shall be periodically adjusted by the Food and Nutrition Service to reflect a change in the cost of living for a prior period of time as determined by the Food and Nutrition Service pursuant to 7 C.F.R. Part 273;

(2) Twenty (20) percent of gross earned income that is reported within ten (10) days of the date that the change of income becomes known to the household;

(3) A payment:

(a) For the actual cost for the care of:

1. A child; or

2. Other dependent; and

(b) Necessary for a household member to:

1. Seek, accept, or continue employment;

2. Attend training; or

3. Pursue education preparatory to employment;

(4) A homeless standard allowance of a shelter expense for a household in which all members are homeless and are not receiving free shelter throughout the calendar month, unless that household verifies higher expenses;

(5) An allowable medical expense in excess of thirty-five (35) dollars per month incurred by a household member who meets the

definition of being elderly or having a disability as defined in 921 KAR 3:010, Section 1(9) or (11) [1(11) or (13)]:

(a) Including:

1. Medical and dental care;

2. Hospitalization or outpatient treatment and nursing care;

3. Medication and medical supplies;

4. A health insurance premium;

5. A hospitalization insurance premium;

6. Dentures, a hearing aid, eyeglasses, prosthetics; or

7. Similar medical expense; and

(b) Excluding special diet cost;

(6) Actual child support payment made by a household member shall be allowed as a deduction if:

(a) The household member is legally obligated to pay child support; and

(b) Verification is provided showing a payment is currently being made.

Section 6. Monthly Shelter Cost Deduction. (1) The monthly shelter cost deduction shall be that amount in excess of fifty (50) percent of the household's income after allowable deductions have been made.

(2) The shelter deduction shall not exceed the current shelter maximum, except that a household shall not be subject to the maximum if a member is:

(a) Elderly; or

(b) Disabled.

(3) The excess shelter maximum shall be adjusted periodically by the Food and Nutrition Service to reflect change in the cost of living.

(4) Allowable monthly shelter expense shall include the following:

(a) Continuing charge for the shelter occupied by the household including:

1. Rent;

2. Mortgage;

3. Payment on mobile home loan;

4. Condominium and association fees;

5. Interest on a payment; and

6. Similar charge leading to ownership of the shelter;

(b) Property tax;

(c) State and local assessment;

(d) Insurance on the structure itself;

(e) The cost of:

1. Heating and cooking fuel;

2. Cooling;

3. Electricity;

4. Water and sewage;

5. Garbage and trash collection fee;

6. Telephone standard deduction; and

7. A fee charged by a utility provider for the initial installation of the utility;

(f) The shelter cost for the home if:

1. Temporarily unoccupied by the household because of:

a. Employment or training away from home;

b. Illness; or

c. Abandonment caused by a natural disaster or casualty loss; 2. The current occupant is not claiming shelter cost for food

stamp purposes; and

3. The home is not leased or rented during the absence of the household; and

(g) A charge for the repair of the home if substantially damaged or destroyed by fire, flood, or other natural disaster, except to the extent the cost is reimbursed by:

1. A private or public relief agency;

2. Insurance; or

3. A similar source.

(5) The standard utility allowance shall be used to calculate shelter cost for a household:

(a) Receiving Low Income Home Energy Assistance Program benefits; or

(b) Incurring cost, separate from its rent or mortgage payment, for:

1. Heating; or

2. Cooling (by air conditioning unit only).

(6) The standard utility allowance shall be adjusted periodically.

(7) If the household is not entitled to the utility standard or homeless standard allowance, it shall be given the basic utility allowance in accordance with 7 U.S.C. 2014, if the household is billed for two (2) of the following:

(a) Electricity (nonheating and noncooling);

(b) Water or sewage;

(c) Garbage or trash;

(d) Cooking fuel; or

(e) Telephone service.

(8) The basic utility allowance shall be adjusted annually.

(9) A household whose only expense is for telephone service shall be given a telephone standard.

(10) A household not entitled to a standard specified in subsection (7) or (9) of this section may use actual utility expense to calculate shelter deduction.

Section 7. Resources. (1) Uniform national resource standards of eligibility shall be utilized pursuant to 7 C.F.R. 273.8.

(2) Eligibility shall be denied or terminated if the total value of a household's liquid and nonliquid resources, not exempt <u>pursuant to</u> [under] Section 8 of this administrative regulation, exceed:

(a) <u>\$3,500</u> [\$3,000] for a household member:

1. With a disability as defined in 921 KAR 3:010, Section 1(9) [1(11)]; or

2. Sixty (60) years or older; or

(b) <u>\$2,250</u> [\$2,000] for any other household.

(3) Eligibility shall be denied or terminated for a household receiving one-time lottery or gambling winnings of \$3,500 or more.

(4) A household that is categorically eligible in accordance with 921 KAR 3:030, Section 6, shall meet the <u>SNAP</u> [food_stamp] resource requirement.

Section 8. Exempt Resources. The following resources shall not be considered in determining eligibility:

(1) All real estate, in accordance with 7 U.S.C. 2014;

(2) Household goods;

(3) Personal effects;

(4) A burial plot;

(5) The cash value of life insurance policies;

(6) In accordance with 7 U.S.C. 2014;

(a) A tax-preferred retirement account;

(b) A prepaid burial account;

(c) A licensed or unlicensed vehicle;

(d) A recreational vehicle;

(e) A resource deemed to an alien from a sponsor or spouse of a sponsor;

(f) Principal and accrued interest of an irrevocable trust during a period of unavailability;

(g) A tax-preferred educational account; and

(h) Another resource that is excluded for <u>SNAP</u> [food stamp] purposes;

(7) A governmental payment that is designated for the restoration of a home damaged in a disaster, if the household is subject to legal sanction $and[_{T}]$ if funds are not used as intended;

(8) A resource, of which the cash value is not accessible to the household;

(9) A resource that has been prorated as income;

(10) Income that is withheld by the employer to pay a certain expense directly to a third party as a vendor payment, to the extent that the remainder of the withheld income is not accessible to the household at the end of the year; and

(11) The earned income tax credit income received by a member of the household for a period of twelve (12) months from receipt if the member was participating in <u>SNAP</u> [the Food Stamp Program]:

(a) At the time the credit was received; and

(b) Continuously during the twelve (12) month period of exclusion.

Section 9. Transfer of Resources. A household that has transferred a resource knowingly for the purpose of qualifying or attempting to qualify for \underline{SNAP} [food stamps] shall be disqualified from participation in the program for up to one (1) year from the date of the discovery of the transfer.

Section 10. Failure to Comply with Other Programs. (1) Except as provided in subsection (2) of this section, if the benefits of a household are reduced under a federal, state, or local law relating to a means-tested public assistance program for the failure of a member of the household to perform an action required under the law or program, for the duration of the reduction, the <u>SNAP</u> [feed stamp] allotment of the household shall be reduced by twenty-five (25) percent.

(2) If the benefits of a household are reduced as defined in a federal, state, or local law relating to a means-tested public assistance program for the failure of a household member to perform a work requirement, the individual shall be subject to the disqualification procedures established [procedure as defined] in 921 KAR 3:025 [3:042], Section 5 or 6[7].

MARTA MIRANDA-STRAUB, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 6, 2020

FILED WITH LRC: October 12, 2020 at 10:24 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on December 21, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by December 14, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until December 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Laura Begin and Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the financial eligibility qualification criteria for the Supplemental Nutrition Assistance Program (SNAP).

(b) The necessity of this administrative regulation: This administrative regulation is necessary to set financial standards used to determine SNAP eligibility.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the authorizing statutes by establishing the financial eligibility requirements for SNAP.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing the financial eligibility requirements for SNAP.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative

regulation: The amendment to this administrative regulation updates the resource limits for SNAP households to the current amounts mandated by the USDA Food and Nutrition Service, removes interest income from the list of income excluded from financial review, and establishes a SNAP household disqualification for one-time lottery or gambling winnings in excess of \$3,500. One instance of the term "alien" is being replaced with "immigrant", consistent with the U.S. Citizenship and Immigration Services Systematic Alien Verification for Entitlements (SAVE) sponsorship initiative, which now refers to sponsored aliens as sponsored immigrants.

(b) The necessity of the amendment to this administrative regulation: This amendment to the administrative regulation is necessary to comply with the most recent federal change in SNAP resource limits and to add the lottery and gambling winnings disqualification mandated by the Agricultural Act of 2014.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment conforms to the content of the authorizing statues by conforming to federal law. The amendment creates a lottery and gambling SNAP disqualification per 7 C.F.R. 273.12(a)(5)(iii)(G) and updates SNAP resource limits consistent with the USDA.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will assist in the effective administration of the statutes through compliance with federally mandated resource limits and implementation of the lottery disgualification.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: All SNAP applicants and recipients will be subject to this administrative regulation amendment, potentially affected by the revised resource limits and the new lottery winnings disqualification. There were 265,158 households receiving SNAP assistance as of April 2020.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Households with substantial lottery or gambling winnings will be required to report the change in income or resources and will be denied or disqualified from SNAP if the winnings are over the specified amount.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The administrative regulation amendment does not create new costs to SNAP recipients.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Compliance with federal regulations enable the agency to operate the SNAP program with integrity, there is no new benefit to affected entities.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: Initial costs include system updates, a one-time system design change of less than \$500,000 to be able to match with lottery data.

(b) On a continuing basis: There are no known ongoing costs associated with this amendment.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: SNAP benefits are 100% federally funded through the Department of Agriculture. Program administrative costs are funded 50% federal and 50% state, which has been appropriated in the enacted budget.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: There is no increase in fees or funding required to implement this administrative regulation amendment.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applied because

the financial eligibility requirements contained in this administrative regulation will be applied in a like manner statewide.

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 7 C.F.R. 271.4, 7 U.S.C. 2011-2029.

2. State compliance standards. KRS 194A.010(2), 194A.050(1)

3. Minimum or uniform standards contained in the federal mandate. The provisions of the administrative regulation comply with the federal mandate.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation does not impose stricter, additional, or different responsibilities or requirements than those required by the federal mandate.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Justification for the imposition of a stricter standard, or additional or different responsibilities or requirements, is not applicable.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Cabinet for Health and Family Services is impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.010(2), 194A.050(1), 7 C.F.R. 271.4, 7 U.S.C. 2011-2029.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate new revenue for state or local government.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate new revenue for state or local government.

(c) How much will it cost to administer this program for the first year? This administrative regulation amendment will require one-time system design changes of less than \$500,000 to be able to match with lottery data.

(d) How much will it cost to administer this program for subsequent years? Once the system changes are in place, there will no costs to administer for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

CABINET FOR HEALTH AND FAMILY SERVICES Department for Community Based Services Division of Family Support (Amendment)

921 KAR 3:030. Application process.

RELATES TO: KRS 116.048, <u>205.2005.</u> 7 C.F.R. 273.2, [273.10,] 7 U.S.C. 2020(e)(2)(B)[(ii), (iii), (iv)], 42 U.S.C. 2000d, 52 U.S.C. 20506[, Pres. EO 13166]

STATUTORY AUTHORITY: KRS 116.048(1), <u>194A.010(2)</u>, 194A.050(1), 7 C.F.R. 271.4, 7 C.F.R. 273.2(i), [7 U.S.C. 2020(e)(2)(B),] 7 U.S.C. 2011-2029[, 52 U.S.C. 20506]

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.010(2) requires the Cabinet for Health and Family Services to administer income-supplement programs that protect, develop, preserve, and maintain families and children in the Commonwealth. KRS 194A.050(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to implement programs mandated by federal law or to qualify for the receipt of federal funds and necessary to cooperate with other state and federal agencies for the proper administration of the cabinet and its programs. 7 U.S.C. 2011 to 2029 and 7 C.F.R. 271.4 authorize the cabinet to administer a Supplemental Nutrition Assistance Program (SNAP) and prescribe the manner in which the program shall be implemented. 7 U.S.C. 2020(e)(2)(B) requires the cabinet to develop a uniform application process. KRS 116.048(1) designates the cabinet as a voter registration agency in accordance with 52 U.S.C. 20506. This administrative regulation establishes the application and the voter registration processes used by the cabinet in the administration of the SNAP.

Section 1. Right to Apply or Reapply. (1) An individual shall have the right to apply or reapply for SNAP benefits on the same day that the household first contacts the Department for Community Based Services (DCBS) office [in person] during office hours.

(2) The cabinet shall make the application process readily accessible to a household.

(3) In accordance with the procedures established in 920 KAR 1:070, interpreter services shall be provided for a person who is:

(a) Deaf; or

(b) Hard of hearing.

(4) In accordance with 42 U.S.C. 2000d [and Presidential EO 13166], interpreter services shall be provided for a person who is Limited English Proficient.

(5) An application shall be considered filed if:

(a) A FS-1, Application for SNAP, containing the name, address, and signature of the applicant is received by a DCBS office; or

(b) Application for benefits and another public assistance program is made in accordance with 921 KAR 2:040 and Section 6 of this administrative regulation.

(6) An application shall be processed after the:

(a) Applicant or representative is interviewed;

(b) Required information and verification for the application is provided to the DCBS office; and

(c) Application and <u>all</u> related documents are received by the DCBS office, in accordance with Section 3(1) of this administrative regulation.

Section 2. Who May Sign an Application. An application for SNAP shall be signed by:

(1) An adult or emancipated child who is a responsible member of the household; or

(2) The household's authorized representative.

Section 3. Where an Application is Filed. (1) Except as provided in subsection (2) of this section, an application shall be filed in any DCBS office or online at benefind.ky.gov.

(2) A concurrent application for Supplemental Security Income (SSI) and SNAP shall be filed in the service area office of the Social Security Administration.

Section 4. Prompt Action on an Application. The cabinet shall provide an eligible household that completes the initial SNAP application process an opportunity to participate as soon as possible. The cabinet shall not provide an opportunity to participate later than:

(1) Thirty (30) days after the application is filed for a household ineligible for expedited services; or

(2) The fifth calendar day following the date an application is filed for a household eligible for expedited services.

Section 5. Expedited Service. The cabinet shall provide expedited services to a household that is eligible in accordance with 7 C.F.R. 273.2(i).

Section 6. Public Assistance Application Process. (1) A household applying for Kentucky Transitional Assistance Program (KTAP) shall be allowed to simultaneously apply for SNAP benefits. A single interview shall be conducted for both programs.

(2) Time standards established in Section 4 of this administrative regulation shall not apply to a public assistance application. A public assistance application shall be governed by the time standards established in 921 KAR 2:035, Section 3.

(3) A household in which every member receives, or is authorized to receive, SSI shall be considered categorically eligible unless:

(a) The entire household is institutionalized;

(b) A household member is ineligible due to a drug-related felony conviction and does not meet the criteria to remain eligible established in KRS 205.2005;

(c) A household member is disqualified due to an intentional program violation, defined [established] in 921 KAR 3:010; [er]

(d) The head of the household is disqualified for failure to comply with the work requirements established in 921 KAR <u>3:025;</u> or

(e) The entire household is disqualified due to lottery or gambling winnings pursuant to 921 KAR 3:020, Section 7 [3:042].

(4) A household in which any member receives, or is authorized to receive cash, in-kind, or other benefits funded under the Temporary Assistance for Needy Families (TANF) Block Grant shall be considered categorically eligible unless:

(a) The entire household is institutionalized;

(b) A household member is ineligible due to a drug-related felony conviction and does not meet the criteria to remain eligible established in KRS 205.2005;

(c) A household member is disqualified due to an intentional program violation, defined [established] in 921 KAR 3:010; [er]

(d) The head of household is disqualified for failure to comply with the work requirements established in 921 KAR <u>3:025; or</u>

(e) The entire household is disqualified due to lottery or gambling winnings pursuant to 921 KAR 3:020, Section 7 [3:042].

(5) If verified by the program, a categorically eligible household shall not be required to verify the following eligibility factors:

(a) Resources;

- (b) Gross and net income;
- (c) Social Security number;

(d) Sponsored immigrant [alien] information; and

(e) Residency.

(6) A household that receives a TANF information sheet at application, which makes the household aware of other programs for which the household may qualify, shall be considered expanded categorically eligible.

(7) If verified by the program, an expanded categorically eligible household shall not be required to verify the following factors:

(a) Resources;

(b) Social Security number;

(c) Sponsored immigrant [alien] information; and

(d) Residency.

Section 7. Joint SSI and SNAP Application Process. A household in which every member is an applicant or recipient of SSI shall be allowed to simultaneously apply for both SSI and SNAP in accordance with Section 3(2) of this administrative regulation.

Section 8. Voter Registration. (1) In accordance with KRS 116.048 and 52 U.S.C. 20506, a SNAP applicant or recipient shall be provided the opportunity to complete an application to register to vote or update current voter registration if the applicant or recipient is:

(a) Age eighteen (18) or over; and

(b) Not registered to vote or not registered to vote at his <u>or her</u> current address.

(2) PAFS-706, Voter Registration Rights and Declination, shall be utilized to document a SNAP applicant or recipient's choice to:

(a) Register to vote;

(b) Not register to vote; or

(c) Indicate that they are currently registered to vote.

(3) A voter registration application shall be completed if a SNAP applicant or recipient wants to:

(a) Register to vote; or

(b) Update voter registration to provide a new address.

(4) The voter registration process shall not apply to an individual not included in the assistance application, such as an authorized representative.

(5) All information utilized in the voter registration process shall remain confidential and be used only for voter registration purposes.

(6) The State Board of Elections shall approve the application to register to vote and send a confirmation or denial notice to the voter registration applicant.

Section 9. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "FS-1, Application for SNAP", 10/18; and

(b) "PAFS-706, Voter Registration Rights and Declination", 8/10.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department for Community Based Services, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

MARTA MIRANDA-STRAUB, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 6, 2020

FILED WITH LRC: October 12, 2020 at 10:24 a.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on December 21, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by December 14, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until December 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Laura Begin and Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the application and the voter registration processes used by the Cabinet for Health and Family Services, Department for Community Based Services (DCBS), in the administration of the Supplemental Nutrition Assistance Program (SNAP).

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish uniform application standards for SNAP.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing an application process for SNAP.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the administration of the statutes by establishing procedures used in the administration of SNAP.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment clarifies that households denied or disqualified due to receipt of one-time lottery or gambling winnings in excess of \$3,500 pursuant to 921 KAR 3:020 are not categorically eligible for public assistance and replaces the term "alien" with "immigrant" for consistency with federal programs and definitions.

(b) The necessity of the amendment to this administrative regulation: The lottery and gambling winnings disqualification is necessary for compliance with the Agricultural Act of 2014. The term "alien" is being replaced with "immigrant", consistent with the definitions of the Department of Homeland Security, the Immigration and Nationality Act, and the U.S. Citizenship and Immigration Services Systematic Alien Verification for Entitlements (SAVE) sponsorship initiative because an immigrant is federally defined to be a permanent resident alien.

(c) How the amendment conforms to the content of the authorizing statutes: The amendment conforms to the content of the authorizing statutes through its adherence for federal law, thereby preserving the program and its federal funding.

(d) How the amendment will assist in the effective administration of the statutes: The amendment is necessary for compliance with federal regulations.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: All SNAP applicants are subject to this administrative regulation amendment, potentially affected by the new lottery and gambling winnings disqualification. There were 265,158 households receiving SNAP assistance as of April 2020.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Households with substantial lottery or gambling winnings will be required to report the winnings and will be denied or disqualified from SNAP if the winnings are over the specified amount.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The administrative regulation amendment does not create new costs to SNAP recipients.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Compliance with federal regulations enable the agency to operate the SNAP program with integrity; there is no new benefit to affected entities.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: There are no additional costs to implement this amendment, required for compliance with federal law and consistency with the amendment to 921 KAR 3:020.

(b) On a continuing basis: There are no continuing costs associated with this amendment.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: SNAP benefits are 100% federally funded through the Department of Agriculture. Program administrative costs are funded 50% federal and 50% state, which has been appropriated in the enacted budget.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: There is no increase in fees or funding required to implement this administrative regulation amendment.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. This administrative regulation does not establish any fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applied, because the application requirements contained in this administrative regulation will be applied in a like manner statewide.

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 7 C.F.R. 271.4, 7 C.F.R. 273.2(i), 7 U.S.C. 2011-2029

2. State compliance standards. KRS 116.048(1), 194A.010(2), 194A.050(1)

3. Minimum or uniform standards contained in the federal mandate. The provisions of the administrative regulation comply with the federal mandate.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation does not impose stricter, additional, or different responsibilities or requirements than those required by the federal mandate.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

Justification for the imposition of a stricter standard, or additional or different responsibilities or requirements, is not applicable.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Cabinet for Health and Family Services is impacted by this administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 116.048(1), 194A.010(2), 194A.050(1), 7 C.F.R. 271.4, 7 C.F.R. 273.2(i), 7 U.S.C. 2011-2029.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate revenue in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation amendment will not generate new revenue for state or local government.

(c) How much will it cost to administer this program for the first year? There is no cost to administer this amendment in the first year, this amendment is necessary for compliance with federal programs and consistency with the amendment to 921 KAR 3:020.

(d) How much will it cost to administer this program for subsequent years? There will no costs to administer this for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

CABINET FOR HEALTH AND FAMILY SERVICES Department for Community Based Services Division of Child Care (Amendment)

922 KAR 2:120. Child-care center health and safety standards.

RELATES TO: KRS Chapter 151, 158.030, Chapter 186, 189.125, 199.011(3), 199.894(1), <u>199.8951</u>, 199.896(2), (18), (19), <u>199.8962</u>, 199.898, 211.350-211.380, Chapter 217, [<u>227.220</u>,] 311.646, 314.011(5), Chapter 318, 527.070(1), 620.030, 7 C.F.R. 226.20, 16 C.F.R. 1219, 1220, 1221, 45 C.F.R. 98.2, 49 C.F.R. 571.213, 20 U.S.C. 6081-6084, 42 U.S.C. 9857-9858q

STATUTORY AUTHORITY: KRS 194A.050(1), 199.896(2), 199.8962(2)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the Secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to operate programs and fulfill the responsibilities vested in the cabinet, qualify for the receipt of federal funds, and cooperate with other state and federal agencies for the proper administration of the cabinet and its programs. KRS 199.896(2) authorizes the Cabinet for Health and Family Services to promulgate administrative regulations and standards for child-care centers. KRS 199.8962(2) requires the Cabinet for Health and Family Services to promulgate administrative regulations and standards for child-care centers. KRS 199.8962(2) requires the Cabinet for Health and Family Services to promulgate administrative regulations to establish the requirements and procedures for the implementation of standards contained therein. This administrative regulation establishes health and safety standards for child-care centers.

Section 1. Definitions. (1) "Cabinet" is defined by KRS 199.011(3) and 199.894(1).

(2) "Corporal physical discipline" is defined by KRS 199.896(18).

(3) "Developmentally appropriate" means suitable for the specific age range and abilities of a child.

(4) "Director" means an individual:

(a) Who meets the education and training requirements as specified in 922 KAR 2:090, Section 10:

(b) Whose primary full-time job responsibilities are to ensure compliance with 922 KAR 2:090, 922 KAR 2:280, and this administrative regulation; and

(c) Who is responsible for directing the program and managing the staff at the child-care center.

(5) "Health professional" means a person currently licensed as a:

- (a) Physician;
- (b) Physician assistant;

(c) Advanced practice registered nurse; or

(d) Registered nurse as defined by KRS 314.011(5) under the

supervision of a physician or advanced practice registered nurse.(6) "Infant" means a child who is less than twelve (12) months

of age. (7) "Licensee" means the owner or operator of a child-care

center to include:

- (a) Sole proprietor;
- (b) Corporation;

(c) Limited liability company;

- (d) Partnership;
- (e) Association; or
- (f) Organization, such as:
- 1. Board of education;
- Private school;
- 3. Faith-based organization;
- 4. Government agency; or
- 5. Institution.
- (8) "Nontraditional hours" means the hours of:
- (a) 7 p.m. through 5 a.m. Monday through Friday; or
- (b) 7 p.m. on Friday until 5 a.m. on Monday.
- (9) "Parent" is defined by 45 C.F.R. 98.2.

(10) "Premises" means the building and contiguous property in which child care is licensed.

(11) "Preschool-age" means a child who is older than a toddler and younger than school-age.

(12) "Protective surface" means loose surfacing material not installed over concrete, which includes:

(a) Wood mulch;

(b) Double shredded bark mulch;

(c) Uniform wood chips;

(d) Fine sand;

(e) Coarse sand;

(f) Pea gravel, except for areas used by children under three (3) years of age;

(g) Certified shock absorbing resilient material; or

(h) Other material approved by the cabinet or designee, based on recommendation from a nationally recognized source.

(13) "Related" means having one (1) of the following relationships with the operator of the child-care center:

(a) Child; (b) Grandchild:

(c) Niece; (d) Nephew;

(e) Sibling;

(f) Stepchild; or

(g) Child in legal custody of the operator.

(14) "School-age" means a child who meets the age requirements of KRS 158.030 or who attends kindergarten, elementary, or secondary education.

(15) "Toddler" means a child between the age of twelve (12) months and thirty-six (36) months.

(16) "Transition" means the changing from one (1) child care arrangement to another.

(17) "Transition plan" means a document outlining the process to be used in moving a child from one (1) child care arrangement to another.

(18) "Type I child-care center" means a child-care center licensed to regularly provide child care services for:

(a) Four (4) or more children in a nonresidential setting; or

(b) Thirteen (13) or more children in a residential setting with designated space separate from the primary residence of a licensee

(19) "Type II child-care center" means the primary residence of the licensee in which child care is regularly provided for at least seven (7), but not more than twelve (12), children including children related to the licensee.

Section 2. Child Care Services. (1) Services established in this administrative regulation shall be maintained during all hours of operation that child care is provided.

(2) For an operating child-care center, minimum staff-to-child ratios and group size shall be maintained as established in the table established in this subsection.

Age of Children	Ratio	Maximum Group Size*
Infant	1 staff for 5 children	10
Toddler 12 to 24 months	1 staff for 6 children	12
Toddler 24 to 36 months	1 staff for 10 children	20
Preschool-age 3 to 4 years	1 staff for 12 children	24
Preschool-age 4 to 5 years	1 staff for 14 children	28
School-age 5 to 7 years	1 staff for 15 children	30
School-age 7 and older	1 staff for 25 children (for before and after school)	30
	1 staff for 20 children (full day of care)	30
*Maximum Group Size shall be applicable only to Type I child-care centers.		

(a) In a Type I child-care center, a group size shall:

1. Be separately maintained in a defined area unique to the group; and

2. Have specific staff assigned to, and responsible for, the group.

(b) The age of the youngest child in the group shall determine the:

1. Staff-to-child ratio; and

Maximum group size.

(c) This subsection and subsection (9) of this section shall not apply during traditional school hours to a center:

1. Providing early childhood education to mixed-age groups of children whose ages range from thirty (30) months to six (6) years; and

2. Accredited by or affiliated with a nationally-recognized education association that has criteria for group size and staff-tochild ratios contrary to the requirements of this subsection.

(d) If a child related to the director, employee, or person under the supervision of the licensee is receiving care in the center, the child shall be included in the staff-to-child ratio.

(3)(a) Each center shall maintain a child-care program that assures each child shall [will] be:

1. Provided with adequate supervision at all times by a qualified staff person who ensures the child is:

a. Within scope of vision and range of voice; or

b. For a school-age child, within scope of vision or range of voice: and

2. Protected from abuse and [or] neglect.

(b) The program shall include:

1. A procedure to ensure compliance with and inform child care staff of the laws of the Commonwealth pertaining to child abuse or neglect set forth in KRS 620.030; and

2. Written policy that states that the procedures that were taught at the orientation training shall be implemented by each child-care center staff member.

(4) The child-care center shall provide a daily planned program:

(a) Posted in writing in a conspicuous location with each age group and followed:

(b) Of activities that are individualized and developmentally appropriate for each child served;

(c) That provides experience to promote the individual child's physical, emotional, social, and intellectual growth and well-being; and

(d) Unless the child-care center is a before- or after-school program that operates part day or less, that offers a variety of creative activities including:

1. Art or music;

2. Math or numbers;

3. Dramatic play;

4. Stories and books;

5. Science or nature;

6. Block building or stacking;

7. Tactile or sensory activity;

8. Multi-cultural exposure;

9. Indoor [or] and outdoor play in which a child makes use of both small and large muscles;

10. A balance of active and quiet play, including group and individual activity;

11. An opportunity for a child to:

a. Have some free choice of activities;

b. If desired, play apart from the group at times; and

c. Practice developmentally appropriate self-help procedures in respect to:

(i) Clothing;

(ii) Toileting;

(iii) Hand-washing; and

(iv) Eating; and

12. The use [Use] of screen time, electronic viewing, and listening devices if the:

a. Material is developmentally appropriate to the child using the equipment:

b. Material is not a replacement for active play or a substitute for engagement and interaction with other children and adults;

c. Material does not include any violence, adult content viewing, or inappropriate language;

d. Child is over twenty-four (24) months of age;

e. [c. Viewing or individual listening is limited to two (2) hours per day:]

d.] Viewing or listening is discussed with parents <u>beforehand</u> [prior to viewing or listening]; and

<u>f.</u> [e-] Viewing or listening is designed as an educational tool used to help children explore, create, problem solve, interact, and learn with and from one another.

(5) Screen time shall be:

(a) Utilized for:

1. A maximum of thirty (30) minutes per day in a half-day program;

2. A maximum of sixty (60) minutes per day in a full-day program; or

3. The time needed for school-age children to complete assigned non-traditional instruction; and

(b) Prohibited for a child under twenty-four (24) months of age.

(6) A child who does not wish to use an [the] electronic device [devices] during the planned program shall be offered other appropriate activities.

(7)[(6)] Regularity of routines shall be implemented to afford the child familiarity with the daily schedule of activity.

(8)[(7)] Sufficient time shall be allowed for an activity so that a child may progress at his or her own developmental rate.

 $(9)[(\hat{e})]$ A child shall not be required to stand or sit for a prolonged period of time:

(a) During an activity;

(b) While waiting for an activity to start; or

(c) As discipline.

(10)[(9)] If school-age care is provided:

(a) A separate area or room shall be provided in a Type I childcare center; and

(b) Each child shall be provided a snack after school.

(11)[(10)] A child shall not be subjected to:

(a) Corporal physical discipline pursuant to KRS 199.896(18);

(b) Loud, profane, threatening, frightening, humiliating, or abusive language; or

(c) Discipline that is associated with:

1. Rest;

2. Toileting; [or]

3. Play time; or

4. Food.

(12)[(11)] If nontraditional hours of care are provided:

(a) Including time spent in school, a child shall not be permitted to spend more than sixteen (16) hours in the child-care center during one (1) twenty-four (24) hour period;

(b) At least one (1) staff member shall be assigned responsibility for each sleeping room;

(c) A child present for an extended period of time during waking hours shall receive a program of well-balanced and constructive activity that is developmentally appropriate for the child;

(d) A child sleeping three (3) hours or more shall sleep in:

1. Pajamas; or

2. A nightgown;

(e) <u>A</u> [$\frac{\text{If a]}}{\text{main and a strends school from the child-care center[}_{\tau} the child] shall be offered breakfast <u>prior to leaving for school</u>; and$

(f) Staff shall: 1. If employed by a Type I child-care center, remain awake

while on duty; or

2. If employed by or is the operator of a Type II child-care center, remain awake until every child in care is asleep.

(13)[(12)](a) Care for a child with a special need shall be consistent with the nature of the need as documented by the child's health professional.

(b) A child may include a person eighteen (18) years of age if the person has a special need for which child care is required.

Section 3. General Requirements. (1) <u>Screen time, electronic</u> [Electronic] viewing, and listening devices shall only be used in the center as a part of the child's planned program of activity as established in Section 2(4) and (5) of this administrative regulation.

(2) Activity areas, equipment, and materials shall be arranged

so that the child's activity is adequately supervised by staff.

(3) Computer equipment shall be equipped with a monitoring device that limits access by a child to items inappropriate for a child to view or hear.

(4) A child shall:

(a) Be helped with personal care and cleanliness based upon his or her developmental skills;

(b) Except as established in paragraph (c) of this subsection, wash his or her hands with liquid soap and warm running water:

1. a. Upon arrival at the center; or

b. Within thirty (30) minutes of arrival for school-age children;

2. Before and after eating or handling food;

3. After toileting or diaper change;

4. After handling animals;

5. After touching an item or an area of the body soiled with body fluids or wastes; and

6. After outdoor or indoor play time; and

(c) Use hand sanitizer or hand-sanitizing wipes if liquid soap and warm running water are not available in accordance with paragraph (b) of this subsection. The child shall wash the child's hands as soon as practicable once liquid soap and warm running water are available.

(5) Staff shall:

(a) Maintain personal cleanliness;

(b) Conform to hygienic practices while on duty;

(c) Except as established in paragraph (d) of this subsection, wash their hands with liquid soap and running water:

1. Upon arrival at the center;

2. After toileting or assisting a child in toileting;

3. Before and after diapering each child;

4. After wiping or blowing a child's or own nose;

5. After handling animals;

6. After caring for a sick child;

7. Before and after feeding a child or eating;

8. Before dispensing medication;

9. After smoking or vaping: and

10. If possible, before administering first aid; and

(d) Use hand sanitizer or hand-sanitizing wipes if liquid soap and warm running water are not available in accordance with paragraph (c) of this subsection. The staff shall wash the staff's hands as soon as practicable once liquid soap and warm running water are available.

(6) A staff person suspected of being infected with a communicable disease shall:

(a) Not perform duties that could allow for the transmission of the disease until the infectious condition can no longer be transmitted; and

(b) Provide a statement <u>of fitness to return to work</u> from a health professional, if requested.

(7) The following shall be inaccessible to a child in care:

(a) Toxic cleaning supplies, poisons, and insecticides;

(b) Matches, cigarettes, lighters, and flammable liquids; and

(c) Personal belongings and medications of staff.

(8) The following shall be inaccessible to a child in care unless under direct supervision and part of planned program of instruction:

(a) Knives and sharp objects;

(b) Litter and rubbish;

(c) Bar soap; and

(d) Plastic bags not used for personal belongings.

(9) In accordance with KRS 527.070(1), firearms and ammunition shall be stored separately <u>from each other</u> in a locked area outside of the designated child care area.

(10) Smoking or vaping shall:

(a) Be permitted in accordance with local ordinances;

(b) Be allowed only in outside designated areas; and

(c) Not be permitted in the presence of a child.

(11) While bottle feeding a child, the:

(a) Child shall be held; and

(b) Bottle or beverage container shall not be:

1. Propped;

2. Left in the mouth of a sleeping child; or

3. Heated in a microwave.

(12) A fire drill shall be:

(a) Conducted during hours of operation at least monthly; and (b) Documented.

(13) An earthquake drill, lockdown drill, and [a] tornado drill shall be

(a) Conducted during hours of operation at least quarterly; and (b) Documented.

Section 4. Premises Requirements. (1) The premises shall be:

(a) Suitable for the purpose intended;

(b) Kept clean and in good repair; and

(c) Equipped with:

1. A working telephone accessible to a room used by a child; and

2. A list of emergency numbers posted by the telephone or maintained in the telephone's contact, including numbers for the:

a. Police department;

b. Fire department [station];

c. Emergency medical care and rescue squad; and

d. Poison control center.

(2) A child-care center shall be in compliance with the codes administered by the Kentucky [State] Fire Marshal and the local zoning laws.

(3) Fire and emergency exits shall be kept clear of debris.

(4) A working carbon monoxide detector shall be required in a licensed child-care center that is in a home if the home:

(a) Uses fuel burning appliances; or

(b) Has an attached garage.

(5) The building shall be constructed to ensure the:

(a) Building is:

1. Dry;

2. Ventilated; and

3. Well lit, including clean light fixtures that are:

a. In good repair in all areas; and

b. Shielded or have shatter-proof bulbs installed; and

(b) Following are protected:

1. Windows:

2. Doors;

3. Stoves;

4. Heaters;

5. Furnaces;

6. Pipes; and

7. Stairs.

(6) Exclusive of the kitchen, bathroom, hallway, and storage area, there shall be a minimum of thirty-five (35) square feet of space per child.

(7) Measures shall be utilized to control the presence of:

(a) Rodents;

(b) Flies;

(c) Roaches; and

(d) Other vermin.

(8) An opening to the outside shall be effectively protected against the entrance of vermin by:

(a) Self-closing doors;

(b) Closed windows;

(c) Screening;

(d) Controlled air current; or

(e) Other effective means.

(9) Floors, walls, and ceilings shall be smooth, in good repair, and constructed to be easily cleaned.

(10) The water supply shall be:

(a) Potable:

(b) Protected from contamination;

(c) Adequate in quality and volume;

(d) Under sufficient pressure to permit unrestricted use; and

(e) Obtained from an approved public water supply or a source approved by the local health department.

(11) Groundwater supplies for a child-care center caring for:

(a) More than twenty-five (25) children shall comply with requirements of the Energy and Environment Cabinet, Division of Water, established in KRS Chapter 151 and 401 KAR Chapter 8, as applicable; or

(b) Twenty-five (25) children or less shall secure approval from the:

1. Energy and Environment Cabinet; or

2. Local health department.

(12) Sewage shall be properly disposed by a method approved by the:

(a) Energy and Environment Cabinet; or

(b) Cabinet.

(13) All plumbing shall comply with the State Plumbing Code established in KRS Chapter 318.

(14) Solid waste shall be kept in a suitable receptacle in accordance with local, county, and state law, as governed by KRS 211.350 to 211.380.

(15) If a portion of the building is used for a purpose other than child care:

(a) Necessary provisions shall be made to avoid interference with the child-care program; and

(b) A separate restroom shall be provided for use only by those using the building for its child care purpose.

(16) The temperature of the indoor [inside] area of the premises shall be sixty-five (65) to eighty-two (82) degrees Fahrenheit.

(17) Outdoor activity shall be restricted based upon:

(a) Temperature:

(b) Weather conditions; [or]

(c) Weather alerts, advisories, and warnings issued by the National Weather Service; or

(d) Age or temperament of the child.

(18) A kitchen shall not be required if:

(a) The only food served is an afternoon snack to school-age children; and

(b) Adequate refrigeration is maintained.

(19) The Department of Housing, Buildings and Construction, the Kentucky [State] Fire Marshal's Office, and cabinet shall be contacted concerning a planned new building, addition, or major renovation prior to construction.

(20) An outdoor play area shall be:

(a) Except for an after-school child-care program, located on the premises of a public or state-accredited nonpublic school, fenced for the safety of the children;

(b) A minimum of sixty (60) square feet per child, separate from and in addition to the thirty-five (35) square feet minimum pursuant to subsection (6) of this section;

(c) Free from:

1. Litter:

2. Glass;

3. Rubbish; and

4. Flammable materials;

(d) Safe from foreseeable hazard;

(e) Well drained;

(f) Well maintained:

(g) In good repair; and

(h) Visible to staff at all times.

(21) A protective surface shall: (a) Be provided for outdoor play equipment used to:

1. Climb; 2. Swing: and

active play that:

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3. Slide; and

(b) Have a fall zone equal to the height of the equipment.

(22) If a child-care center does not have access to an outdoor play area, an indoor space shall:

(a) Be used as a play area;

(b) Have a minimum of sixty (60) square feet per child, separate from and in addition to the thirty-five (35) square feet minimum pursuant to subsection (6) of this section;

(c) Include equipment for gross motor skills; and

(d) Have a protective surface of at least two (2) inches thick around equipment intended for climbing.

(a) Have moderate to vigorous activity each day, including

1. Includes outdoor play unless unavailable pursuant to

a. Thirty (30) minutes per day in a half-day program; or

(23) While attending, a child shall:

subsections (17) or (22) of this section;

2. Shall occur for a minimum of;

b. Sixty (60) minutes per day in a full-day program; and

3. May be broken into smaller increments of time throughout a day; and

(b) Not be punished or rewarded in regards to play time.

(24) Fences shall be:

(a) Constructed of safe material;

(b) Stable; and

(c) In good condition.

(25)((24)] Supports for climbing apparatus and large equipment shall be securely fastened to the ground.

(26)[(25)] Crawl spaces, such as tunnels, shall be short and wide enough to permit access by adults.

(27)[(26)] A sandbox shall be:

(a) Constructed to allow for drainage;

(b) Covered while not in use;

(c) Kept clean; and

(d) Checked for vermin prior to use.

(28)[(27)] Bodies of water that shall not be utilized include:

(a) Portable wading pools;

(b) Natural bodies of water; and

(c) Unfiltered, nondisinfected containers.

(29)(28)] A child-care center shall have enough toys, play apparatus, and developmentally appropriate materials to provide each child with a variety of activities during the day, as specified in Section 2 of this administrative regulation.

(30)[(29)] Storage space shall be provided:

(a) In the form of:

1. Shelves; or

2. Other storage device accessible to the children; and

(b) In sufficient quantity for each child's personal belongings.

(31)((30)] Supplies shall be stored so that the adult can reach them without leaving a child unattended.

Section 5. Infant and Toddler Play Requirements. (1) Indoor [Inside] areas for infants and toddlers under twenty-four (24) months of age shall:

(a) Be separate from an area used by an older child;

(b) Not be an exit or entrance; and

(c) Have adequate crawling space for an infant or toddler away from general traffic patterns of the center.

(2) While awake, an infant shall have short periods of supervised tummy time throughout each day.

(3) Except in accordance with subsection (4)[(3)] of this section or Section 2(2)(c) of this administrative regulation, an infant or toddler under twenty-four (24) months of age shall not participate in an activity with an older child for more than one (1) hour per day.

(4)[(3)] If a toddler is developmentally appropriate for a transition to a preschool age group, a toddler may participate in an activity with an older child for more than one (1) hour per day if:

(a) Space for the toddler is available in the preschool-age group;

(b) The staff-to-child ratios and group sizes are maintained based on the age of the youngest child;

(c) The center has a procedure for listing a transitioning toddler on attendance records, including a specific day and time the toddler is with either age group; and

(d) The child care center has obtained the signature and approval of the toddler's parent on the toddler's transition plan.

(5)[(4)] If a child-care center provides an outdoor play area for an infant or toddler under twenty-four (24) months of age, the outdoor area shall be:

(a) Shaded; and

(b) In a [A] separate area or scheduled at a different time than an older child.

(6)[(5)] Playpens and play yards shall:

(a) Meet federal standards as issued by the Consumer Product Safety Commission, including 16 C.F.R. 1221;

(b) Be manufactured for commercial use; and

(c) Not be used for sleeping or napping.

Section 6. Sleeping and Napping Requirements. (1) An infant shall sleep or nap on the infant's back unless the infant's health professional signs a waiver that states the infant requires an

alternate sleeping position.

(2) Rest time shall be provided for each child who is not school-age and who is in care for more than four (4) hours.

(3) Rest time shall <u>occur in an</u> [include] adequate space <u>according to</u> [specified by] the child's age as follows:

(a) For an infant:

1. An individual non-tiered crib that meets Consumer Product Safety Commission standards established in 16 C.F.R. 1219-1220;

2. A firm crib mattress in good repair with a clean tight-fitted sheet that shall be changed:

a. Weekly; or

b. Immediately if it is soiled or wet;

 No [loose] bedding <u>other than a clean tight-fitted sheet[</u>, such as a bumper or a blanket]; and

4. No toys or other items except the infant's pacifier; or

(b) For a toddler or preschool-age child:

1. An individual bed, a two (2) inch thick waterproof mat, or cot in good repair: and

2. Bedding that is in good repair and is changed:

a. Weekly; or

b. Immediately if it is soiled or wet.

(4) Rest time shall not exceed two (2) hours for a preschoolage child unless the child is attending the child-care center during nontraditional hours.

(5) A child who does not sleep shall be permitted to play quietly and shall be visually supervised.

(6) Cots, equipment, and furnishings used for sleeping and napping shall be spaced twelve (12) inches apart to allow free and safe movement by a person.

(7) If cots or mats are used, floors shall be free from:

(a) Drafts;

(b) Liquid substances;

(c) Dirt; and

(d) Dampness.

(8)(a) Cots or mats not labeled for individual use by a child shall be cleaned after each use.

(b) Cots or mats labeled for individual use by a child shall be:

1. Cleaned at least weekly; and

2. Disinfected immediately if it is soiled or wet.

(9) Individual bedding shall be stored in a sanitary manner.

Section 7. First Aid and Medicine. (1) First aid supplies shall:

(a) Be available to provide prompt and proper first aid treatment:

(b) Be stored out of reach of a child;

(c) Be periodically inventoried to ensure the supplies have not expired;

(d) If reusable, be:

1. Sanitized; and

2. Maintained in a sanitary manner; and

(e) Include:

1. Liquid soap;

2. Adhesive bandages;

3. Sterile gauze;

4. Medical tape;

Scissors;

6. A thermometer;

7. Flashlight;

8. Cold pack;
 9. First aid book;

10. Disposable gloves; and

11. A cardiopulmonary resuscitation mouthpiece protector.

(2) A child showing signs of an illness or condition that could be communicable shall not be admitted to the regular child-care program.

(3) If a child becomes ill while at the child-care center:

(a) The child shall be placed in a supervised area isolated from the rest of the children;

(b) The parent shall be contacted immediately; and

(c) Arrangements shall be made to remove the child from the child-care center as soon as practicable.

(4) Prescription and nonprescription medication shall be administered to a child in care:

(a)1. With a written request of the child's parent or the child's prescribing health professional; and

2. According to the directions or instructions on the medication's label; or

(b) For epinephrine, in accordance with KRS 199.8951 and 311.646.

(5) The child-care center shall keep a written record of the administration of medication, including:

(a) Time of each dosage;

(b) Date;

(c) Amount;

(d) Name of staff person giving the medication;

(e) Name of the child; and

(f) Name of the medication.

(6) Medication, including refrigerated medication, shall be:

(a) Stored in a separate and locked place, out of the reach of a child unless the medication is:

1. A first aid supply and is maintained in accordance with subsection (1) of this section;

2. Diaper cream, sunscreen, or toothpaste. Diaper cream, sunscreen, or toothpaste shall be inaccessible to a child;

3. An epinephrine auto-injector. A licensed child-care center shall comply with KRS 199.8951 and 311.646, including:

a. An epinephrine auto-injector shall be inaccessible to a child;

b. A child-care center shall have at least one (1) person onsite who has received training on the administration of an epinephrine auto-injector if the child-care center maintains an epinephrine autoinjector;

c. A child-care center shall seek emergency medical care for a child if an auto-injector is administered to the child; and

d. A child-care center shall report to the child's parent and the cabinet in accordance with 922 KAR 2:090, Section $\underline{13(1)(b)}$, $[\underline{12(1)(b)}]$ if an epinephrine auto-injector is administered to a child; or

4. An emergency or rescue medication for a child in care, such as medication to respond to diabetic or asthmatic condition, as prescribed by the child's physician. Emergency or rescue medication shall be inaccessible to a child in care;

(b) Kept in the original bottle; and

(c) Properly labeled.

(7) Medication shall not be given to a child if the medication's expiration date has passed.

Section 8. Kitchen Requirements. (1) The kitchen shall:

(a) Be clean;

(b) Be equipped for proper food:

1. Preservation;

2. Storage;

3. Preparation; and

4. Service;

(c) Be adequately ventilated to the outside air; and

(d) Except in a Type II child-care center when a meal is not being prepared, not be used for the activity of a child.

(2) A child-care center required to have a food service permit shall be in compliance with 902 KAR 45:005 and this administrative regulation.

(3) Convenient and suitable sanitized utensils shall be:

(a) Provided; and

(b) Used to minimize handling of food during preparation.

(4) A cold-storage facility used for storage of perishable food in

a nonfrozen state shall: (a) Have an indicating thermometer or other appropriate

temperature measuring device;

(b) Be in a safe environment for preservation; and

(c) Be forty (40) degrees Fahrenheit or below.

(5) Frozen food shall be:

(a) Kept at a temperature of zero degrees Fahrenheit or below;

and

(b) Thawed:

At refrigerator temperatures;
 Under cool, potable running water;

3. As part of the cooking process; or

4. By another method in accordance with the Department for

[of] Public Health's food safety standards and permits, established in KRS Chapter 217.

- (6) Equipment, utensils, and surfaces contacting food shall be: (a) Smooth;
- (b) Free of breaks, open seams, cracks, and chips;
- (c) Accessible for cleaning; and
- (d) Nontoxic.
- (7) The following shall be clean and sanitary:
- (a) Eating and drinking utensils;
- (b) Kitchenware;
- (c) Food contact surfaces of equipment;
- (d) Food storage utensils;
- (e) Food storage containers;
- (f) Cooking surfaces of equipment; and
- (g) Nonfood contact surfaces of equipment.
- (8) A single-service item shall be:
- (a) Stored;
- (b) Handled and dispensed in a sanitary manner; and
- (c) Used only once.
- (9) Bottles shall be:
- (a) Individually labeled;
- (b) Promptly refrigerated;
- (c) Covered while not in use; and

(d) Consumed within one (1) hour of being heated or removed from the refrigerator.

Section 9. Food and <u>Drink [Meal]</u> Requirements. (1) Food shall be:

(a) Clean;

(b) Free from:

1. Spoilage;

- 2. Adulteration; and
- 3. Misbranding;

(c) Safe for human consumption;

(d) Withheld from service or discarded if the food is hermetically sealed, nonacidic, or low-acidic food that has been processed in a place other than a commercial food-processing establishment;

(e) Obtained from a source that is in compliance with the Department <u>for</u> [ef] Public Health's food safety standards and permits, established in KRS Chapter 217;

(f) Acceptable if from an established commercial food store;

(g) Served in a quantity that is developmentally appropriate for the child with additional portions provided upon request of the child; and

- (h) Protected against contamination from:
- 1. Dust;

2. Flies;

- 3. Rodents and other vermin;
- 4. Unclean utensils and work surfaces;

5. Unnecessary handling;

- 6. Coughs and sneezes;
- 7. Cuts in skin;
- 8.Communicable disease;
- 9. Flooding;
- 10. Drainage; and
- 11. Overhead leakage.
- (2) Food shall not be:
- (a) Used for reward;(b) Used for discipline;

parent or the child's physician;

prepared and labeled.

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- (c) Withheld until all other foods are consumed; or
- (d) Served while viewing electronic devices.
- (3) A serving of milk shall consist of:

1. Age birth to twelve (12) months; or

(12) months to twenty-four (24) months; or

(a) Breast milk or iron-fortified formula for a child:

2. Beyond twelve (12) months of age as documented by the

(b) Pasteurized unflavored whole milk for children ages twelve

(c) Pasteurized unflavored low fat one (1) percent or fat-free

(4) Formula or breast milk provided by the parent shall be

skim milk for children ages twenty-four (24) months to school-age.

(5) A child-care center may participate in the Child and Adult Care Food Program (CACFP).

(6) A serving of bread shall only consist of whole or enriched grain.

(7) Drinking water shall be freely available to a child throughout the day.

(8) Food shall be stored on:

(a) Clean racks;

(b) Clean shelves;

(c) Other clean surfaces; or

(d) If maintained in a sanitary condition, in nonabsorbent labeled containers a minimum of six (6) inches off the floor.

(9) Fruits and vegetables shall be washed before cooking or serving.

(10) <u>Children shall not be served food that has been deep-fried</u> on-site.

(11) Meat salads, poultry salads, and cream-filled pastries shall be:

(a) Prepared with utensils that are clean; and

(b) Refrigerated unless served immediately.

(12)[(11)] An individual portion of food served to a child or adult shall not be served again.

(13)[(12)] Wrapped food that is still wholesome and has not been unwrapped may be reserved.

(14)[(13)] Meals shall be:

(a) Served every two (2) to three (3) hours; and

(b) Served to a child:

1. Seated with sufficient room to manage food and tableware; and

2. Supplied with individual eating utensils designed for use by a child.

(15) Drinks served to children shall not have added sugar. Children shall drink water, milk, or 100% juice with meals.

(16) Juice shall:

(a) Not include added sugar;

(b) Not be served more than once per day;

(c) Not be served to children under the age of twelve (12) months; and

(d) Serve as a fruit or vegetable meal component replacement. (17) A meat alternative shall include:

(a) Tofu;

(b) Soy products;

(c) Cheese, including cottage or ricotta cheese;

(d) Eggs;

(e) Cooked dry beans;

(f) Peanut butter or soy nut butter;

(g) Yogurt, plain or flavored; or

(h) Peanuts, soy nuts, tree nuts, or seeds.

(18) Cheese shall be natural and pasteurized processed cheese. Children shall not be served cheese product, imitation cheese, cheese food, or cheese spread as a meat alternative.

(19)[(15)] All children in the center shall be offered the same food items unless:

(a) A parent provides written authorization to substitute the food with an alternative that meets the same component requirement; or

(b) A physician provides written authorization to substitute the food or the food component and includes the food that the child shall not have and the food substitution that the child shall have [the child's parent or health professional documents a dietary restriction that necessitates an alternative food item for the child].

(20) Children shall be served all daily food components required by Section 10 or 11 of this administrative regulation.

Section 10. Meal Planning Requirements for a Center that Provides Meals. (1) [(15) A child-care center shall serve:

(a)1. Breakfast; or

2. A mid-morning snack;

(b)1. Lunch; or

2. A mid-afternoon snack; and

(c) If appropriate, dinner.

(16) A weekly menu shall be:

(a) Prepared;

(b) Dated;

(c) Posted in advance in a conspicuous place;

(d) Kept on file for thirty (30) days; and

(e) Amended in writing with any substitutions on the day the meal is served.] Breakfast shall include the following three (3) components:

(a) Milk;

(b) Bread or grain, which may:

1. Be exchanged for a meat or meat alternative up to three (3) times per week; and

2. Include ready-to-eat cereal with six (6) grams of sugar or less per dry ounce; and

(c)1. Fruit;

2. Vegetable; or

3. 100 percent juice.

(2)[(18)] A snack shall include two (2) of the following components:

(a) Milk;

(b) Meat or meat alternative[Protein];

(c) Bread or grain; or

(d)1. Fruit;

2. Vegetable; or

3. 100 percent juice.

(3)[(+9)] Lunch, and dinner if served, shall include the following components:

(a) Milk;

(b) Meat or meat alternative[Protein];

(c) Bread or grain; and

(d)1. Two (2) different vegetables; or

2. [Two (2) fruits; or

3.] One (1) fruit and one (1) vegetable.

(4) A grain-based dessert shall not replace the bread or grain component of a meal.

(5) Yogurt served to children shall have twenty-three (23) grams of sugar or less per six (6) ounces.

(6) The serving size for milk shall be:

(a) Four (4) ounces for one (1) or two (2) year old children;

(b) Six (6) ounces for three (3) to five (5) year old children; or

(c) Eight (8) ounces for school-age children.

(7) At least one (1) whole grain bread or grain shall be served daily.

(8) A component shall be considered "whole grain" if:

(a) The product is listed by any state agency's Special Supplemental Nutrition Program for Women, Infant, and Children as whole grain;

(b) The product is labeled as "whole wheat" and has a Standard of Identity issued by the U.S. Food and Drug Administration (FDA);

(c) The product includes one of the FDA-approved whole grain health claims on its packaging, exactly as written;

(d) The product meets the whole grain-rich criteria under the National School Lunch Program (NSLP);

(e) The product is identified on the package as "whole grain," "whole wheat," or "whole grain-rich"; or

(f) Proper documentation from a manufacturer or standardized recipe demonstrates that whole grains are the primary grain

ingredient by weight.

(9) A weekly menu shall be:

(a) Prepared; (b) Dated;

(b) Dated,

(c) Posted in advance in a conspicuous place;

(d) Kept on file for thirty (30) days; and

(e) Amended in writing with any substitutions on the day the meal is served.

Section 11. Meal Planning Requirements for a Center that Does Not Provide Meals. (1) A child-care center that does not provide meals shall serve:

(a)1. Breakfast; or

2. A mid-morning snack;

(b)1. Lunch; or

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2. A mid-afternoon snack; and

(c) Dinner, if appropriate.

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(2) Breakfast shall include three (3) of the following components: (a) Milk; (b) Bread or grain; (c) Meat or meat alternative; or (d)1. Fruit; 2. Vegetable; or 3. 100 percent juice. (3) A snack shall include two (2) of the following components: <u>(a) Milk;</u> (b) Bread or grain; (c) Meat or meat alternative; or (d)1. Fruit; 2. Vegetable; or 3. 100 percent juice. (4) Lunch, and dinner if served, shall include: (a) Milk; (b) Bread or grain; (c) Meat or meat alternative; and (d)1. Two (2) different vegetables; or 2. One (1) fruit and one (1) vegetable. [

(20) A child-care center shall meet requirements of subsections (3), (15), and (17) through (19) of this section if the child-care center participates in the Child and Adult Food Care Program and meets meal requirements specified in 7 C.F.R. 226.20.]

Section <u>12[10]</u>. Toilet, Diapering, and Toiletry Requirements. (1) A child-care center shall have a minimum of one (1) toilet and one (1) lavatory for each twenty (20) children. Urinals may be substituted for up to one-half (1/2) of the number of toilets required for a male toilet room.

(2) A toilet room shall:

(a)1. Be provided for each gender; or

A plan shall be implemented to use the same toilet room at separate times:

(b) Have a supply of toilet paper; and

(c) Be cleaned and disinfected daily.

(3) A sink shall be:

(a) Located in or immediately adjacent to toilet rooms;

(b) Equipped with hot and cold running water that allows for hand washing;

(c) Equipped with hot water at a minimum temperature of ninety (90) degrees Fahrenheit and a maximum of 120 degrees Fahrenheit;

(d) Equipped with liquid soap;

(e) Equipped with hand-drying blower or single use disposable hand drying material;

(f) Equipped with an easily cleanable waste receptacle; and

(g) Immediately adjacent to a changing area used for infants and toddlers.

(4) Each toilet shall:

(a) Be kept in clean condition;

(b) Be kept in good repair;

(c) Be in a lighted room; and

(d) Have ventilation to outside air.

(5) Toilet training shall be coordinated with the child's parent.(6) An adequate quantity of freshly laundered or disposable

diapers and clean clothing shall be available.

(7) If a toilet training chair is used, the chair shall be:

(a) Used over a surface that is impervious to moisture;

(b) Out of reach of other toilets or toilet training chairs;

(c) Emptied promptly; and(d) Disinfected after each use.

(8) Diapers or clothing shall be:

(a) Changed when soiled or wet;

(b) Stored in a covered container temporarily: and

(b) Stored in a covered container temporarily, and

(c) Washed or disposed of at least once a day.

(9) The proper methods of diapering and hand-washing shall be posted at each diaper changing area.

(10) When a child is diapered, the child shall:

(a) Not be left unattended; and

(b) Be placed on a surface that is:

3. Free of holes, rips, tears, or other damage;

4. Nonabsorbent;

5. Easily cleaned; and

6. Free of any items not used for diaper changing.

(11) Unless the child is allergic, individual disposable washcloths shall be used to thoroughly clean the affected area of the child.

(12) Staff shall disinfect the diapering surface after each child is diapered.

(13) If staff wears disposable gloves, the gloves shall be changed and disposed after each child is diapered.

(14) Combs, towels or washcloths, brushes, and toothbrushes used by a child shall be:

(a) Individually stored in separate containers; and

(b) Plainly labeled with the child's name.

(15) Toothbrushes shall be:

(a) Individually identified;

(b) Allowed to air dry; and

(c) Protected from contamination.

(16) Toothpaste used by multiple children shall be dispensed onto an intermediate surface, such as waxed paper, to avoid cross contamination.

Section 13[14]. Toys and Furnishings. (1) All toys and furniture contacted by a child shall be:

(a) Kept clean and in good repair; and

(b) Free of peeling, flaking, or chalking paint.

(2) Indoor and outdoor equipment shall:

(a) Be clean, safe, and in good repair;

(b) Meet the physical, developmental needs, and interests of children of different age groups;

(c) Be free from sharp points or corners, splinters, protruding nails or bolts, loose or rusty parts, hazardous small parts, leadbased paint, poisonous material, and flaking or chalking paint; and

(d) Be designed to guard against entrapment or situations that may cause strangulation.

(3) Toys shall be:

(a) Used according to the manufacturer's safety specifications;

(b) Durable; and

(c) Without sharp points or edges.

(4) A toy or another item that is considered a mouth contact surface by a child not toilet trained shall be sanitized daily by:

(a)1. Scrubbing in warm, soapy water using a brush to reach into crevices;

2. Rinsing in clean water;

3. Submerging in a sanitizing solution for at least two (2) minutes; and

4. Air dried; or

(b) Cleaning in a dishwasher if the toy or other item is dishwasher safe.

(5) Tables and chairs shall be of suitable size for children.

(6) Chairs appropriate for staff shall be provided to use while feeding, holding, or playing with a child.

Section <u>14[12]</u>. Transportation. (1) A center shall document compliance with KRS Chapter 186 and 603 KAR 5:072 pertaining to:

(a) Vehicles;

(b) Drivers; and

(c) Insurance.

(2) A center providing or arranging transportation service shall:

(a) Be licensed and approved by the cabinet or its designee prior to transporting a child;

(b) Have a written plan that details the type of transportation, staff schedule, transportation schedule, and transportation route; and

(c) Have written policies and procedures, including emergency procedures practiced monthly by staff who transports children.

(3) Prior to transporting a child, a center providing transportation services of a child shall notify the cabinet or its designee in writing of the:

(a) Type of transportation offered;

^{1.} Clean; 2. Padded;

(b) Type of vehicle used for transportation;

(c) Plan for ensuring staff perform duties relating to transportation properly;

(d) Full insurance coverage for each vehicle;

(e) Agency policy and procedures relating to an emergency plan for evacuating the vehicle;

(f) Contracts, agreements, or documents detailing arrangements with any third party for services; and

(g) Safety procedures for:

1. Transporting a child;

2. Loading and unloading a child; and

3. Providing adequate supervision of a child.

(4) A vehicle used to transport children shall be equipped with:

(a) A fire extinguisher;

(b) First aid supplies as established in Section 7 of this administrative regulation;

(c) Emergency reflective triangles; and

(d) A device to cut the restraint system, if necessary.

(5) Transportation provided by licensed public transportation or

a school bus shall comply with subsections (1) and (2) of this section.

(6) A vehicle used to transport children shall comply with the requirements established in paragraphs (a) through (d) of this subsection.

(a) For a twelve (12) or more passenger vehicle, the child-care center shall maintain a current certification of inspection from the Transportation Cabinet.

(b) A vehicle that requires traffic to stop while loading and unloading a child shall be equipped with a system of:

1. Signal lamps;

Identifying colors; and

3. Cautionary words.

(c) A vehicle shall be equipped with seat belts for each occupant to be individually secured.

(d) A vehicle shall not transport children and hazardous materials at the same time.

(7) The appropriate car safety seat meeting federal and state motor vehicle safety standards in 49 C.F.R. 571.213 and KRS 189.125 shall be used for each child.

(8) A daily inspection of the vehicle shall be performed prior to the vehicle's use and documented for:

(a) Tire inflation consistent with tire manufacturer's recommended air pressure;

(b) Working lights, signals, mirrors, gauges, and wiper blades;

(c) Working safety restraints;

(d) Adequate fuel level; and

(e) Cleanliness and good repair.

(9)(a) The staff-to-child ratios set forth in Section 2(2) of this administrative regulation shall apply to vehicle transport, if not inconsistent with special requirements or exceptions in this section.

(b) An individual who is driving with a child in the vehicle shall supervise no more than four (4) children under the age of five (5).

(10) Each child shall:

(a) Have a seat;

(b) Be individually belted or harnessed in the seat; and

(c) Remain seated while the vehicle is in motion.

(11) A child shall not be left unattended:

(a) At the site of aftercare delivery; or

(b) In a vehicle.

(12) If the parent or designee is unavailable, a prearranged written plan shall be completed to designate where the child can be picked up.

(13) A child shall not be picked up or delivered to a location that requires crossing the street or highway unless accompanied by an adult.

(14) A vehicle transporting a child shall have the headlamps on.

(15) If a vehicle needs to be refueled, it shall be refueled only while not being used to transport a child. If emergency refueling or repair is necessary during transporting, all children shall be removed and supervised by an adequate number of adults while refueling or repair is occurring.

(16) If the driver is not in the driver's seat, the:

(a) Engine shall be turned off;

(b) Keys shall be removed; and

(c) Emergency brake shall be set.

(17) Transportation services provided shall:

(a) Be recorded in writing and include:

1. The first and last name of the child transported; and

2. The time each child gets on and the time each child gets off;

(b) Be completed by a staff member other than the driver; and (c) Be kept for five (5) years.

(18) A driver of a vehicle transporting a child for a center shall:

(a) Be at least twenty-one (21) years old;

(b) Complete:

1. The background checks as described in 922 KAR 2:280; and

2. An annual check of the:

a. Kentucky driver history records in accordance with KRS 186.018; or

b. Driver history records through the state transportation agency that issued the driver's license;

(c) Hold a current driver's license that has not been suspended or revoked during the last five (5) years; and

(d) Not caused an accident that resulted in the death of a person.

(19) Firearms, ammunition, alcohol, or illegal substances shall not be transported in a vehicle transporting children.

(20)(a) Based on the harm, threat, or danger to a child's health, safety, and welfare, the cabinet shall revoke a center's privilege to transport a child or pursue an adverse action in accordance with Section [14,] 15, 16, [er] 17, or 18 of 922 KAR 2:090:

1. For a violation of this section; or

2. If the center:

a. Fails to report an accident in accordance with 922 KAR 2:090, Section <u>13[12];</u> or

b. Transports more passengers than the vehicle's seating capacity and safety restraints can accommodate.

(b) Revocation of a center's privilege to provide transportation services in accordance with paragraph (a) of this subsection shall:

1. Apply to each site listed under the licensee; and

2. Remain effective for no less than a twelve (12) month period.

(21) A parent may use the parent's vehicle to transport the parent's child during a field trip.

Section <u>15[</u>13]. Animals. (1) An animal shall not be allowed in the presence of a child in care:

. (a) Unless:

1. The animal is under the supervision and control of an adult;

2. Written parental consent has been obtained; and

3. The animal is certified as vaccinated against rabies; or

(b) Except in accordance with subsection (3) of this section.

(2) A parent shall be notified in writing if a child has been bitten or scratched by an animal.

(3) An animal that is considered undomesticated, wild, or exotic shall not be allowed at a child-care center unless the animal is:

(a) A part of a planned program activity led by an animal specialist affiliated with a zoo or nature conservatory; and

(b) In accordance with 301 KAR 2:081 and 301 KAR 2:082.

(4) This section shall not apply to wild animals on the outer property of the child-care center that are expected to be found outdoors, such as squirrels and birds, if they are not:

(a) Disturbed; or

(b) Brought indoors.

MARTA MIRANDA-STRAUB, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: September 25, 2020

FILED WITH LRC: September 29, 2020 at 2:00 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on December 21, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by December 14, 2020,

five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until December 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact persons: Laura Begin or Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes health and safety standards for child-care centers.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish standards regarding health and safety for child-care centers.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing minimum health and safety standards for child-care centers as condition of their licensure.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing the health and safety standards for child-care centers.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: Senate Bill 45 (Regular Session 2020, Acts ch. 8) required child-care centers licensed pursuant to KRS 199.896 to have standards relating to nutrition, physical activity, screen time, and sugary drinks. Centers that provide food were required to have nutrition standards consistent with the meal and snack patterns of the most recent version of the United States Department of Agriculture's Food and Nutrition Service standards for the Child and Adult Care Food Program. Subsection (2) of the Act required the cabinet to promulgate administrative regulations, in consultation with the Kentucky Early Childhood Advisory Council, the Kentucky Child Care Advisory Council, and state and national organizations, to establish these requirements and procedures for implementation of these standards within ninety (90) days of the effective date of the Act. This bill was passed and codified as KRS 199.8962. This amendment includes the required standards relating to nutrition, physical activity, screen time, and sugary drinks, as recommended by the Kentucky Early Childhood Advisory Council, the Kentucky Child Care Advisory Council, the Kentucky Department of Education Child and Adult Care Food Program, Caring for Our Children National Standards, and others.

(b) The necessity of the amendment to this administrative regulation: The passage of Senate Bill 45 (Regular Session 2020, Acts ch. 8) requires this amendment. The cabinet consulted with the required councils and organizations to establish standards relating to nutrition, physical activity, screen time, and sugary drinks, as required by the bill codified into statute. Pursuant to KRS 199.8962(2), promulgation is required by October 13, 2020.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 199.8962(2) requires the cabinet to promulgate administrative regulations to establish the requirements and procedures for the implementation of standards relating to

nutrition, physical activity, screen time, and sugary drinks, which is included in this amendment.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will assist in the effective administration of the statutes through its provision of enhanced health and safety standards for licensed child care providers consistent with recently passed legislation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: As of August 2020, there were 1,835 licensed child care programs in Kentucky subject to this administrative regulation. The Department for Community Based Services, Division of Child Care, and the Office of the Inspector General, Division of Regulated Child Care, will be impacted as the child care regulating and monitoring agencies, respectively.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Given the impact that the COVID-19 pandemic has had on child care providers, the cabinet has attempted to minimize any detrimental impact on regulated entities, but must implement recently enacted legislation as required by law. Licensed child care centers will be required to implement the new standards relating to nutrition, physical activity, screen time, and sugary drinks once this amendment becomes effective.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are not additional costs associated with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Licensed child-care centers will be providing a higher standard of care for children regarding nutrition, physical activity, screen time, and sugary drinks. This action is required by KRS 199.8962, passed as Senate Bill 45 in Regular Session 2020.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: The amendment to this administrative regulation will not result in any new initial costs to the administrative body.

(b) On a continuing basis: The amendment to this administrative regulation will not result in any ongoing costs to the administrative body.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Child Care and Development Fund Block Grant, state match and maintenance of effort for the block grant, and limited agency funds support the implementation of this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: There is no increase in fees or funding required as a result of this amendment.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish any fees, or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering is not applied as all licensed child care centers are regulated by this administrative regulation. The only difference in standards in this amendment is between centers that provide food to children and centers that serve food to children, but do not provide it.

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 7 C.F.R. 226.20, 16 C.F.R. 1219, 1220, 1221, 45 C.F.R. 98.2, 49 C.F.R. 571.213, 20 U.S.C. 6081-6084, 42 U.S.C. 9857-9858q

2. State compliance standards. KRS 194A.050(1), 199.896(2), 199.8962(2)

3. Minimum or uniform standards contained in the federal mandate. The provisions of the administrative regulation comply with the federal mandate.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? This administrative regulation does not impose stricter, additional or different responsibilities or requirements than those required by the federal mandate. The federal rules give states flexibility in setting standards specific to state needs.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. The federal rules give states flexibility in setting standards specific to state needs and this amendment is necessary for compliance with recently passed state law.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Cabinet for Health and Family Services is impacted by this administrative regulation. A local government or a school district operating a licensed child-care center, in whole or in part, will be impacted.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.050(1), 199.896(2), 199.8962(2), 7 C.F.R. 226.20, 16 C.F.R. 1219, 1220, 1221, 45 C.F.R. 98.2, 49 C.F.R. 571.213, 20 U.S.C. 6081-6084, 42 U.S.C. 9857-9858q

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The amendment to this administrative regulation will generate no revenue in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The amendment to this administrative regulation will generate no revenue in the subsequent years.

(c) How much will it cost to administer this program for the first year? There will be no additional costs to administer this program in the first year.

(d) How much will it cost to administer this program for subsequent years? There are no additional costs to administer this program in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

NEW ADMINISTRATIVE REGULATIONS

Public comment periods are at least two months long. For other regulations with open comment periods, please also see last month's *Administrative Register of Kentucky*.

EDUCATION AND WORKFORCE DEVELOPMENT CABINET Kentucky Board of Education Kentucky Department of Education (New Administrative Regulation)

704 KAR 8:100. Kentucky Academic Standards for Library Media Elective.

RELATES TO: KRS 156.070, 156.160, 158.645, 158.6451, 156.850, 158.102, 158.791, 160.290, 704 KAR 3:305

STATUTORY AUTHORITY: 156.070, 156.160

NECESSITY, FUNCTION, AND CONFORMITY: KRS 156.160 requires the Kentucky Board of Education to establish courses of study for the different grades and kinds of common schools, with the courses of study to comply with the expected goals, outcomes, and assessment strategies developed under KRS 158.645 and 158.6451. KRS 156.070(1) requires the Kentucky Board of Education to manage and control the common schools and all programs operated in the schools. KRS 160.290 authorizes local boards of education to provide for courses and other services for students consistent with the administrative regulations of the Kentucky Board of Education. KRS 156.850 requires compliance with federal provisions and acts relating to vocational education. KRS 158.102 requires boards of education for each local school district to establish and maintain library media centers in every school to promote information literacy, technology in the curriculum, and to facilitate teaching, student achievement, and lifelong learning. KRS 158.791 details the provision of high-quality library media programs to support reading proficiency. This administrative regulation incorporates by reference the Kentucky Academic Standards for Library Media, which contain the general courses of study and academic content standards of library media for use in Kentucky's common schools.

Section 1. Public schools offering a library media program shall meet the minimum content requirements established in the Kentucky Academic Standards for Library Media Elective.

Section 2. Incorporation by Reference. (1) The "Kentucky Academic Standards for Library Media Elective", October 2020, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department of Education, 5th floor, 300 Sower Boulevard, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

This is to certify that the chief state school officer has reviewed and recommended this administrative regulation prior to its adoption by the Kentucky Board of Education, as required by KRS 156.070(5).

JASON E. GLASS, Ed.D., Commissioner

LU YOUNG, Ed.D., Chairperson

APPROVED BY AGENCY: October 13, 2020 FILED WITH LRC: October 13, 2020 at 4:14 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A

public hearing on this administrative regulation shall be held on December 22, 2020 at 10:00 a.m. in the State Board Room, 5th Floor, 300 Sower Blvd., Frankfort, Kentucky. Individuals interested in being heard at this hearing shall notify this agency in writing by 5 workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be cancelled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through Written comments shall be accepted through December 31, 2020. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Todd Allen, General Counsel, Kentucky Department of Education, 300 Sower Boulevard, 5th Floor, Frankfort, KY 40601, phone (502) 564-4474, fax (502) 564-9321, email: regcomments@education.ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation incorporates by reference the Kentucky Academic Standards for Library Media, which contain the general courses of study and academic content standards of Library Media for use in Kentucky's common schools.

(b) The necessity of this administrative regulation: KRS 156.160 requires the Kentucky Board of Education to establish courses of study for the different grades and kinds of common schools, with the courses of study to comply with the expected outcomes for students and school established in KRS 158.6451.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 158.6453 requires the revision of academic content standards. KRS 156.070(1) requires the Kentucky Board of Education to manage and control the common schools and all programs operated in the schools. KRS 160.290 authorizes local boards of education to provide for courses and other services for students consistent with the administrative regulations of the Kentucky Board of Education. KRS 156.160 requires the Kentucky Board of Education (KBE) to establish courses of study for the different grades and kinds of common schools, with the courses of study to comply with the expected goals, outcomes and assessment strategies developed under KRS 158.645, 158.6451 and 158.6453. KRS 156.070 (1) requires the KBE to manage and control the common schools and all programs operated in the schools. KRS 160.290 authorizes local boards of education to provide for courses and other services for students consistent with the administrative regulations of the KBE. KRS 158.102 requires boards of education for each local school district to establish and maintain library media centers in every school to promote information literacy, technology in the curriculum, and to facilitate teaching, student achievement, and lifelong learning. KRS 158.791 details the provision of high-quality library media programs to support reading proficiency.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation incorporates by reference the *Kentucky Academic Standards for Library Media*, which contain the general courses of study and academic content standards for use in Kentucky's common schools pursuant to KRS 158.6451.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: N/A - This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: N/A - This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: N/A – This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statues: N/A – This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Those affected by this regulation include

all public schools, school districts, school councils and the Kentucky Department of Education as it will provide support to this administrative regulations.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The standards outlined in 704 KAR 8:100 are the standards for library media programs. All public schools, school districts and school-based decision-making councils are required to follow the standards through school library media programs outlined in the document incorporated by reference in 704 KAR 8:100. Curriculum and content decisions are made at the local level and will be expected to be aligned to these outlined standards.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Implementation of this administrative regulation may present a number of cost variables, which include curriculum development and/or vendor fees for program development and implementation, as well as professional learning for appropriate staff. While there are many free resources that exist for supplemental instruction, many districts may choose to purchase supplemental resources that are developed externally. The cost of these resources may vary, depending upon the vendor/product chosen.

Kentucky Department of Education: In the development process of library media standards required by statute, the Department spent approximately \$15,000 as of the date of filing in the development of the standards, in addition to staff time. Additional staff time will be needed as the regulation moves through the legislative and implementation processes.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The compliance of public schools, school districts and school councils will ensure that each library media program will implement the highest quality in information and library media instruction for the student who participates in the library media program.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: The Kentucky Department of Education spent approximately \$15,000 in administrative costs for the development of the library media standards that are incorporated by reference in 704 KAR 8:100.

(b) On a continuing basis: Additional staff time will be needed as the regulation moves through the legislative and implementation process.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State funds have been utilized.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change, if it is an amendment: No increase in funding will be necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? Tiering was no appropriate for this administrative regulation because the administrative regulations applies equally to all schools and local education agencies.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? Local education agencies and the Kentucky Department of Education.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 158.6453 required the Kentucky Department of Education (KDE) to implement a comprehensive process for the review of academic standards and assessment. KRS 156.070(1) requires the Kentucky Board of Education to manage and control the common schools and all programs operated in the schools. KRS160.290 authorizes local boards of education to provide for courses and other services for students consistent with the administrative regulations of the Kentucky Board of Education. This regulation fulfills the requirements of these mentioned statutes. KRS 158.102 requires boards of education for each local school district to establish and maintain library media centers in every school to promote information literacy, technology in the curriculum, and to facilitate teaching, student achievement, and lifelong learning. KRS 158.791 details the provision of high-quality library media programs to support reading proficiency.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. This administrative regulation will not have any impact on expenditures or revenues.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? None

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? None

(c) How much will it cost to administer this program for the first year? Schools and Districts: Implementation of this administrative regulation may present a number of cost variables, which include curriculum development and/or vendor fees for program development and implementation, as well as professional learning for appropriate staff. While there are many free resources that exist for supplemental instruction, many districts may choose to purchase supplemental resources that are developed externally. The cost of these resources may vary, depending upon the vendor/product chosen.

For the Kentucky Department of Education, in the creation process of the library media standards, the Department spent approximately \$15,000 as of the date of filing in the development of the standards, in addition to staff time. Additional staff time will be needed as the regulation moves through the legislative and implementation processes. Minimal staff time by Kentucky Department of Education will be required to implement this amendment.

(d) How much will it cost to administer this program for subsequent years? Minimal staff time at the Kentucky Department of education will be required on an annual basis after the initial implementation of this administrative regulation.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): N/A Expenditures (+/-): N/A Other Explanation: N/A

CABINET FOR HEALTH AND FAMILY SERVICES Department for Public Health Division of Public Health Protection and Safety (New Administrative Regulation)

902 KAR 45:190. Hemp-derived cannabidiol products and labeling requirements.

RELATES TO: KRS 217.015, 217.037, 217.025, 217.035, 217.155

STATUTORY AUTHORITY: KRS 217.125, 217.127, 217.135 NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act, KRS 217.005 to 217.215. KRS 217.125(2) requires the secretary to provide by administrative regulation a schedule of fees for permits to operate and for inspection activities carried out by the cabinet pursuant to KRS 217.025 through 217.390. KRS 217.135 authorizes the secretary to establish food standards by administrative regulation including a reasonable definition, standard of identity, and designation of optional ingredients that shall be named on the label. This administrative regulation establishes the registration process to utilize hemp-derived cannabidiol products in foods and cosmetics, the labeling requirements for products containing hemp-derived cannabidiol, and methods for use of hemp-derived cannabidiol as an additive to food products.

Section 1. Definitions. (1) "Cabinet" is defined by KRS 217.015(3).

(1) "Cannabidiol" or "CBD" means a non-intoxicating cannabinoid found in the hemp plant Cannabis sativa.

(2) "Cosmetic" is defined by KRS 217.015(7).

(3) "Department" means the Kentucky Department for Public Health.

(4) "Food service establishment" is defined by KRS 217.015(21).

(5) "Home-based processor" is defined by KRS 217.015(56).

(6) "Person" is defined by KRS 217.015(32).

Section 2. Permits. (1) A person seeking to manufacture, market, sell, or distribute a hemp-derived CBD ingestible or cosmetic product shall submit an Application for Permit to Operate a Food Plant or Cosmetic Manufacturing Plant, incorporated by reference in 902 KAR 45:160, to the department.

(2) The permit shall be:

(a) Nontransferable in regards to person or address; and

(b) Renewed annually.

(3) The fee shall be paid in accordance with:

(a) 902 KAR 45:180, for a food processing establishment;

(b) 902 KAR 45:180, for a cosmetic manufacturer; and

(c) 902 KAR 45:110, Section 1(3), (4), and (5), for a food service establishment.

(4) Ingestible hemp-derived products shall not be manufactured, marketed, sold, or distributed by a home-based processor.

Section 3. Product labeling. (1) Each hemp-derived CBD product manufactured, marketed, sold, or distributed in the Commonwealth shall be labeled in accordance with KRS 217.037 and this administrative regulation.

(2) An ingestible or cosmetic product label shall include, in a print no less than six (6) point font, the following information:

(a) A statement of identity or common product name that shall be stated upon the principal display panel of the label;

(b) The net quantity of contents expressed in both standard English and metric units of measurement located in the lower thirty percent (30%) of the label parallel to the base of the container;

(c) The ingredients of the hemp-derived CBD product, in descending order of predominance by weight;

(d) The name of the manufacturer or distributor;

(e) A statement that the hemp-derived CBD product is within the federal legal limit of three-tenths of one percent (0.3%) delta-9 tetrahydrocannabinol;

(f) The total amount of cannabidiol per serving for ingestible products, or the total amount per container for cosmetic products;

(g) Suggested use instructions or directions, including serving sizes;

(h) The statement, or a similar statement, "Consult your physician or healthcare professional before use";

(i) An expiration date, if any; and

(j) The Kentucky Hemp or Kentucky Proud logo or a similar marking that denotes the product was produced in Kentucky.

(3) Each container of ingestible or cosmetic hemp-derived CBD product shall bear either a foil seal on the inside or a plastic sealant on the outside.

(4) Product labeling or advertising material for any hempderived CBD product shall not bear any implicit or explicit health claims stating that the product can diagnose, treat, cure, or prevent any disease. Section 4. Hemp-derived ingestible CBD product as a food additive. (1) Hemp-derived CBD may be added to an ingestible product during the manufacturing process or prior to retail sale at a food service establishment.

(2) A food service establishment offering hemp-derived CBD products in a finished food product shall provide the following information to consumers upon request:

(a) The common name of the product;

(b) The manufacturer or distributor of the product; and

(c) A statement that the hemp-derived CBD product is within the federal legal limit of three-tenths to one percent (0.3%) delta-9 tetrahydrocannabinol.

STEVEN J. STACK, MD, MBA, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 6, 2020

FILED WITH LRC: October 8, 2020 at 2:22 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on December 21, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by December 14, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until December 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Julie Brooks or Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the registration process to utilize hemp-derived cannabidiol (CBD) products in foods and cosmetics, the labeling requirements for products containing hemp-derived cannabidiol, and methods for use of hemp-derived cannabidiol as an additive to food products.

(b) The necessity of this administrative regulation: With the passage of the federal Agriculture Improvement Act of 2018, hemp-derived CBD products are one of the fastest growing manufactured food or cosmetic product markets. This administrative regulation is necessary to ensure the safety of food and cosmetic products containing hemp-derived CBD.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 217.037 requires that all foods and cosmetics shall conform to the Fair Packaging and Labeling Act, and the regulations promulgated thereto. KRS 217.125(1) requires the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations for the efficient administration and enforcement of the Kentucky Food, Drug and Cosmetic Act.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes the requirements for using hemp-derived CBD in food and cosmetics, and ensures these products are properly labeled.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The number of businesses affected by this administrative regulation is unknown. A web search yielded a list of twenty (20) businesses producing hemp-derived CBD or offer hemp-derived CBD products for sale.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment: Individuals interested in marketing, manufacturing, selling, or distributing hemp-derived CBD ingestible and cosmetic products will need to be aware of the additional application and permitting requirements, and will need to ensure all products comply with the labeling requirements of this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): Those persons seeking to manufacture ingestible hemp-derived CBD products will pay the fee outlined in 902 KAR 45:180. Those persons seeking to manufacture a hemp-derived CBD cosmetic product will pay the \$150 fee as outlined in 902 KAR 45:180. A retail food service establishment offering hempderived CBD as an additive to prepared food will pay the fee outlined in 902 KAR 45:110.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Those offering hemp-derived food or cosmetic products will be able to provide a safe product to the consumer.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: What is the costs associated with this new regulation? The department will need to hire additional staff to oversee the permitting and inspection process related to this administrative regulation. The salary for this staff could range between \$38,770 to \$62,033 per year.

(b) On a continuing basis: The ongoing costs associated with this administrative regulation could be between \$38,770 to \$62,033.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: State general fund dollars, and revenue received from the permitting fees.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an amendment: An increase in funding is necessary to implement this administrative regulation. The department will incur costs associated with hiring staff to perform the permitting and inspection processes required by this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees. The fee required to manufacture, market, sell, or distribute hempderived CBD food or cosmetic products will be paid in accordance with the application fee regulation. A separate fee is not required.

(9) TIERING: Is tiering applied? Tiering is not applied. The permitting and labeling requirement will impact those seeking to produce ingestible and cosmetic hemp-derived CBD products equally.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation will impact the Food Safety Branch in the Division of Public Health Protection and Safety.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 217.037, 217.125, 217.127, 217.135, and 217.145.

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation does not generate revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation does not generate revenue.

(c) How much will it cost to administer this program for the first year? It will cost between \$38,770 to \$62,033 to administer this program in the first year.

(d) How much will it cost to administer this program for subsequent years? It will cost between \$38,770 to \$62,033 to administer this program in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

CABINET FOR HEALTH AND FAMILY SERVICES Department for Medicaid Services Division of Policy and Operations (New Administrative Regulation)

907 KAR 3:250. Programs of All-Inclusive Care for the Elderly (PACE).

RELATES TO: KRS 205.520, 205.5605, 205.5606, 205.5607, 42 C.F.R. Part 460, 42 C.F.R. 489.100-489.104, 42 U.S.C. 1396a, 1396b, 1396d, 1396n

STATUTORY AUTHORITY: KRS 194A.030(2), 194A.050(1), 205.520(3), 205.5606(1), 205.6317

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Department for Medicaid Services, has responsibility to administer the Medicaid Program. KRS 205.520(3) authorizes the cabinet, by administrative regulation, to comply with any requirement that may be imposed, or opportunity presented, by federal law to qualify for federal Medicaid funds. 42 C.F.R. Part 460 establishes the federal requirements for PACE to provide comprehensive, capitated health services that enhance the lives of frail, older adults, and enable those adults to live in the community as long as medically and socially feasible. This administrative regulation establishes the department's coverage and reimbursement for Programs of All-Inclusive Care for the Elderly (PACE).

Section 1. Definitions. (1) "Emergency medical condition" is defined by 42 C.F.R. 460.100(c).

 $\ensuremath{(2)}$ "PACE" means Programs of All-Inclusive Care for the Elderly.

(3) "PACE program agreement" means an agreement that:

(a) Is between a PACE organization, the Centers for Medicare and Medicaid Services (CMS), and the department for the operation of a PACE program; and

(b) Meets the requirements of Section 7 of this administrative regulation.

(4) "Participant" means an individual who is enrolled in a PACE

program.

(5) "Post stabilization care" is defined by 42 C.F.R. 460.100(e)(3)(i).

(6) "Restraint" means a physical or chemical restraint as defined by 42 C.F.R. 460.114(a)(1) and (2).

PACE Participant Eligibility, Section 2. Enrollment, Disenrollment, and Reinstatement. (1) To be eligible to enroll in a PACE program, an individual shall:

(a) Be fifty-five (55) years of age or older;

(b) Be determined by the department to meet a nursing facility level of care determination, pursuant to 907 KAR 1:022;

(c) Reside in the service area of a PACE organization;

(d) Be able to live in a community setting without jeopardizing the participant's health or safety; and

(e)1. Be eligible for Medicaid services pursuant to 907 KAR Chapter 20;

2. Pay the full capitation payment if not eligible for Medicaid or Medicare: or

3. Pay the Medicaid portion of the capitation payment if eligible for Medicare but not Medicaid.

(2) The PACE program enrollment process shall be in accordance with 42 C.F.R. 460.152.

(3) In order to enroll in a PACE program, a participant shall sign an enrollment agreement, which shall include all information required by 42 C.F.R. 460.154.

(4) Upon enrollment, a participant shall receive the following information from the PACE organization:

(a) A copy of the enrollment agreement, which shall:

1. Be explained to the participant or their representative or caregiver in a manner that they understand; and

2. If there are any changes, be updated and provided to the participant, with an explanation as required by subparagraph 1. of this paragraph.

(b) A PACE membership card as required by 42 C.F.R. 460.156: and

(c) Emergency information, which shall also be posted in the participant's home, identifying the individual as a PACE participant and explaining how to access emergency services.

(5) Enrollment in a PACE program shall be effective on the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement.

(6) Enrollment shall be continued in accordance with 42 C.F.R. 460,160

(7) A participant shall have the right to voluntarily disenroll from the program at any time without cause. Any disenrollment shall:

(a) Be processed on the monthly enrollment cycle; and

(b) Comply with 42 C.F.R. 460.162.

(8) Involuntary disenrollment shall:

(a) Be reviewed by the department to determine that the PACE organization has acceptable grounds for disenrollment, pursuant to 42 C.F.R. 460.164; and

(b) Be in accordance with 42 C.F.R. 460.166.

(9) If a participant is disenrolled from a PACE program, the PACE organization shall:

(a) Make appropriate referrals and ensure medical records are made available to new providers within thirty (30) days; and

(b) Work with CMS and the department to reinstate the participant in other Medicaid programs for which the participant is eligible.

(10) A previously disenrolled participant shall not be precluded from being reinstated in a PACE program.

Section 3. PACE Covered Services. (1) Pursuant to 42 C.F.R. 460.90, if an eligible Medicaid participant elects to enroll in a PACE program:

(a) Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing shall not apply; and

(b) The participant, while enrolled in the PACE program, shall receive Medicare or Medicaid benefits solely through the PACE organization.

(2) Pursuant to 42 C.F.R. 460.92, the following shall be included in the PACE benefits package and provided to participants as applicable:

(a) All Medicare-covered goods and services for which the participant would otherwise qualify;

(b) All Medicaid-covered goods and services for which the participant would otherwise qualify; and

(c) Other services that are necessary, as determined by the interdisciplinary team, to improve and maintain the participant's overall health status.

(3) Emergency medical services shall be covered as applicable and pursuant to Section 4 of this administrative regulation.

Section 4. Emergency Services. (1) A PACE organization shall: (a) Establish and maintain a written plan to handle emergency care that provides for services including:

1. An on-call provider, available twenty-four (24) hours per day to address participant questions about emergency services and respond to requests for authorization of urgently needed out-ofnetwork services and post stabilization care services following emergency services; and

2. Coverage of urgently needed out-of-network and post stabilization care services if:

a. The services are preapproved by the PACE organization; or

b. The services are not preapproved by the PACE organization because the PACE organization did not respond to a request for approval within one (1) hour of being contacted or cannot be contacted for approval;

(b) Ensure that the following are held harmless if the PACE organization does not pay for emergency services:

1. PACE participants;

2. CMS; and 3. The department; and

(c) Ensure that the participant, caregiver, or both, understand when and how to get access to emergency services and that prior authorization is not needed.

(2) Emergency services shall:

(a) Be provided if:

1. Services are needed immediately because of an injury or sudden illness; and

2. The time to reach the PACE organization or one (1) of its contract providers would cause risk of permanent damage to the participant's health; and

(b) Include inpatient and outpatient services that:

1. Are furnished by a qualified emergency services provider, other than the PACE organization or one (1) of its contract providers, either in or out of the PACE organization's service area; or

2. Are needed to evaluate or stabilize an emergency medical condition.

Section 5. Exclusions to PACE Covered Services. The following services shall not be covered under a PACE program:

(1) Any service that is not authorized by the interdisciplinary team, unless the service is deemed to be an emergency service;

(2) In an inpatient facility:

(a) Private room and private duty nursing services, unless medically necessary; and

(b) Nonmedical items for personal convenience, unless specifically authorized by the interdisciplinary team as part of the participant's plan of care;

(3) Surgery that is purely cosmetic in nature and purpose, and does not meet an exception pursuant to 42 C.F.R. 460.96(c);

(4) Experimental medical, surgical, or other health procedures; or

(5) Services furnished outside of the United States, except:

(a) In accordance with 42 C.F.R. 424.122 and 424.124; and

(b) As otherwise permitted pursuant to Title 907 KAR.

Section 6. PACE Organization Requirements. A PACE organization shall:

(1) Have an agreement as required by 42 C.F.R. 460.30 with CMS and the department in order to provide services pursuant to this administrative regulation;

(2) Meet all requirements established in 42 C.F.R. 460 Subpart E, 460.60 to 460.86;

(3) Comply with all requirements established in 907 KAR 1:671 and 907 KAR 1:672;

(4) Not provide services designated as excluded from the program pursuant to Section 5 of this administrative regulation;

(5) Establish and implement a written plan to furnish care that meets the needs of each participant in all care settings for twenty-four (24) hours a day, every day of the year and provide services pursuant to 42 C.F.R. 460.98;

(6) Provide at each PACE center, at a minimum:

(a) Primary care;

(b) Social services;

(c) Restorative therapies, including physical and occupational therapy;

(d) Personal care and supportive services;

(e) Nutritional counseling;

(f) Recreational therapy; and

(g) Meals;

(7) Operate at least one (1) PACE center in or contiguous to its defined service area with sufficient capacity to allow routine attendance by participants;

(8) Ensure accessible and adequate services to meet participant needs;

(9) Establish a written participant bill of rights, which shall:

(a) Be displayed:

1. In English and any other principal languages of the community as required by 42 C.F.R. 460.116(c)(1); and

2. In a prominent place within the PACE center; and

(b) Include all rights specified in 42 C.F.R. 460.112;

(10) Ensure that the rights specified in subsection (9) of this section, as well as the participant's responsibilities and appeal rights, are conveyed to the participant in writing and explained in a manner understood by the participant or their representative upon enrollment pursuant to 42 C.F.R. 460.116 and 42 C.F.R. 460.124:

(11) Protect and provide for the exercise of the participant's rights;

(12) Pursuant to 42 C.F.R. 460.118, establish documented procedures to respond to and rectify a violation of a participant's rights;

(13) Pursuant to 42 C.F.R. 460.114, limit the use of restraints to the least restrictive and most effective method available, regardless of whether the restraint is physical or chemical in nature:

(14) Ensure that any restrained participant be continually assessed, monitored, and reevaluated;

(15) Meet the following conditions if the interdisciplinary team determines that a restraint is needed to ensure the participant's physical safety or the safety of others:

(a) The restraint shall be imposed for a defined, limited time, and based upon the assessed needs of the participant;

(b) The restraint shall be imposed in accordance with safe and appropriate restraining techniques;

(c) The restraint shall be imposed only if other less restrictive measures have been found to be ineffective to protect the participant or others from harm; and

(d) The restraint shall be removed or ended at the earliest possible time;

(16) Establish, implement, maintain, and evaluate an effective, data-driven quality improvement program, in writing, pursuant to 42 C.F.R. 460.130 and 460.132 and containing, all requirements contained in 42 C.F.R. 460.134;

(17) Ensure that the quality improvement plan complies with 42 C.F.R. 460.130 and reflects the full range of services offered by the PACE organization, and take actions that result in improvements in the organization's performance in all types of care, including all requirements established in 42 C.F.R. 460.136;

(18) Pursuant to 42 C.F.R. 460.138, establish one (1) or more committees with community input to:

(a) Evaluate data collected pertaining to quality outcome measures;

(b) Address the implementation of, and results from, the quality

improvement plan; and

(c) Provide input related to ethical decision making, including: 1. End-of-life issues: and

2. Implementation of the Patient Self Determination Act pursuant to 42 C.F.R. 489.102;

(19) Comply with all requirements for the PACE organization in the enrollment process, disenrollment process, and reinstatement process pursuant to Section 2 of this administrative regulation;

(20) Establish and maintain a procedure to document the reasons for all voluntary and involuntary disenrollments, and that documentation shall be available for review by CMS and the department;

(21) Utilize the information received under subsection (20) of this section relating to voluntary disenrollments in the quality improvement program;

(22) Pursuant to 42 C.F.R. 460.196, post a notice of the availability of the results of the most recent review conducted pursuant to Section 9 of this administrative regulation and any plan of correction or response to that review, and make these results available for examination in a place readily accessible to participants, their families, caregivers, or representatives; and

(23) Maintain records, collect all data, report all required data and information, and comply with all other requirements contained in 42 C.F.R. 460 Subpart L, 460.200 to 260.210.

Section 7. PACE Program Agreement Requirements. (1) A PACE program agreement shall meet the requirements for authorization pursuant to 42 C.F.R. 460.30.

(2) The PACE program agreement between the department and a PACE organization shall include:

(a) All content required by 42 C.F.R. 460.32;

(b) The criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting, pursuant to 42 C.F.R. 460.150(c)(2);

(c) The criteria for determining the continuing eligibility of a participant, pursuant to 42 C.F.R. 460.160(b)(3)(ii).

(d) Pursuant to 42 C.F.R. 460.202 and 42 C.F.R. 460.32(a)(11), a comprehensive list of data and information pertaining to the PACE organization's provision of participant care:

1. Collected by the PACE organization; and

2. To be furnished to CMS and the department in the manner, and at the time intervals, specified by CMS and the department.

 (e) The specific eligibility conditions pursuant to Section 2 of this administrative regulation;

(f) Any additional terms and conditions agreed to by the parties, subject to limitations pursuant to 42 C.F.R. 460.32(b)(2); and

(g) Pursuant to 42 C.F.R. 460.32(a)(12), procedures for any adjustments to account for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants in that month.

(3) A PACE program agreement shall be effective for one (1) contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate, pursuant to 42 C.F.R. 460.34.

(4) The department shall limit the number of PACE program agreements pursuant to 42 C.F.R. 460.24.

Section 8. Interdisciplinary Team. (1)(a) Each PACE organization shall establish an interdisciplinary team that fulfills each of the positions described in paragraph (b) of this subsection at each PACE center to comprehensively assess and meet the individual needs of each participant.

(b) An interdisciplinary team shall meet the composition requirements of 42 C.F.R. 460.102(b) and be composed of at least a:

1. Primary care provider, who shall:

a. Furnish primary medical care to a participant; and

b. Be responsible for managing a participant's medical needs and overseeing a participant's use of medical specialists and inpatient care;

2. Registered nurse;

3. Master's-level social worker;

4. Physical therapist;

5. Occupational therapist;

6. Recreational therapist or activity coordinator;

7. Dietitian;

8. PACE center manager;

9. Home care coordinator;

10. Personal care attendant or their representative; and

11. Driver or their representative.

(2) A PACE organization shall assign each participant to an interdisciplinary team functioning at the PACE center that the participant attends.

(3) A PACE organization shall establish, implement, and maintain documented internal procedures pursuant to 42 C.F.R. 460.102(f) and consistent with the confidentiality requirements of 42 C.F.R. 460.200(e).

(4) An interdisciplinary team that complies with the requirements of 42 C.F.R. 460.102 shall be responsible for the initial assessment, periodic reassessments, plan of care pursuant to 42 C.F.R. 460.106, and coordination of twenty-four (24) hour care delivery, and shall meet all requirements of 42 C.F.R. 460.104.

(5) Each member of the interdisciplinary team shall:

(a) Regularly inform the interdisciplinary team of the medical, functional, and psychosocial condition of each participant;

(b) Remain alert to pertinent input from other team members, participants, and caregivers; and

(c) Document changes of a participant's conditions in the participant's medical record consistent with documentation policies established by the medical director.

Section 9. PACE Organization Monitoring. (1) The department, in cooperation with CMS, shall conduct continued reviews of PACE organizations as appropriate, and shall take into account the quality of care furnished and the organization's compliance with all requirements of 42 C.F.R. 460, and Title 907 KAR.

(2) Continued reviews shall include on-site visits at least every two (2) years.

(3) The department, in cooperation with CMS, shall monitor the effectiveness of actions taken to correct deficiencies identified during a review pursuant to Section 10 of this administrative regulation.

(4) The results of a review conducted under this section shall be:

(a) Promptly reported to the PACE organization, along with recommendations for changes to the organization's program; and

(b) Made available to the public upon request.

Section 10. Corrective Actions Regarding the PACE organization. (1) The department shall have the authority, upon a determination by CMS or the department that the PACE organization is not in substantial compliance with 42 C.F.R. Part 460. to:

(a) Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan;

(b) Withhold some or all payments under the PACE program agreement until the organization corrects the deficiency; or

(c) Terminate the PACE program agreement.

(2) Termination of the PACE program agreement by the department, including termination for cause, shall comply with 42 C.F.R. 460.50, as appropriate.

(3) If a PACE program agreement is being terminated, the PACE organization shall:

(a) Follow all procedures regarding termination pursuant to the PACE program agreement; and

(b) Provide transitional care to participants and comply with all other requirements established pursuant to 42 C.F.R. 460.52.

Section 11. PACE Organization Payments. (1) The department shall make a monthly payment to a PACE organization. The payment shall be:

(a) A prospective payment, based upon the estimated number of participants a PACE organization will provide services to in the relevant month; and (b) Subject to adjustment based on the estimated and actual number of participants who received services from the organization in a given month, as provided in the PACE program agreement.

(2) The amount of the department's monthly payment to the PACE organization shall:

(a) Be less than the amount that the department would have otherwise paid for a participant under other state plan services providing the same level of care;

(b) Take into account the comparative frailty of PACE participants;

(c) Be a fixed amount, regardless of changes in a participant's health status; and

(d) Be open to renegotiation on an annual basis.

(3) A PACE organization shall:

(a) Accept the negotiated payment as payment in full for Medicaid participants; and

(b) Not bill, charge, collect, or receive any other form of payment from the department or from, or on behalf of, the participant, except a:

1. Payment with respect to any applicable liability under 42 C.F.R. 435.121 and 42 C.F.R. 435.831 and any amounts due under the post-eligibility treatment of income process under 42 C.F.R. 460.184; or

2. Medicare payment received from CMS or from other payers, in accordance with 42 C.F.R. 460.180(d).

(4) A PACE organization shall not charge a premium to a participant who is eligible for Medicaid.

Section 12. Appeals and Grievances. (1) An appeal of a department decision regarding a participant or applicant relating to the delivery of PACE services shall be in accordance with 907 KAR 1:563.

(2) An appeal of a department decision regarding the eligibility of an individual for Medicaid services shall be in accordance with 907 KAR 1:560.

(3) The following shall not be considered a sanction against a PACE organization and shall not be appealable:

(a) A voluntary moratorium;

(b) A decision not to renew a certification;

(c) A citation; or

(d) Denial of an initial certification.

(4) A PACE organization's appeals shall be in accordance with 42 C.F.R. 460.122.

(5) A PACE participant may register any grievance or complaint regarding a PACE service provision or a PACE organization by contacting the department via:

(a) Email at dmsweb@ky.gov; or

(b) Mail at Department for Medicaid Services, Division of Policy and Operations, 275 E. Main Street 6W-D, Frankfort, Ky. 40621.

Section 13. Federal Approval and Federal Financial Participation. The department's coverage and reimbursement of services pursuant to this administrative regulation shall be contingent upon:

(1) Receipt of federal financial participation for the coverage and reimbursement; and

(2) Centers for Medicare and Medicaid Services' approval of the coverage and reimbursement.

Section 14. Use of Electronic Signatures. The creation, transmission, storage, or other use of electronic signatures and documents shall comply with the requirements established in KRS 369.101 to 369.120.

LISA D. LEE, Commissioner

ERIC FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 2, 2020

FILED WITH LRC: October 8, 2020 at 12:41 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on December 21, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this

hearing shall notify this agency in writing by December 14, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until December 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact persons: Jonathan Scott and Donna Little

(1) Provide a brief summary of:

What this administrative regulation does: This (a) regulation establishes the coverage administrative and reimbursement requirements for Programs of All-Inclusive Care for the Elderly (PACE). PACE is a program allowed under federal law to provide comprehensive, capitated health services that enhance the lives of frail, older adults, and enable frail, older adults to live in the community as long as medically and socially feasible. In addition, PACE can preserve and support the older adult's family unit. This administrative regulation establishes participant eligibility standards, covered services, requirements for the PACE organization, excluded services, a requirement to establish an interdisciplinary team at each center, departmental monitoring of PACE organizations, corrective procedures, and appeals and grievances procedures. This administrative regulation also establishes reimbursement policies and provisions for PACE organizations.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to implement the department's coverage of and payment for PACE organizations.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the content of the authorizing statutes by establishing PACE within Kentucky Medicaid in line with 42 C.F.R. Part 460.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing PACE within Kentucky Medicaid.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation. This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: There are currently no enrolled PACE organizations within Kentucky. Kentucky expects at least 2 PACE organizations to enroll and begin providing services by January 1, 2021. This administrative regulation will also affect an unknown number of eligible individuals over the age of 55 who meet the appropriate nursing level of care and requirements of this administrative regulation as well as specialized providers who offer PACE programs.

(4) Provide an analysis of how the entities identified in guestion

(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment. Providers will need to enroll as PACE organizations and comply with 42 C.F.R. Part 460 in providing PACE organization services. Recipients will need to meet the appropriate nursing level of care

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3). Enrollees and recipients should not experience any additional costs in complying with this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3). Enrollees and recipients will be able to access a new Medicaid benefit, and qualifying providers will be able to provide the service of PACE.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: The Department for Medicaid Services (DMS) anticipates no additional costs to implement this administrative regulation. DMS is hopeful that PACE could produce a modest cost savings of up to 17% for PACE recipients compared to similar recipients in a similar HCBS waiver.

(b) On a continuing basis: The Department for Medicaid Services (DMS) anticipates no additional costs to implement this administrative regulation. DMS is hopeful that PACE could produce a modest cost savings of up to 17% for PACE recipients compared to similar recipients in a similar HCBS waiver.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The sources of revenue to be used for implementation and enforcement of this administrative regulation are federal funds authorized under Title XIX of the Social Security Act and matching funds from general fund appropriations.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: Neither an increase in fees nor funding will be necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation neither establishes nor increases any fees.

(9) Tiering: Is tiering applied? Tiering is not applied as the policies apply equally to the regulated entities.

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 42 C.F.R. Part 460, 42 U.S.C. 1396a, 1396b, 1396d, 1396n

2. State compliance standards. KRS 205.520(3) and KRS 194A.050(1).

3. Minimum or uniform standards contained in the federal mandate. 42 C.F.R. Part 460 establishes requirements relating to PACE, including authorizing state Medicaid programs to pay for PACE.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? No.

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Stricter or different requirements are not imposed.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services (DMS) will be affected by this administrative regulation.

2. Identify each state or federal regulation that requires or

authorizes the action taken by the administrative regulation. 42 C.F.R. Part 460, 42 U.S.C. 1396a, 1396b, 1396d, 1396n

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? DMS does not expect this administrative regulation to generate revenue for state or local government.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? DMS does not expect this administrative regulation to generate revenue for state or local government.

(c) How much will it cost to administer this program for the first year? The Department for Medicaid Services (DMS) anticipates no additional costs as a result of this administrative regulation. DMS is hopeful that PACE could produce a modest cost savings of up to 17% for PACE recipients compared to similar recipients in a similar HCBS waiver.

(d) How much will it cost to administer this program for subsequent years? The Department for Medicaid Services (DMS) anticipates no additional costs as a result of this administrative regulation. DMS is hopeful that PACE could produce a modest cost savings of up to 17% for PACE recipients compared to similar recipients in a similar HCBS waiver.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

CABINET FOR HEALTH AND FAMILY SERVICES Department for Aging and Independent Living Division of Operations and Support (Repealer)

910 KAR 1:151. Repeal of 910 KAR 1:150, and 910 KAR 1:160.

RELATES TO: KRS Chapter 13B, 194A.060(2), 194A.700(1), (2), 205.010(6), (15), 205.201, 205.203, 205.204(1), 205.455(4), 205.460, 205.465, 205.950, 205.955, 209.030(2), (3), 216.787.

STATUTORY AUTHORITY: KRS 194A.050(1), 205.204(2), 205.950.

NECESSITY, FUNCTION, AND CONFORMITY: 2020 Ky. Acts ch 36, sec 44, effective July 15, 2020, repealed KRS 205.950 and 205.955, which previously required the cabinet to promulgate 910 KAR 1:150 and 910 KAR 1:160. As the statutory authorization for those two administrative regulations has been repealed, this administrative regulation repeals 910 KAR 1:150 and 910 KAR 1:160.

Section 1. The following administrative regulations are hereby repealed:

(1) 910 KAR 1:150 Program and certification requirements for the private pay adult day and Alzheimer's respite program; and

(2) 910 KAR 1:160 Program and certification requirements for the adult day and Alzheimer's respite program.

VICTORIA L. ELRIDGE, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 6, 2020

FILED WITH LRC: October 8, 2020 at 12:01 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on December 21, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this

hearing shall notify this agency in writing by December 14, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until December 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; Phone: 502-564-6746; Fax: 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact persons: Phyllis W. Sosa or Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This repealer administrative regulation repeals 910 KAR 1:150 and 910 KAR 1:160.

(b) The necessity of this administrative regulation: This repealer administrative regulation repeals 910 KAR 1:150 and 910 KAR 1:160. The requirements contained in 910 KAR 1:150 and 910 KAR 1:160 are no longer needed due to the repeal of KRS 205.950 and 205.955.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation conforms to the authorizing statutes by repealing the certification of adult day care centers and conducting unannounced site reviews, as repealed during the 2020 legislative session.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the administration of the statutes by removing current administrative regulations that are no longer viable. 2020 Ky. Acts ch 36, sec 44, effective July 15, 2020, repealed KRS 205.950 and 205.955, which previously required the cabinet to promulgate 910 KAR 1:150 and 910 KAR 1:160. As the statutory authorization for those two administrative regulations has been repealed, this administrative regulation repeals 910 KAR 1:150 and 910 KAR 1:150.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation. This is a repealer administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a repealer administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a repealer administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a repealer administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Two (2) certified adult day care centers are affected by this repealer administrative regulation.

(4) Provide an analysis of how the entities identified in question(3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: There will be no new action required on the part of regulated entities. The certified adult day centers have the option to become a licensed adult day health care center or they may continue to operate as a social gathering place, as long as they are not providing the services of an adult day health care center.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There will be no cost associated with this repeal.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This repealer administrative regulation repeals 910 KAR 1:150 and 910 KAR 1:160, therefore eliminating the certification requirements for social model adult day centers. The statutory authority for these administrative regulations was repealed during the 2020 Regular Session.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation: a) Initially: There will be no initial cost to implement this repealer administrative regulation.

(b) On a continuing basis: There will be no continual cost to implement this repealer administrative regulation.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: There is no source of funding for this repealer administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: The administrative regulation does not require an increase in fees or funding.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This repealer administrative regulation does not establish any fees or directly or indirectly increase any fees.

(9) TIERING: Is tiering applied? This repealer administrative regulations does not apply tiering as it repeals 910 KAR 1:150 and 910 KAR 1:160.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Cabinet for Health and Family Services will be impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.050(1), 205.950 and 205.955

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This repealer administrative regulation will not generate revenue.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This repealer administrative regulation will not generate revenue.

(c) How much will it cost to administer this program for the first year? There will be no cost to administer this repealer administrative regulation the first year.

(d) How much will it cost to administer this program for subsequent years? There will be no cost to administer this repealer regulation for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

CABINET FOR HEALTH AND FAMILY SERVICES Department for Aging and Independent Living Division of Operations and Support (New Administrative Regulation)

910 KAR 2:060. Guardianship Trust Fund.

RELATES TO: KRS Chapter 13B, 210.290, 387.010(6), 387.510(15), 387.760

STATUTORY AUTHORITY: 194A.050(1), 387.760(2)

NECESSITY, FUNCTION, AND CONFORMITY: Pursuant to KRS 210.290(4)-(6), the Cabinet for Health and Family Services is authorized to establish a guardianship trust fund that may be used for the benefit of individuals under state guardianship who are indigent. This administrative regulation establishes procedures used by the cabinet to provide public notice of any funds remaining after expenses are paid following the death of an individual under state guardianship who has an estate of less than ten thousand dollars (\$10,000) of personal property or money and the process for claiming that property. This administrative regulation establishes the procedures used for any funds that remain unclaimed after the expiration of one (1) year to escheat to the guardianship trust fund and how the guardianship trust fund may be utilized.

Section 1. Definitions. (1) "Applicant" or "Claimant" means the person who has applied to receive unclaimed personal property or funds of a deceased ward listed on the registry.

(2) "Beneficiary" means an individual or entity that has been identified as a recipient of the estate pursuant to the order of a probate court in this or any other state.

(3) "Cabinet" means the Cabinet for Health and Family Services.

(4) "Department" means the Department for Aging and Independent Living.

(5) "Guardianship trust fund" or "trust" means the guardianship trust fund established by KRS 210.290(4)-(6).

(6) "Guardianship unclaimed funds registry" or "registry" means the registry maintained by the department to post unclaimed funds of a deceased ward.

(7) "Heir" means a legal relative, limited to a spouse, parent, child, or sibling of the deceased appointee.

(8) "Individual under guardianship" means a ward of the state as defined by KRS 387.010(6).

Section 2. Public Notice of Remaining Funds. (1) Upon the death of an individual under guardianship who has less than \$10,000 in personal property or funds, the department shall pay, in priority order, the following:

(a) Funeral expenses:

1. When not prepaid; and

2. When not covered by life insurance.

(b) Outstanding bills related to living expenses including:

1. Rent to a landlord; and

2. Utility companies; and

(c) Medicaid estate recovery owed.

(2) Funds remaining after expenses listed in Subsection 1(a) -

(c) of this section shall be listed on the registry for a period of one (1) year from the date posted.

(3) The registry shall be maintained on the department's website and shall include:

(a) Name of deceased individual under guardianship;

(b) Year of birth;

(c) Date of death;

(d) Last known city of residence;

(e) Date notice is posted on the registry;

(f) The date the notice expires;

(g) If the amount or value remaining in the estate is more or less than 100; and

(h) The account number.

Section 3. Notice of Registry for Claiming Funds. The cabinet may utilize public announcements, interagency agreements, and

announcements to creditors associations, including funeral homes and nursing home associations, in order to provide notice to the public of the registry.

Section 4. Filing a Claim for Funds as a Creditor, Heir, or Beneficiary.

(1) The cabinet shall make available on its website the:

 ${\rm (a)}$ "GUF-1 Guardianship Unclaimed Funds Registry Claim Form - Creditor" for any creditor; and

(b) "GUF-2 Guardianship Unclaimed Funds Registry Claim Form - Individual" for any heir or beneficiary of the deceased ward.

(2) All claims shall be submitted by mail. No claim shall be accepted in person, by fax, or by email.

(3) The cabinet shall review all claims received no later than thirty (30) days of the expiration of one (1) year after the public notice of estate funds is listed. No funds shall be released prior to the expiration of the one (1) year period for filing claims.

(4) Creditors shall have first preference to receive payment from the estate in order as set forth in KRS 210.290(4)(b).

(5) A beneficiary of the estate shall submit a "GUF-2 Guardianship Unclaimed Funds Registry Claim Form - Individual", and the following documentation:

(a) A copy of the will of the deceased individual under guardianship;

(b) A verified copy of an order of a probate court that the beneficiary is entitled to the funds or personal property, or is the administrator or executor of the deceased's estate; and

(c) A copy of the applicant's driver's license or identification card as proof of identity.

(6) An heir of the estate shall submit a "GUF-2 Guardianship Unclaimed Funds Registry Claim Form - Individual", and the following documentation:

(a) A copy of the applicant's driver's license or identification card as proof of identity; and

(b) If a spouse, a copy of the marriage certificate;

(c) If a sibling or child of the deceased individual under guardianship, a copy of the applicant's birth certificate; or

(d) If a parent of the deceased individual under guardianship, a copy of the deceased's birth certificate.

(7) A creditor, other than Medicaid Estate Recovery Program, of the deceased individual under guardianship shall submit a "GUF-1 Guardianship Unclaimed Funds Registry Claim Form - Creditor", and the following documentation:

(a) An affidavit setting out the relationship to the deceased, the services provided, and the amount owed; and

(b) An itemized copy of the statement of charges owed, a description of the service provided, and dates of service; or

(c) Medicaid Estate Recovery Program may file a claim by providing the notice required by 907 KAR 1:585.

(8) All claims submitted within one (1) year of the public notice of a deceased individual under guardianship's funds shall be:

(a) Processed; and

(b) Paid, if valid;

(9) Any remaining funds of the ward shall escheat to the guardianship trust fund.

Section 5. Informal Dispute Resolution and Appeal of Determination Regarding Claim.

(1) Any person or entity aggrieved over a determination by the department regarding a claim may file an informal dispute resolution, which shall be received by the department within fifteen (15) calendar days of the date on the written decision letter.

(2) The request for informal dispute resolution shall be in writing and mailed to the commissioner of the department.

 $(\bar{\mathbf{3}})$ The informal dispute resolution shall include the following information:

(a) Name, address, and telephone number of the claimant;

(b) Justification for the dispute;

(c) Documentation supporting the dispute; and

(d) Signature of person requesting the informal dispute resolution.

(4) The commissioner, or his or her designee, may:

(a) Hold an informal dispute resolution meeting to consider the

sufficiency of the claim; and

(b) Provide an opportunity for the claimant to appear to present facts or concerns about the claim.

(5) A complete record of the informal dispute resolution meeting shall be kept for three (3) years. The claimant shall be notified of the determination, including the reason, and the right to appeal, in writing within ten (10) business days.

(6) A claimant dissatisfied with the determination of the informal dispute resolution may request an administrative hearing be conducted in accordance with KRS Chapter 13B.

(7) The request for administrative hearing shall be received:

(a) Within thirty (30) calendar days from the date on the letter providing the decision of the informal dispute resolution;

(b) In writing; and

(c) To the Office of the Ombudsman and Administrative Review, Quality Advancement Branch, 275 E. Main Street, 2 E-O, Frankfort, Kentucky 40621.

Section 6. Matters not Appealable: No administrative hearing shall be conducted if:

(1) The applicant has submitted a claim for funds within one (1) year of the date public notice is posted on the registry.

(2) The applicant has failed to submit a request for administrative hearing within the thirty (30) day time period.

(3) The applicant has failed to produce the documentation required by this administrative regulation when submitting a claim for funds.

(4) The applicant is not an heir as defined by Section 1(7) of this administrative regulation.

Section 7. Guardianship Trust Fund: Investments and Disbursements.

(1) The cabinet may establish the trust with a bank, taking into consideration the location of the bank and if the bank has an established trust division.

(2) The cabinet shall be trustee and shall invest in such funds as authorized by KRS 210.290(5).

(3) Funds may be utilized from the trust for banking fees and charges and for the cost of personnel needed within the department to maintain the registry and process disbursements. All other funds of the trust shall be utilized for the needs of indigent individuals under guardianship of the cabinet.

(4) The trust may accept donations and conduct fundraising functions.

(5) Disbursements from the trust may be authorized in a uniform manner by the commissioner of the department or by his or her designee.

(6) Requests for disbursements from the trust for an individual under guardianship may be made by any employee of the department or by an individual under guardianship.

(7) The following disbursements may be authorized to the extent funds are available in the trust:

(a) Temporary housing costs not to exceed the cost of housing for two months for an individual under guardianship:

1. With no housing;

2. Who has received an eviction notice; or

3. Who is the victim of abuse, neglect, or exploitation and due to the circumstance is no longer able to safely remain in their current living environment and has no access to alternative living arrangements;

(b) Medical supplies, medication, or medical transportation that are not covered by Medicaid or another insurance plan;

(c) Emergency personal needs including clothing or food;

(d) The reasonable cost of burial or cremation:

1. For an individual under guardianship at least six (6) months prior to death, and

2. Not to exceed \$5,000, for an individual under guardianship who has no:

a. Burial plan or life insurance;

b. Family able to cover the cost in full; or

c. The county of death has no fund for indigent burials; or

(e) Expenses necessary to ensure the health, safety, and wellbeing when no other funds are available or accessible in a timely

manner.

Section 8. Right of Reimbursement of the Trust. (1) The trust shall have the right of reimbursement from an individual under guardianship.

(2) The trust shall be reimbursed as follows by the individual under guardianship:

(a) Funds received are in excess of the individual under guardianship's cost of living expenses; or

(b) Other funding sources are obtained to cover the individual's cost of living expenses and allow for repayment to the trust; and

(c) No other debts are owed by the individual under guardianship for living expenses.

Section 9. Incorporated by Reference. (1) The following material is incorporated by reference:

(a) "GUF-1 Guardianship Unclaimed Funds Registry Claim Form - Creditor" edition 7/2020.

(b) "GUF-2 Guardianship Unclaimed Funds Registry Claim Form - Individual" edition 7/2020.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department for Aging and Independent Living, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.

VICTORIA L. ELRIDGE, Commissioner

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: October 2, 2020

FILED WITH LRC: October 8, 2020 at 12:41 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on December 21, 2020, at 9:00 a.m. in Suites A & B, Health Services Building, First Floor, 275 East Main Street, Frankfort, Kentucky 40621. Individuals interested in attending this hearing shall notify this agency in writing by December 14, 2020, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date. the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until December 31, 2020. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Donna Little, Deputy Executive Director, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; Phone: 502-564-6746; Fax: 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact persons: Phyllis W. Sosa or Donna Little

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the guardianship trust fund as established pursuant to KRS 210.290(4), (5), and (6), requirements for public notice, claiming funds, appealing decisions, matters not appealable, investments and disbursements, and the right of reimbursement of the trust.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish the process for the guardianship trust fund in compliance with KRS 210.290. This administrative regulation sets forth:

The process for providing public notice of remaining funds upon the death of an individual under guardianship;

The requirements for an individual or a creditor to submit a claim for remaining funds;

The process to appeal a decision regarding a claim;

The list of what matters are not appealable;

Reporting on investments and disbursements of the trust fund; The notice of right of reimbursement of the trust fund; and The required forms needed to submit a claim.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

This administrative regulation conforms to KRS 210.290 by establishing the guardianship trust fund. This administrative regulation provides that the cabinet may close out the estate of a deceased individual that has been under guardianship when the estate is under \$10,000.00 and pay any outstanding bills related to living expenses, reasonable funeral expenses, and the Medicaid Estate Recovery Program. Any funds remaining after payment of the aforementioned expenses may be paid to other creditors or family, and this administrative regulation establishes the online registry for potential claims. Any unclaimed funds are placed into the guardianship trust fund pursuant to KRS 210.290(4), (5), and (6).

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation establishes the guardianship trust fund established in the 2019 Regular Session and provides for all aspects of administering the guardianship trust fund. This administrative regulation provides for the establishment of the online registry of unclaimed funds of individuals under guardianship and the process for claiming these funds by creditors and family members. This administrative regulation also provides for those unclaimed funds to escheat to the trust fund to provide for individuals under guardianship that have no resources.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Currently the state's guardianship program has over 4,800 individuals appointed to the Cabinet for Health and Family Services. All of these individuals could be affected by this administrative regulation. Those that are indigent have no resources or family support and may be eligible for funding from the guardianship trust fund to meet their essential needs such as medication, deposits for setting up housing or utilities, or at the end of life to allow an individual a proper burial or cremation. Those individuals under guardianship that have unspent funds after all expenses have been paid upon their death will have their funds held and placed on the online registry for one (1) year, to allow potentially eligible claimants to file a claim. All unclaimed funds shall escheat to the guardianship trust fund.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The individuals under guardianship will not have to take any actions. The potential claimant will be required to follow the process for filing a claim for the funds they believe they are eligible to receive and provide the required documents to verify they are entitled to receive the funds.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): No additional costs are expected.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The individuals under guardianship that receive funds from the guardianship trust fund will be able to access needed resources. These resources are potentially life sustaining, such as medication they cannot otherwise afford, or resources to get them into affordable housing including deposits. The guardianship trust fund will also be utilized to provide a proper burial

for individuals that have been under guardianship when they have no insurance or funds to pay for their own. Currently, individuals may remain in the morgue for months until the funeral home is able to secure a court order for cremation or they work with the county to provide for an indigent burial. Those individuals that file a claim and are found to be legitimate will receive the balance of the individual's funds rather than the funds going to the guardianship trust fund.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: Initially, the implementation of this administrative regulation will be a total of \$11,400 for the startup in the first year: approximately \$5,000 for the creation of the online registry and database, and \$6,400 for staff time based on approximately \$16 per hour for 400 hours.

(b) On a continuing basis: On a continuing basis, the online registry and guardianship trust fund will cost approximately \$3,200. This will fluctuate based on the number of claims filed.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The initial and ongoing costs of this administrative regulation will be funded through the guardianship restricted funds from compensation fee collection.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increased funding is necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: There are no fees established or increased by this regulation.

(9) TIERING: Is tiering applied? Tiering is not applied for this administrative regulation. This administrative regulation is applied equally across the state.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Cabinet for Health and Family Services, Department for Aging and Independent Living, and the Department for Medicaid Services.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 210.290; 387.510(15); 387.760(2).

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate additional revenue in the first year for any state or local government agency.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate additional revenue in subsequent years for any state or local government agency.

(c) How much will it cost to administer this program for the first year? For FY 2021, the program will cost \$11,400.00. The cost of the program will be paid through guardianship restricted funds from compensation fee collection.

(d) How much will it cost to administer this program for subsequent years? In subsequent years, the program will cost \$3,200 through guardianship restricted funds from compensation fee collection.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Expenditures (+/-): Other Explanation:

VOLUME 47, NUMBER 5- NOVEMBER 1, 2020

ADMINISTRATIVE REGULATION REVIEW SUBCOMMITTEE Minutes of October 13, 2020

Call to Order and Roll Call

The October meeting of the Administrative Regulation Review Subcommittee was held on Tuesday, October 13, 2020 at 1 p.m. In Room 171 of the Capitol Annex. Representative Hale, Co-Chair, called the meeting to order, the roll call was taken. The minutes from the September 2020 meeting were approved.

Present were:

Members: Senators Julie Raque Adams, Alice Forgy Kerr, Reginald Thomas, and Stephen West. Representatives David Hale, Deanna Frazier, Marylou Marzian, and Tommy Turner.

LRC Staff: Stacy Auterson, Emily Caudill, Ange Darnell, Emily Harkenrider, Karen Howard, Carrie Nichols, and Christy Young.

Guests: Stephen McMurry, UK Agricultural Experiment Station; Todd Allen, Cassie Trueblood, Education Professional Standards Board; Mary Elizabeth Bailey, Rosemary Holbrook, Personnel Cabinet; Larry Hadley, Board of Pharmacy; Leanne Diakov, Board of Medical Licensure; David Trimble, Board of Chiropractic Examiners; Amy Barker, Natasha Burikhanov, Brandon Lynch, Department of Corrections; Robin Kinney, Matt Ross, Department of Education; John Wood, Michael Kurtsinger, Kentucky Fire Commission; DJ Wasson, Department of Insurance; Julie Brooks, Donna Little, Kelli Rodman, Department for Public Health; Laura Begin, Tara Cecil, Melanie Taylor, Department for Community Based Services.

The Administrative Regulation Review Subcommittee met on Tuesday, October 13, 2020, and submits this report:

Administrative Regulations Reviewed by the Subcommittee:

AGRICULTURAL EXPERIMENT STATION: Fertilizer

<u>12 KAR 4:075</u>. Licenses and fertilizer product registration. Stephen McMurry, program director, represented the Agricultural Experiment Station.

A motion was made and seconded to approve the following amendment: to amend Section 2 to comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendment was approved.

12 KAR 4:080. Plant nutrient guarantees and labeling.

A motion was made and seconded to approve the following amendments: to amend Sections 1 through 3 and 5 to comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

<u>12 KAR 4:091</u>. Repeal of 012 KAR 004:090, 004:120, and 004:160.

12 KAR 4:100. Slowly released nutrients; labeling.

12 KAR 4:110. Definitions for 012 KAR Chapter 004.

12 KAR 4:130. Investigational allowances.

A motion was made and seconded to approve the following amendments: to amend Sections 1 through 4 to comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

12 KAR 4:140. Monetary penalties.

A motion was made and seconded to approve the following amendments: to amend Sections 1 through 6 to comply with the drafting and formatting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

<u>12 KAR 4:170</u>. Maximum chlorine guarantees for tobacco fertilizers.

A motion was made and seconded to approve the following amendments: to amend the RELATES TO and NECESSITY, FUNCTION, AND CONFORMITY paragraphs and Section 1 to comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

EDUCATION AND WORKFORCE DEVELOPMENT CABINET: Education Professional Standards Board: Administrative Certificates

<u>16 KAR 3:090</u>. Certifications for advanced educational leaders. Todd Allen, general counsel, and Cassie Trueblood, policy advisor and special counsel, represented the board.

A motion was made and seconded to approve the following amendments: to amend the STATUTORY AUTHORITY paragraph and Sections 3, 5, 9, and 10 to comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

Alternative Routes to Certification

<u>16 KAR 9:010</u>. Professional certificate for exceptional work experience.

A motion was made and seconded to approve the following amendments: to amend Sections 1 and 2 to comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

PERSONNEL CABINET: Organ Donor Leave

<u>101 KAR 6:010 & E</u>. Living organ donor leave. Mary Bailey, commissioner, and Rosemary Holbrook, assistant general counsel, represented the cabinet.

In response to questions by Representative Marzian, Ms. Bailey stated that living organ donor provisions provided state employee leave with pay. The amount of leave varied, depending on the type of donation, but all leave was provided regardless of the employee's sick leave balance.

Co-Chair Hale stated that this administrative regulation was very important.

BOARDS AND COMMISSIONS: Board of Pharmacy

<u>201 KAR 2:311</u>. Compounding for veterinary use. Larry Hadley, executive director, represented the board.

A motion was made and seconded to approve the following amendments: to amend the RELATES TO and NECESSITY, FUNCTION, AND CONFORMITY paragraphs and Sections 2 through 5 to comply with the drafting and formatting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

Board of Medical Licensure

<u>201 KAR 9:016</u>. Restrictions on use of amphetamine and amphetamine-like anorectic controlled substances. Leanne Diakov, general counsel, represented the board.

A motion was made and seconded to approve the following

amendments: to amend the NECESSITY, FUNCTION, AND CONFORMITY paragraph and Sections 1 and 2 to comply with the drafting and formatting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

201 KAR 9:200. National Practitioner Data Bank Reports.

A motion was made and seconded to approve the following amendments: to amend the STATUTORY AUTHORITY and NECESSITY, FUNCTION, AND CONFORMITY paragraphs to comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

201 KAR 9:210. Criminal background checks required for all new applicants.

A motion was made and seconded to approve the following amendments: to amend the STATUTORY AUTHORITY and NECESSITY, FUNCTION, AND CONFORMITY paragraphs to comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

<u>201 KAR 9:230</u>. Required registration in the KASPER system; legal requirements for prescribing controlled substances in the Commonwealth of Kentucky; enforcement.

201 KAR 9:240. Emergency orders and hearings; appeals and other proceedings.

<u>201 KAR 9:260</u>. Professional standards for prescribing, dispensing, and administering controlled substances.

A motion was made and seconded to approve the following amendments: to amend Sections 1 and 4 to comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

<u>201 KAR 9:360</u>. Continuing education requirements for physician assistants.

A motion was made and seconded to approve the following amendments: to amend Sections 2 and 3 to comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

Board of Chiropractic Examiners

201 KAR 21:041. Licensing, standards, fees. David Trimble, counsel, represented the board.

In response to a question by Representative Marzian, Mr. Trimble stated that the fees established in this administrative regulation were not being changed.

A motion was made and seconded to approve the following amendments: (1) to amend Section 3 to comply with the drafting and formatting requirements of KRS Chapter 13A; and (2) to amend Section 7 to update material incorporated by reference. Without objection, and with the agreement of the agency, the amendments were approved.

201 KAR 21:042. Standards, application and approval of continuing education.

A motion was made and seconded to approve the following amendments: (1) to amend the NECESSITY, FUNCTION, AND CONFORMITY paragraph and Sections 1 through 4 to comply with the drafting and formatting requirements of KRS Chapter 13A; and (2) to amend Section 4 to update material incorporated by reference. Without objection, and with agreement of the agency, the amendments were approved.

201 KAR 21:095. Licensure, registration, and standards of persons performing peer review.

A motion was made and seconded to approve the following amendments: to amend the NECESSITY, FUNCTION, AND CONFORMITY paragraph and Sections 1 and 4 to comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

JUSTICE AND PUBLIC SAFETY CABINET: Department of Corrections: Office of the Secretary

501 KAR 6:120. Blackburn Correctional Complex. Amy Barker, assistant general counsel, and Brandon Lynch, program administrator, represented the department.

A motion was made and seconded to approve the following amendments: to amend Section 1 and the material incorporated by reference to clarify provisions, correct citations, update edition dates, and comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

EDUCATION AND WORKFORCE DEVELOPMENT CABINET: Board of Education: Department of Education: School Administration and Finance

<u>702 KAR 3:</u>270E. SEEK funding formula. Todd Allen, general counsel, and Robin Kinney, associate commissioner, represented the department.

In response to a question by Representative Marzian, Mr. Allen stated that 702 KAR 3:270E and 702 KAR 7:125E covered the current school year and into 2021. These changes gave local school boards flexibility to determine the best mode of education, whether in-person attendance, remote learning, or a combination. "Attendance" was temporarily being changed to "participation" to accommodate the various modes of education.

In response to questions by Representative Frazier, Ms. Kinney stated that funding was not affected by which mode of education a local school board chose. Because these emergency administrative regulations would expire on April 10, 2021, it might be necessary to implement further legislative relief during the 2021 Regular Session of the General Assembly. Lacking a 2021 legislative remedy, it might be necessary to take further Executive Branch action.

School Terms, Attendance, and Operation

702 KAR 7:125E. Pupil attendance.

KENTUCKY COMMUNITY AND TECHNICAL COLLEGE SYSTEM: Kentucky Fire Commission: Commission on Fire Protection Personnel Standards and Education

<u>739 KAR 2:040</u>. Survivor benefits for death of a firefighter. Michael Kurtsinger, division director, and John Wood, counsel, represented the commission.

A motion was made and seconded to approve the following amendments: to amend the NECESSITY, FUNCTION, AND CONFORMITY paragraph and Sections 1 through 3 and 5 to comply with the drafting and formatting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

<u>739 KAR 2:155</u>. Alan "Chip" Terry Professional Development and Wellness Program.

A motion was made and seconded to approve the following amendments: to amend the STATUTORY AUTHORITY and NECESSITY, FUNCTION, AND CONFORMITY paragraphs and Sections 1, 2, 5, and 7 to comply with the drafting and formatting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

PUBLIC PROTECTION CABINET: Department of Insurance: Authorization of Insurers and General Requirements

<u>806 KAR 3:170</u>. Annual audited financial reports. DJ Wasson, deputy commissioner, represented the department. A motion was made and seconded to approve the following amendments: to amend the RELATES TO and STATUTORY AUTHORITY paragraphs and Sections 1 through 14 and 16 through 18 to comply with the drafting and formatting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

Assets and Liabilities

806 KAR 6:010. Valuation standards; audits.

A motion was made and seconded to approve the following amendments: (1) to amend the NECESSITY, FUNCTION, AND CONFORMITY paragraph and Sections 1 through 8 to comply with the drafting and formatting requirements of KRS Chapter 13A; and (2) to amend Section 1 to add a definition for "life actuary." Without objection, and with agreement of the agency, the amendments were approved.

<u>806 KAR 6:080</u>. Reserve standards for individual health insurance policies.

A motion was made and seconded to approve the following amendments: to amend the STATUTORY AUTHORITY and NECESSITY, FUNCTION, AND CONFORMITY paragraphs and Sections 1 through 5 to comply with the drafting and formatting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

806 KAR 6:100. Actuarial opinion and memorandum.

A motion was made and seconded to approve the following amendments: to amend the STATUTORY AUTHORITY and NECESSITY, FUNCTION, AND CONFORMITY paragraphs and Sections 1 through 5, 7, and 8 to comply with the drafting and formatting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

Investments

806 KAR 7:035. Finance committee of domestic insurers. A motion was made and seconded to approve the following amendments: to amend the RELATES TO; STATUTORY AUTHORITY; and NECESSITY, FUNCTION, AND CONFORMITY paragraphs to comply with the drafting

requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

<u>806 KAR 7:090</u>. Custodial accounts for investment securities of insurance companies.

A motion was made and seconded to approve the following amendments: (1) to amend Section 3 to require all custodian banks to have capital and surplus funds equal to or exceeding \$25,000,000; and (2) to amend the NECESSITY, FUNCTION, AND CONFORMITY paragraph and Sections 1, 2, and 5 to comply with the drafting and formatting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

Administration of Deposits

806 KAR 8:010. Valuation of assets on deposit.

A motion was made and seconded to approve the following amendments: to amend the RELATES TO paragraph and Sections 1 and 5 to comply with the drafting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

Captive Insurers

<u>806 KAR 49:020</u>. Captive insurer application requirements. A motion was made and seconded to approve the following amendments: to amend the RELATES TO and NECESSITY, FUNCTION, AND CONFORMITY paragraphs and Sections 2 and 4 through 7 to comply with the drafting and formatting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

<u>806 KAR 49:030</u>. Captive insurer reporting requirements. A motion was made and seconded to approve the following amendments: to amend the RELATES TO and NECESSITY, FUNCTION, AND CONFORMITY paragraphs and Sections 2 and 3 to comply with the drafting and formatting requirements of KRS Chapter 13A. Without objection, and with agreement of the agency, the amendments were approved.

CABINET FOR HEALTH AND FAMILY SERVICES: Department of Public Health: Division of Women's Health: Maternal and Child Health

<u>902 KAR 4:110</u>. Abortion information. Julie Brooks, regulation coordinator, represented the division.

In response to a question by Representative Marzian, Ms. Brooks stated that the requirement that a provider shall give information on abortion pill reversal was established in Senate Bill 50 from the 2019 Regular Session of the General Assembly. The statute did not include provisions for who would be deemed responsible if injury or death resulted from use of abortion pill reversal.

Representative Marzian stated that there was insufficient evidence to support the safety and efficacy of abortion pill reversal. It was unfortunate to provide false information.

In response to questions by Representative Frazier, Ms. Brooks stated that the one (1) dollar fee established in this administrative regulation was to recover the cost of printing the informational material if the printing was performed by the agency. The agency had not received any requests to do this printing in the last two (2) years. Providers, not individuals, paid this fee. If a private citizen, rather than a provider, requested this information to be printed by the agency, the fee was not charged. Ms. Brooks stated that she would provide follow-up information to the subcommittee regarding other fees the division might charge for materials.

In response to a question by Co-Chair West, staff stated that the fee for printing the information was statutorily required.

Division of Public Health Protection and Safety: Milk and Milk Products

902 KAR 50:010. Definitions for milk and milk products.

<u>902 KAR 50:031</u>. Standards for producer eligibility for manufactured grade milk.

<u>902 KAR 50:032</u>. Standards for farm requirements for manufactured grade milk.

In response to questions by Co-Chair West, Ms. Brooks stated that 902 KAR 50:032 and 50:033 pertained to milk that did not fall into the classification of pasteurized milk. Enforcement action for a violation was only implemented after education, an opportunity for correction, and a reinspection.

In response to questions by Co-Chair Hale, Ms. Brooks stated that there were two (2) classifications for milk, manufactured grade milk and pasteurized milk, which was regulated by the US Food and Drug Administration. These administrative regulations had not been revised since the 1990s. Changes were made to update provisions, and technical corrections were made commensurate with amendments to KRS Chapter 13A. This division did not intend to increase the burden on Kentucky's dairy farmers.

Co-Chair Hale stated that it was important to ensure milk safety and sanitation; however, it was also important not to overregulate the few dairy farmers remaining in Kentucky.

<u>902 KAR 50:033.</u> Standards for enforcement procedures for manufactured grade milk.

Radiology

902 KAR 100:012. Fee schedule.

A motion was made and seconded to approve the following amendments: (1) to amend Sections 1, 2, and 7 to comply with the drafting requirements of KRS Chapter 13A; and (2) to amend Section 8 to incorporate material by reference. Without objection, and with agreement of the agency, the amendments were approved.

Department for Community Based Services: Division of Protection and Permanency: Child Welfare

<u>922 KAR 1:330.</u> Child protective services. Laura Begin, regulation coordinator; Tara Cecil, branch manager; and Melanie Taylor, assistant division director, represented the division.

A motion was made and seconded to approve the following amendments: to amend Section 3(15)(a) to add human trafficking to the list of reports that may trigger a medical or psychological examination. Without objection, and with agreement of the agency, the amendments were approved.

The following administrative regulations were deferred or removed from the October 13, 2020, subcommittee agenda:

FINANCE AND ADMINISTRATION CABINET: Teachers' Retirement System

<u>102 KAR 1:340</u>. Calculation of final average salary if there is a corresponding change in position or in length of employment during any of the final three (3) years prior to retirement.

BOARDS AND COMMISSIONS: Board of Pharmacy

201 KAR 2:050. Licenses and permits; fees.

<u>201 KAR 2:105</u>. Requirements for wholesalers, medical gas wholesalers, wholesale distributors, and virtual wholesale distributors.

201 KAR 2:106. Licensed or permitted facility closures.

 $\underline{201 \text{ KAR } 2:225}.$ Special limited pharmacy permit – medical gas.

201 KAR 2:240. Special limited pharmacy permit- charitable.

201 KAR 2:320. Requirements or manufacturers and virtual manufacturers.

COMMUNITY AND TECHNICAL COLLEGE SYSTEM: Board of Emergency Medical Services

202 KAR 7:201. Emergency Medical Responders.

202 KAR 7:301. Emergency Medical Technician.

202 KAR 7:330. Advanced Emergency Medical Technician.

202 KAR 7:401. Paramedics.

202 KAR 7:601. Training, education and continuing education.

TRANSPORTATION CABINET: Department of Vehicle Regulation: Division of Drivers Licensing: Administration

601 KAR 2:231. Repeal of 601 KAR 2:030.

601 KAR 2:232 & E. Kentucky Ignition Interlock Program.

LABOR CABINET: Department of Workers' Claims

803 KAR 25:089 & E. Workers; compensation medical fee schedule for physicians.

PUBLIC PROTECTION CABINET: Department of Alcoholic Beverage Control: Licensing

804 KAR 4:415. Direct shipper license.

Horse Racing Commission: Licensing

810 KAR 3:020. Licensing of racing participants.

Department of Charitable Gaming 820 KAR 1:050 & E. Raffles.

CABINET FOR HEALTH AND FAMILY SERVICES: Department of Public Health: Division of Epidemiology and Health Planning: Vital Statistics

901 KAR 5:120. Abortion reporting.

Communicable Diseases

<u>902 KAR 2:020 & E</u>. Reportable disease surveillance.

Division of Maternal and Child Health: Maternal and Child Health

902 KAR 4:030. Newborn screening program.

Division of Administration and Financial Management: Local Health Departments

<u>902 KAR 8:160</u> & E. Local health department operations requirements.

<u>902 KAR 8:170</u> & E. Local health department financial management requirements.

Division of Public Health Protection and Safety: Sanitation

<u>902 KAR 10:030</u>. Registered environmental health specialists and sanitarians.

902 KAR 10:036. Repeal of 902 KAR 010:035

Division of Public Health Protection and Safety: Food and Cosmetics

<u>902 KAR 45:110</u>. Permits and fees for retail food establishments, vending machine companies, and restricted food concessions.

<u>902 KAR 45:180</u>. Permits and fees for food manufacturing plants, food storage warehouses, salvage processors and distributors, cosmetic manufacturers, and certificate of free sale.

Milk and Milk Products

902 KAR 50:040. Hauler requirements.

Department for Behavioral Health, Developmental and Intellectual Disabilities: Division of Behavioral Health: Substance Abuse

908 KAR 1:381. Repeal of 908 KAR 001:380.

<u>908 KAR 1:400</u>. Licensing and standards for substance use and misuse prevention.

Department for Community Based Services: Division of Protection and Permanency: Child Welfare

922 KAR 1:450 & E. Eligibility confirmation for tuition waiver.

922 KAR 1:520 & E. Supplements to per diem rates.

The subcommittee adjourned at 1:50 p.m. The next meeting of the subcommittee is tentatively scheduled for November 9, 2020, at 1 p.m.

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OTHER COMMITTEE REPORTS

COMPILER'S NOTE: In accordance with KRS 13A.290(10), the following reports were forwarded to the Legislative Research Commission by the appropriate jurisdictional committees and are hereby printed in the Administrative Register. The administrative regulations listed in each report became effective upon adjournment of the committee meeting at which they were considered.

INTERIM JOINT COMMITTEE ON NATURAL RESOURCES AND ENERGY Meeting of October 22, 2020

The following administrative regulation was available for consideration and placed on the agenda of the Interim Joint Committee on Natural Resources and Energy for its meeting of October 22, 2020, having been referred to the Committee on October 7, 2020, pursuant to KRS 13A.290(6):

921 KAR 004:116

The following administrative regulations were found to be deficient pursuant to KRS 13A.290(7) and 13A.030(2):

None

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CUMULATIVE SUPPLEMENT

Unless otherwise noted, information contained in these indexes relates only to administrative regulations printed in this, the 47th year of the *Administrative Register of Kentucky*, from July 2020 through June 2021.

Locator Index - Effective Dates

Lists all administrative regulations published or continuing through the KRS Chapter 13A review process during this Register year. It also lists the page number on which each regulation is published, the effective date of the regulation after it has completed the review process, and other actions that may affect the regulation. NOTE: Regulations listed with a "45 Ky.R." or "46 Ky.R." notation are regulations that were originally published in previous years' issues of the Administrative Register of Kentucky but had not yet gone into effect when the last Register year ended.

KRS Index

A cross-reference of statutes to which administrative regulations relate. These statute numbers are derived from the RELATES TO line of each regulation submitted for publication during this Register year.

Certifications Index

A list of administrative regulations for which certification letters have been filed pursuant to KRS 13A.3104 during this Register year. Additionally, this index includes information regarding regulations that had letters that stated a regulation shall be amended within 18 months.

Technical Amendment Index

A list of administrative regulations that have had technical, non-substantive amendments made during this Register year. These technical changes have been made by the Regulations Compiler pursuant to KRS 13A.040(9) and (10), 13A.2255(2), 13A.312(2), or 13A.320(1)(d). Because these changes were not substantive in nature, administrative regulations appearing in this index will NOT be published in the Administrative Register of Kentucky; however, they are usually available for a short time on the Legislative Research Commission's Web site.

Subject Index

A general index of administrative regulations published during this Register year, and is mainly broken down by agency.

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Administrative regulations published in previous Register years may appear in this index if a regulation had not completed the KRS Chapter 13A review process by the beginning of *Register* year 47. The "*Register* number" or "Ky.R. number" is listed the first time a regulation is published during that Register year. Once the regulation has been published in another *Register* year, the new Ky.R. number will appear next to the page number entry. To view versions of regulations published in 45 Ky.R. or 46 Ky.R., please visit our online *Administrative Registers of Kentucky*.

SYMBOL KEY:

- * Statement of Consideration not filed by deadline
- ** Withdrawn, deferred more than twelve months (KRS 13A.300(2)(e) and 13A.315(1)(d))
- *** Withdrawn before being printed in Register
- IJC Interim Joint Committee
- (r) Repealer regulation: KRS 13A.310(3)-on the effective date of an administrative regulation that repeals another, the regulations compiler shall delete the repealed administrative regulation and the repealing administrative regulation.

EMERGENCY ADMINISTRATIVE REGULATIONS

NOTE: Emergency regulations filed after 7/15/2019 are automatically set to expire 270 days from the date filed. The 270 days may be extended by one month, if comments were received. Emergency regulations expire upon the conclusion of the 270 days (or 270 days plus the number of days of the requested extension) or upon replacement by an ordinary regulation, whichever occurs first.

009 KAR 001:040E	47 Ky.R.	8	6-9-2020
010 KAR 001:011E	46 Ky.R.	2863	4-22-2020
030 KAR 008:005E	46 Ky.R.	2206	1-3-2020
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031 KAR 004:190E	46 Ky.R.	2865	5-5-2020
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031 KAR 004:191E	47 Ky.R.	***	6-22-2020
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031 KAR 004:192E	47 Ky.R.	678	8-28-2020
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031 KAR 004:193E	47 Ky.R.	893	10-2-2020
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101 KAR 006:010E	47 Ky.R.	246	7-15-2020
105 KAR 001:149E	46 Ky.R.	1775	11-15-2019
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201 KAR 020:225E	46 Ky.R.	2769	3-31-2020
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201 KAR 020:470E	46 Ky.R.	2771	3-31-2020
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201 KAR 032:110E	46 Ky.R.	2776	3-30-2020
501 KAR 001:040E	46 Ky.R.	1780	10-21-2019
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501 KAR 001:071E	46 Ky.R.	1786	10-21-2019
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601 KAR 002:232E	47 Ky.R.	247	6-30-2020
702 KAR 001:190E	47 Ky.R.	503	8-12-2020
702 KAR 003:270E	47 Ky.R.	254	7-14-2020
702 KAR 007:125E	47 Ky.R	258	7-14-2020
702 KAR 007:140E	47 Ky.R.	505	8-12-2020
787 KAR 001:350E	46 Ky.R.	2867	5-1-2020
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800 KAR 001:010E	46 Ky.R.	2872	5-12-2020
802 KAR 001:010E	47 Ky.R.	684	9-2-2020
802 KAR 002:010E	47 Ky.R.	687	9-2-2020
802 KAR 003:010E	47 Ky.R.	691	9-2-2020
803 KAR 025:089E	47 Ky.R.	264	7-1-2020
810 KAR 002:090E	46 Ky.R.	2779	3-20-2020
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820 KAR 001:050E	47 Ky.R.	10	5-22-2020
895 KAR 001:002E	46 Ky.R.	2211	12-27-2019
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900 KAR 006:075E	46 Ky.R.	2213	1-2-2020
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902 KAR 002:020E	47 Ky.R.	12	6-15-2020
902 KAR 002:190E	47 Ky.R.	266	7-10-2020
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902 KAR 002:210E	47 Ky.R.	508	8-10-2020
902 KAR 002:220E	47 Ky.R.	693	9-14-2020
902 KAR 004:140E	47 Ky.R.	21	5-19-2020
902 KAR 008:160E	47 Ky.R.	268	7-10-2020
902 KAR 008:170E	47 Ky.R.	272	7-10-2020
902 KAR 020:160E	47 Ky.R.	897	10-13-2020
902 KAR 020:440E	47 Ky.R.	908	10-13-2020
902 KAR 030:010E	46 Ky.R.	2780	3-23-2020
907 KAR 001:604E	46 Ky.R.	2593	3-13-2020
907 KAR 003:300E	46 Ky.R.	2782	3-19-2020
907 KAR 010:840E	46 Ky.R.	1787	10-30-2019
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907 KAR 015:070E	47 Ky.R.	915	10-13-2020
907 KAR 015:080E	47 Ky.R.	922	10-13-2020
921 KAR 002:015E	46 Ky.R.	2216	12-27-2019
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921 KAR 003:025E	46 Ky.R.	2784	4-15-2020
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921 KAR 003:035E	47 Ky.R.	510	7-29-2020
921 KAR 004:116E	47 Ky.R.	22	5-28-2020
Replaced		215	10-22-2020
922 KAR 001:450E	47 Ky.R.	279	7-10-2020
922 KAR 001:520E	47 Ky.R.	281	7-1-2020
922 KAR 001:490E	46 Ky.R.	2875	5-12-2020
922 KAR 002:400E	47 Ky.R.	27	6-8-2020
Withdrawn	-		9-1-2020
922 KAR 002:405E	47 Ky.R.	695	9-1-2020
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012 KAR 004:170				Amended	46 Ky.R.	1282	
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201 KAR 021:052			Amended	46 Ky.R.		
Amended	47 Ky.R.	783	As Amended		2625 6-4-20)20
201 KAR 021:053		784	302 KAR 010:010 Repealed	AG KU P	2357 7 0 00	120
Amended 201 KAR 021:055	47 Ky.R.	104	Repealed 302 KAR 010:011(r)	46 Ky.R. 46 Ky.R.		120
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302 KAR 010:030		~~		302 KAR 050:013	47 Ky.R.	642
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302 KAR 010:040		2257	7 0 2020	Amended	46 Ky.R.	
Repealed 302 KAR 010:050	46 Ky.R.	2357	7-9-2020	As Amended 302 KAR 050:021	47 Ky.R. 47 Ky.R.	285 9-17-2020 643
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302 KAR 010:070	-			302 KAR 050:031	47 Ky.R.	651
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302 KAR 010:080				Repealed	46 Ky.R.	9-17-2020
Repealed	46 Ky.R.	2357	7-9-2020	302 KAR 050:045	47 Ky.R.	658
302 KAR 010:090		0057	7 0 0000	302 KAR 050:050	40 K D	0.47.0000
Repealed	46 Ky.R.		7-9-2020	Repealed	46 Ky.R.	9-17-2020
302 KAR 010:100 302 KAR 020:012(r)	46 Ky.R. 46 Ky.R.		7-9-2020	302 KAR 050:055 As Amended	46 Ky.R.	
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302 KAR 020:050	io riyira	2110	1 0 2020	302 KAR 050:080	ii ityitti	010 011 2020
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302 KAR 020:052	,			302 KAR 060:010	47 Ky.R.	226
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302 KAR 020:066				401 KAR 005:090		
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302 KAR 020:070				401 KAR 005:091(r)	46 Ky.R.	2003 6-30-2020
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302 KAR 020:090		0470	7 0 2020	Amended	46 Ky.R.	
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Repealed	46 Ky.R.	2178	7-9-2020	Amended	46 Ky.R.	1941
302 KAR 020:110	40 Ry.R.	2110	1 0 2020	As Amended	40 Ry.R.	2629 6-30-2020
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302 KAR 020:185	- ,			500 KAR 010:040		
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702 KAR 001:180	47 Ky.R.	229	803 KAR 002:180	47 Ky.K.	801
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702 KAR 004:090			As Amended	47 Ky.R.	62 9-29-2020
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702 KAR 006:046(r)	46 Ky.R. 2		803 KAR 002:311	47 Ky.K.	517
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703 KAR 005:280			Amended	46 Ky.R.	2837
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739 KAR 002:040	40 Ky.K. 2	.701	803 KAR 025:010	46 Ky.R.	
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803 KAR 025:240 Amended	47 Ky.R.	574		Amended 806 KAR 047:010	47 Ky.R.	831	
803 KAR 025:260 Am Comments	46 Ky.R.			Amended 806 KAR 049:020	47 Ky.R.	1096	
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804 KAR 004:415 Am Comments	47 Ky.R.	485 627		As Amended 806 KAR 049:030		973	
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815 KAR 020:030 Amended	46 Ky.R.	1648		895 KAR 001:020 Repealed	46 Ky.R. 221	1 12-27-2019
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815 KAR 020:071		2429	0-2-2020	Repealed 900 KAR 005:020	46 Ky.R. 221	1 12-27-2019
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815 KAR 020:074	-			Amended	47 Ky.R. 41	8
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815 KAR 020:170 Amended	46 Ky.R.	1689		902 KAR 020:440 Amended	46 Ky.R. 302	20
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	012 KAR 001:140		806 KAR 012:010

304.3-241 806 KAR 000:170 304.4-100 806 KAR 0102:00 304.4-010 806 KAR 000:025 304.1-4-100 806 KAR 000:025 304.5-020 806 KAR 012:160 304.17-467 806 KAR 000:300 304.5-020 806 KAR 012:180 304.17-74-65 806 KAR 000:300 304.4-070 806 KAR 000:010 304.35-030 806 KAR 000:300 304.4-160 806 KAR 000:010 304.35-140 806 KAR 000:310 304.4-171 806 KAR 000:010 304.35-140 806 KAR 000:710 304.4-165 806 KAR 000:010 304.35-140 806 KAR 000:710 304.4-171 806 KAR 000:700 304.35-140 806 KAR 000:710 304.4-161 806 KAR 000:700 304.35-140 806 KAR 000:710 304.4-171 806 KAR 000:700 304.35-140 806 KAR 000:710 304.4-200 806 KAR 000:700 304.35-140 806 KAR 000:710 304.4-200 806 KAR 000:700 304.35-140 806 KAR 000:710 304.4-200 806 KAR 000:700 304.34-700 806 KAR 000:710 304.4-200 806 KAR 000:700 3	KRS SECTION	REGULATION	KRS SECTIO	N	REGULATION
304-4010 806 KAR 002:065 304.14-180 806 KAR 005:27 304.5020 806 KAR 005:25 304.15-310 806 KAR 005:30 304.5020 806 KAR 005:30 304.15-310 806 KAR 005:30 304.5020 806 KAR 005:100 304.30-300 806 KAR 005:30 304.6070 806 KAR 005:100 304.30-030 806 KAR 005:100 304.6150 806 KAR 005:100 304.32-210 806 KAR 003:100 304.6155 806 KAR 005:100 304.32-140 806 KAR 003:100 304.6155 806 KAR 005:100 304.32-140 806 KAR 003:100 304.6155 806 KAR 005:100 304.32-140 806 KAR 003:100 304.7360 806 KAR 005:100 304.37-101 806 KAR 003:100 304.7361 806 KAR 005:100 304.38-00 806 KAR 003:100 304.7361 806 KAR 005:100 304.38-00 806 KAR 003:100 304.7361 806 KAR 005:100 304.38-100 806 KAR 003:100 304.7361 806 KAR 005:100 304.38-100 806 KAR 005:100 304.7360 806 KAR 005:100 304.47-100 <t< td=""><td>304.3-241</td><td>806 KAR</td><td>003:170</td><td>304.14-120</td><td>806 KAR 012:020</td></t<>	304.3-241	806 KAR	003:170	304.14-120	806 KAR 012:020
BIO KAR 000:370 304.15:310 BIO KAR 012:180 304.5-300 BIO KAR 012:120 304.17A-607 BIO KAR 000:380 304.6-707 BIO KAR 012:120 304.17A-607 BIO KAR 000:380 304.6-130 BIO KAR 000:100 304.37A-300 BIO KAR 000:100 304.6-130 BIO KAR 000:100 304.32-210 BIO KAR 003:170 304.6-155 BIO KAR 000:100 304.32-210 BIO KAR 003:170 304.6-155 BIO KAR 000:100 304.32-210 BIO KAR 003:170 304.6-131 BIO KAR 000:100 304.32-010 BIO KAR 003:170 304.6-132 BIO KAR 000:100 304.37-020 BIO KAR 003:170 304.6-130 BIO KAR 000:100 304.34-30-000 BIO KAR 003:170 304.6-140 BIO KAR 000:100 304.43-30-000 BIO KAR 003:170 304.6-140 BIO KAR 000:100 304.43-30-000 BIO KAR 003:170 304.6-140 BIO KAR 000:100 304.44-150 BIO KAR 003:170 304.6-140 BIO KAR 000:100 304.45-030 BIO KAR 000:170 304.6-140 BIO KAR 000:100 304.47-040	304.4-010				
304.5-020 806 KAR (02:180 304.17A-165 806 KAR (00:380 304.5-030 806 KAR (02:180 304.17A-820 806 KAR (00:370 304.6-130 304.617A 304.17A-820 806 KAR (00:370 304.6-130 304.6170 806 KAR (00:100 304.30-601 806 KAR (00:100 304.6-130 806 KAR (00:100 304.32-2140 806 KAR (00:100 304.6-130 806 KAR (00:100 304.32-2140 806 KAR (00:100 304.6-130 806 KAR (00:100 304.37-010 806 KAR (00:100 304.6-130 806 KAR (00:100 304.37-010 806 KAR (00:3170 304.6-140 806 KAR (00:010 304.37-010 806 KAR (00:3170 304.6-202 806 KAR (00:010 304.38-110 806 KAR (00:3170 304.6-30 806 KAR (00:370 304.4-603 806 KAR (00:370 304.6-400 806 KAR (00:370 304.4-703 806 KAR (00:370 304.6-401 806 KAR (00:370 304.4-703 806 KAR (00:370 304.6-403 806 KAR (00:370 304.4-703 806 KAR (00:370 304.6-403 806 KAR (00:37		806 KAR	009:025	304.14-642	806 KAR 009:025
304 5-330 806 KAR (02:120 304 17A-607 806 KAR (06:00 304 5-670 806 KAR (05:00 304 30-30 806 KAR (05:01) 304 5-670 806 KAR (05:01) 304 32:140 806 KAR (05:01) 304 5-150 806 KAR (05:01) 304 32:140 806 KAR (05:01) 304 5-150 806 KAR (05:01) 304 32:140 806 KAR (05:01) 304 5-161 806 KAR (05:01) 304 35:40 806 KAR (05:01) 304 5-171 806 KAR (05:00 304 37:40 806 KAR (03:17) 304 5-161 806 KAR (07:05 304 37:40 806 KAR (03:17) 304 5-20 806 KAR (07:05 304 37:40 806 KAR (03:17) 304 5-20 806 KAR (03:17) 304 45:40 806 KAR (03:10) 304 5-20 806 KAR (03:17) 304 45:40 806 KAR (03:17) 304 5-20 806 KAR (03:17) 304 47:40 806 KAR (03:17) 304 5-20 806 KAR (03:10) 304 47:40 806 KAR (07:10) 304 5-20 806 KAR (03:10) 304 47:40 806 KAR (07:10) 304 5-20 806 KAR (00:30) 304 47:70 <		806 KAR	009:370	304.15-310	806 KAR 012:180
B06 KAR 012:180 304.17A-820 805 KAR 005:010 304.6-70 806 KAR 005:100 304.30-050 806 KAR 005:010 304.6-130 304.6-150 806 KAR 005:100 304.32-210 806 KAR 005:100 304.6-151 806 KAR 005:100 304.32-210 806 KAR 005:170 304.6-153 806 KAR 005:100 304.32-210 806 KAR 005:170 304.6-154 806 KAR 007:080 304.37-010 806 KAR 003:170 304.7-361 806 KAR 007:080 304.37-010 806 KAR 003:170 304.8-404 806 KAR 007:080 304.37-010 806 KAR 003:170 304.8-404 806 KAR 005:01 304.38-41:10 806 KAR 003:170 304.8-120 806 KAR 005:01 304.44-503 806 KAR 003:170 304.9-02 806 KAR 005:02 304.47-020 806 KAR 003:170 304.9-04 806 KAR 005:03 304.47-020 806 KAR 003:170 304.9-04 806 KAR 005:03 304.47-020 806 KAR 003:170 304.9-02 806 KAR 005:03 304.47-020 806 KAR 007:100 304.9-130 806 KAR 005:05 304.47-020 </td <td></td> <td></td> <td></td> <td></td> <td></td>					
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806 FAR 006:100 304 30-060 806 FAR 005:101 304 6-153 806 FAR 005:101 304 32-210 806 FAR 003:101 304 6-155 806 FAR 005:101 304 32-210 806 FAR 003:171 304 6-151 806 FAR 005:100 304 33-40 806 FAR 003:171 304 6-161 806 FAR 005:100 304 37-020 806 FAR 003:171 304 7-361 806 FAR 007:030 304 37-020 806 FAR 003:170 304 7-361 806 FAR 007:030 304 43-020 806 FAR 003:170 304 8-420 806 FAR 002:100 304 33A-110 806 FAR 003:170 304 9-040 806 FAR 002:10 304 44-503 806 FAR 003:170 304 9-040 806 FAR 002:10 304 47-010 806 FAR 007:110 304 9-040 806 FAR 002:5 304 47-020 806 FAR 047:010 304 9-040 806 FAR 005:25 304 47-020 806 FAR 047:010 304 9-041 806 FAR 005:25 304 47-050 806 FAR 047:010 304 9-053 806 FAR 005:25 304 47-050 806 FAR 047:010 304 9-105 806 FAR 005:25 304 47-050 806 FAR 06	204 0 070				
304.6-150 406 KAR 006:10 304.32-140 406 KAR 003:170 304.6-155 406 KAR 006:100 304.32-210 406 KAR 003:170 304.6-155 406 KAR 006:100 304.32-040 806 KAR 003:170 304.6-171 806 KAR 006:100 304.37-010 806 KAR 003:170 304.7-300 806 KAR 007:030 304.37-010 806 KAR 003:170 304.7-301 806 KAR 007:030 304.37-020 806 KAR 003:170 304.7-301 806 KAR 007:030 304.47-010 806 KAR 003:170 304.8-120 806 KAR 009:030 304.47-030 806 KAR 003:170 304.9-020 806 KAR 009:030 304.47-030 806 KAR 003:170 304.9-053 806 KAR 009:030 304.47-030 806 KAR 003:170 304.9-053 806 KAR 009:25 304.47-040 806 KAR 003:170 304.9-053 806 KAR 009:25 304.47-050 806 KAR 003:170 304.9-153 806 KAR 009:25 304.47-050 806 KAR 009:100 304.9-153 806 KAR 009:25 304.48-120 806 KAR 009:100 304.9-250 806 KAR 009:25 304.48-10	304.6-070				
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806 KAR 012:170 311A.095 202 KAR 007:201 304.12-240 806 KAR 009:370 202 KAR 007:301 304.13-051 806 KAR 013:020 202 KAR 007:330	504.12-230				
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CERTIFICATION LETTER SUMMARIES

The certification process is established in KRS 13A.3104. If the certification letter states the regulation shall be amended, the administrative body shall file an amendment to the regulation within 18 months of the date the certification letter was filed. If the certification letter states that the regulation shall remain in effect without amendment, the last effective date of the regulation is changed to the date the regulations compiler received the letter.

* KRS 13A.010(6) - "Effective" or "eff." means that an administrative regulation has completed the legislative review process established by KRS 13A.290, 13A.330, and 13A.331.

Regulation Number	Letter Filed Date	Action
017 KAR 003:020	08-07-2020	Remain As Is
201 KAR 037:010	08-07-2020	Remain As Is
703 KAR 005:080	10-23-2020	Remain As Is
803 KAR 002:411	10-01-2020	To be amended, filing deadline 04-01-22
922 KAR 001:130	09-04-2020	Remain As Is

TECHNICAL AMENDMENT INDEX

The Technical Amendment Index is a list of administrative regulations that have had technical, nonsubstantive amendments made during the 47th year of the *Administrative Register of Kentucky*. These technical changes have been made by the Regulations Compiler pursuant to KRS 13A.040(9) and (10), 13A.2255(2), 13A.312(2), or 13A.320(1)(d). Since these changes were not substantive in nature, administrative regulations appearing in this index will NOT be published to show the technical corrections in the *Register*. NOTE: Technical amendments may be available online for a short period of time before finalized versions of the technically amended regulations are available. To view regulations on the Legislative Research Commission Web site go to https://apps.legislature.ky.gov/law/kar/titles.htm.

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