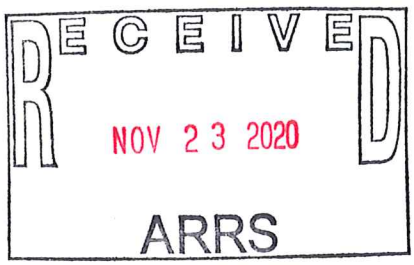
University of Kentucky | College of Agriculture, Food and Environment
Division of Regulatory Services



Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 12 KAR 5:010. Licenses.
12 KAR 5:020. Testing.
12 KAR 5:030. Test Samples.
12 KAR 5:040. Sampling and Weighing.
12 KAR 5:050. Inspections.
12 KAR 5:060. Purchases from Farm Bulk Tanks.
12 KAR 5:070. Uniform Standards for Payment.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 12 KAR 5:010-5:070, the University of Kentucky Division of Regulatory Services proposes the attached amendments to 12 KAR 5:010-5:070.

Sincerely

G. Alan Harrison, PhD.
Director of Feed and Milk Programs
University of Kentucky Division of Regulatory Services
103 Regulatory Services Building
Lexington, KY 40546-0275

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UNIVERSITY OF KENTUCKY
Agriculture Experiment Station

12 KAR 5:010. Licenses.

RELATES TO: KRS 260.775-260.845, 260.992
STATUTORY AUTHORITY: KRS 260.825(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 260.825(1) ***requires[~~authorizes~~]*** the Director of the Agricultural Experiment Station to promulgate administrative regulations necessary for the efficient enforcement of KRS 260.775 ***through[~~to~~]*** 260.845 regarding milk. This administrative regulation establishes a procedure to license a person or entity who is qualified as a milk handler, laboratory, sampler-weigher, tester, or transfer station.

Section 1. (1) License to Handle Milk, Laboratory License, and Transfer Station License. Upon receipt of an ***accurately completed[~~accurately completed~~]*** application with fee as required by KRS 260.815, and if the applicant is deemed to be qualified***, pursuant to this administrative regulation,*** and in compliance with KRS 260.775 ***through[~~to~~]*** 260.845, the director ***shall[~~may~~]*** issue a license to handle, laboratory license, or transfer station license. Each license shall be displayed ***as established in paragraphs (a) through (c) of this subsection.[~~accordingly:~~]***

(a) A current license to handle milk shall be prominently displayed at each handling location***.[;]***

(b) A current laboratory license shall be prominently displayed at each laboratory location***.[; ~~and~~]***

(c) A current transfer station license shall be prominently displayed at each transfer station location.

(2) Temporary license to sample and weigh milk. Upon receipt of an ***accurately completed[~~accurately completed~~]*** application with fee as required by KRS 260.815, and if the applicant is deemed to be qualified***, pursuant to this administrative regulation,*** and in compliance with KRS 260.775 ***through[~~to~~]*** 260.845, the director ***shall[~~may~~]*** issue a 120-day, temporary license to sample and weigh milk. A temporary license ***shall[~~may~~]*** only be reissued if a person does not pass the written examination requirement of paragraph (b) of this subsection.

(a) A person issued a temporary license to sample and weigh milk shall be provided informational material by the director ***with[~~to notify him of~~]*** proper sampling and weighing procedures. ***The person[~~He~~]*** shall become familiar with the informational material and shall perform the procedures under the supervision of a licensed sampler-weigher until a supervisor believes he ***or she*** is competent of proper procedures. ***Once the person[~~When he~~]*** has become familiar with and complies with proper procedures, he ***or she*** may sample and weigh milk without immediate supervision. ***The person[~~He~~]*** shall carry the temporary license to sample and weigh ***while[~~when~~]*** sampling and weighing milk.

(b) A person issued a temporary license to sample and weigh milk shall be scheduled for and required to attend a one (1) day training school and take a written examination administered by

the director. Upon scoring a minimum of seventy (70) percent on the written examination, a license to sample and weigh milk ***shall[~~may~~]*** be issued. The person shall carry the license to sample and weigh ***while[~~when~~]*** sampling and weighing milk.

(3) Temporary license to test milk. Upon receipt of an ***accurately completed[~~accurately-completed~~]*** application with fee as required by KRS 260.815, and if the applicant is deemed to be qualified***, pursuant to this administrative regulation, [~~and~~]***competent, and in compliance with KRS 260.775 ***through[~~to~~]*** 260.845, the director ***shall[~~may~~]*** issue a 120-day temporary license to test milk. A temporary license ***shall[~~may~~]*** only be reissued if a person does not pass the written examination requirement of paragraph (b) of this subsection.

(a) A person issued a temporary license to test milk shall be provided informational material by the director ***with[~~to notify him of~~]*** proper testing procedures. ***The person[~~He~~]*** shall become familiar with the informational material and shall perform the testing procedures for which he ***or she*** seeks approval under the supervision of a licensed tester until a supervisor believes ***the person[~~he~~]*** is competent of proper procedures. ***Once the person[~~When he~~]*** has become familiar with and complies with proper procedures, he ***or she*** may test milk without immediate supervision. A person shall conspicuously post the temporary license to test in the laboratory where testing is performed or carry the temporary license to test ***while[~~when~~]*** he ***or she*** is testing milk.

(b) A person issued a temporary license to test milk shall demonstrate competency in milking[~~milk testing~~] procedures for which ***the person[~~he~~]*** seeks approval to the director and shall take a written examination administered by the director. Upon demonstrating competency and scoring a minimum of seventy (70) percent on the written exam, a license to test milk ***shall[~~may~~]*** be issued. The milk tester shall conspicuously post the license to test in the laboratory where testing is performed or carry the license to test ***while[~~when~~]*** he ***or she*** is testing milk.

(4) Renewal for a license to sample and weigh and renewal for a license to test. Upon receipt of an ***accurately completed[~~accurately-completed~~]*** renewal application with fee as required by KRS 260.815, and if the applicant is deemed by the director***, pursuant to this administrative regulation,*** to be in compliance with KRS 260.775 ***through[~~to~~]*** 260.845, the director ***shall[~~may~~]*** issue a renewed license to sample and weigh or a renewed license to test. An applicant may renew a lapsed license for up to three (3) years past the expiration date by paying back-fees for each year and one (1) penalty fee ***established[~~provided for~~]*** in KRS 260.992(3).

(5) All licenses issued under the authority of KRS 260.775 ***through[~~to~~]*** 260.845 shall expire on June 30 of each year. The licenses shall be renewed on or before July 1 by accurately completing and submitting an application with the appropriate fee to the director.***[~~Applications shall be provided by the director.~~]***

(6) Reciprocity. The director ***shall[~~may~~]*** reciprocate with other states and issue a license to sample and weigh or a license to test upon submission of satisfactory evidence that the requirement for licensure in the other state is equivalent to the requirements of KRS 260.775 ***through[~~to~~]*** 260.845. The director may require an applicant for reciprocity to pass an examination ***if necessary*** to establish his ***or her*** competency. Applicants for reciprocity shall be required to submit an ***accurately completed[~~accurately-completed~~]*** application with fee to the director.

Section 2. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Application for License to Handle Milk", October 2000, Division of Regulatory Services;

(b) "Application for ***Milk*** Laboratory License", October 2000, Division of Regulatory Services;

(c) "Application for ***Milk*** Transfer Station License", October 2000, Division of Regulatory Services;

(d) "Application for Temporary License to Sample and Weigh Milk", March 2015[~~October 2000~~], Division of Regulatory Services;

(e) "Application for Temporary License to Test Milk", March 2015[~~October 2000~~], Division of Regulatory Services;

(f) "***[Renewal]***Application for ***Renewal*** License to Sample and Weigh Milk", March 2015[~~October 2000~~], Division of Regulatory Services; and

(g) "***[Renewal]***Application for ***Renewal*** License to Test Milk", March 2015[~~October 2000~~], Division of Regulatory Services.

(2) These materials may be inspected, copied or obtained, subject to copyright law, at the Division of Regulatory Services, College of Agriculture, 103 Regulatory Services Building, University of Kentucky, Lexington, Kentucky 40546-0275, Monday through Friday, 8 a.m. to 4:30 p.m.

CONTACT PERSON: G. Alan Harrison, Feed and Milk Program Director, University of Kentucky Division of Regulatory Services, 103 Regulatory Services Building, Lexington, Kentucky 40546, phone (859) 257-2785, fax (859) 323-9931, email alan.harrison@uky.edu.

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Agriculture Experiment Station

12 KAR 5:020. Testing.

RELATES TO: KRS 260.775-260.845, 260.992
STATUTORY AUTHORITY: KRS 260.825(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 260.825(1) ***requires[~~authorizes~~]*** the Director of the Kentucky Agricultural Experiment Station to promulgate administrative regulations necessary for the effective enforcement of KRS 260.775 ***through[~~to~~]*** 260.845 regarding milk. This administrative regulation establishes uniform standards and approved procedures and equipment for the analysis of milk components by licensed laboratories and testers.

Section 1. Laboratory Facilities and Environment[~~Equipment~~]. (1) A licensed laboratory's facilities shall meet the criteria ***established[~~described~~]*** in Chapter 2.0310[~~2.3~~] of ***[~~"~~]***Standard Methods for the Examination of Dairy Products***[~~"~~]***, 17th[~~16th~~] Edition, 2004[~~1992~~].

(2) A licensed laboratory shall have established procedures for monitoring equipment performance and preventative maintenance. Specialized instrumentation shall be operated by the manufacturer's recommended procedures for operation and maintenance. Adequate records to document equipment performance monitoring and maintenance shall be kept. As applicable, equipment and supplies used by laboratories shall meet the criteria ***established[~~described~~]*** in Chapter 2.0311[~~2.4~~] of ***[~~"~~]***Standard Methods for the Examination of Dairy Products***[~~"~~]***, 17th[~~16th~~] Edition, 2004[~~1992~~].

Section 2. Approved Testing Methods. (1) A laboratory and tester licensed by the director shall be approved for the methods of analysis routinely used for milk component testing. If the laboratory and tester are approved for an electronic method of analysis, they shall also be approved for any intralaboratory reference method used to monitor the electronic equipment.

(2) Methods of analysis used for testing milk samples for pay purposes or as reference methods ***shall*** include:

(a) Methods in ***[~~"~~]***Official Methods of Analysis of AOAC International***[~~"~~]***, Volume II, Chapter 33, 21st[~~17th~~ Edition], 2019[~~2000~~];

(b) Methods in ***[~~"~~]***Standard Methods for the Examination of Dairy Products***[~~"~~]***, 17th[~~16th~~] Edition, 2004[~~1992~~]; and

(c) Methods of analysis scientifically proven to be acceptable and approved by the director ***based on accuracy***.

Section 3. Electronic Equipment. (1) Laboratories using electronic milk testing equipment associated with approved procedures shall maintain the following supplies and records:

(a) A thermostatically-controlled, circulatory water-bath of suitable size to maintain milk samples in a temperature range of 40-43^0 C (104-109.4^0 F). A milk sample being warmed in the water-bath shall not:

1. Remain in the water-bath in excess of forty (40) minutes prior to being tested; or

2. Be tested for payment purposes if the sample "oils off" while in the water-bath; and

(b) An approved electronic component testing instrument including:

1. All required accessories and reagents; and

2. An instrument operation manual.

(2) Control samples. A minimum of four (4) control samples of unhomogenized milk shall be analyzed daily before routine testing begins. The control samples shall cover the component ranges of samples typically analyzed with the instrument. Control samples for milk fat analysis shall be in the fat range of two (2) to six (6) percent.

(a) The control samples shall be prepared and test results determined for each component tested for pay purposes by recognized procedures or those procedures approved by the director ***based on accuracy***.

(b) Control samples shall be physically handled in a manner to ensure their integrity and in a temperature range of 0.5-4.4^{0}C (33-40^0 F). Control samples to be stored more than seventy-two (72) hours shall be preserved with an approved preservative. Control samples shall be discarded if they appear to be churned, "oiled off," or spoiled.

(3) Daily performance checks. Written procedures shall be established to monitor electronic milk testing equipment for accuracy each day before testing begins. Minimum requirements for these procedures ***shall*** include:

(a) Zero check. Zero the machine for all components as prescribed by the instrument manufacturer. Run a single, unhomogenized milk sample through the machine at least eleven (11) times. Zero the machine again. Within two (2) cycles the instrument shall not deviate greater than 0.02 percent units from the original zero reading*;[.]*

(b) Repeatability check. Ten (10) consecutive readings on a single, well-mixed, unhomogenized milk sample shall be made for each component being tested for pay purposes. The repeatability check shall be acceptable when the comparison range of ten (10) consecutive readings is within ±04 percent units for each of these components. The sample used between the zero checks in paragraph (a) of this subsection may be used for the repeatability check*;[.]*

(c) Accuracy check. A subsample from each of the control samples shall be analyzed to obtain readings for each component tested for pay purposes. These results shall not differ from the control sample by more than ±0.09 percent units for total solids and ±0.05 percent units for each other component when compared to the established values of the control samples*;[.]*

(d) Hourly check. An accuracy check as ***established[described]*** in paragraph (c) of this subsection shall be analyzed on at least one (1) sample each hour during which samples are tested for pay purposes*; and[.]*

(e) Electronic instruments not meeting the ***established[prescribed]*** testing criteria shall not be used to test permitted producer's samples for pay purposes. Deficiencies shall be investigated and corrective action taken. A record of any corrective action shall be maintained for ***at least*** two (2) years.

(4) Calibration requirements.

(a) Electronic instrument calibrations shall be required ***if[when]***:

1. The instrument is installed or significantly moved;

2. The daily performance checks fail and cannot be corrected by other means; and

3. ***[When]***Any part that ***could[may]*** affect proper operation of the instrument has been replaced, rebuilt, or adjusted.

(b) A calibration shall be evaluated for accuracy:

1. At regular intervals not to exceed a thirty (30) day period; and

2. Using a minimum of eight (8) milk samples that shall cover the component ranges of samples typically analyzed with the instrument. These samples shall be in the milk fat range of two (2) to six (6) percent.

(c) Electronic instruments shall be calibrated according to the manufacturer's instructions using milk samples with known component values as determined by ***a[an approved]*** reference method ***approved based on accuracy***. Laboratories may use approved, commercially-prepared calibration samples in lieu of preparing their own reference calibration samples.

Section 4. Wild Tests. (1) A "wild" test ***shall be[is defined as]*** a test result for a producer's bulk-tank milk sample that is dissimilar to other test results for the producer during the pay period and for which the cause of the **difference or differences*[difference(s)]*** cannot be determined.

(2) Each laboratory shall have written specifications for determining a "wild" test. Specifications for "wild" tests shall not exceed 0.50 percent units ***in[when]*** comparing milk fat test results between or among samples for a permitted producer.

(3) "Wild" tests shall not be used for pay purposes and shall be conspicuously identified within laboratory test records.

Section 5. Check Samples. Periodically, the director may provide check samples to a licensed laboratory for test result comparisons and monitoring purposes. A licensed tester at the laboratory shall test each sample for components used for pay purposes using ***[approved]***methods routinely utilized by the tester ***and approved based on accuracy***. The tester's results shall be provided to the director within three (3) working days of receipt of the samples. The licensed laboratory ***shall be[is]*** responsible for returning all check sample shipping containers and equipment to the director.

Section 6. Laboratory Records. (1) Laboratory records shall be kept in a manner consistent with 12 KAR 5:070, Section 2, and shall be retained for ***at least*** a two (2) year period.

(2) Equipment records. Records of the operation and maintenance of each electronic instrument shall include:

(a) Maintenance records;

(b) Daily performance check records; and

(c) Complete calibration records.

(3) Test records. All records of tests to be used for pay purposes shall be original and recorded as tests are conducted.

(a) Records of retests and special tests shall be conspicuously identified.

(b) A licensed tester shall be responsible for the accuracy of test records for samples he ***or she*** tests for pay purposes.

Section 7. Sample Age. A permitted producer's sample being tested for pay purposes shall be tested within seventy-two (72) hours from the time of procurement, as identified on the sample container, unless the sample is preserved with ***a[an approved]*** preservative ***approved based on efficacy***.

Section 8. Hours of Operation. A licensed laboratory that is not open during the normal business hours of Monday through Friday, 8 a.m. to 4:30 p.m. shall submit a monthly testing schedule to the director one (1) month in advance.

Section 9. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Official Methods of Analysis of AOAC International", Volume II, Chapter 33, 21st[~~17th~~] Edition, 2019[~~2000~~]; and

(b) "Standard Methods for the Examination of Dairy Products", 17th[~~16th~~] Edition, 2004[~~1992~~].

(2) These materials may be inspected, copied or obtained, subject to copyright law, at the Division of Regulatory Services, College of Agriculture, 103 Regulatory Services Building, University of Kentucky, Lexington, Kentucky 40546-0275, Monday through Friday, 8 a.m. to 4:30 p.m.

CONTACT PERSON: G. Alan Harrison, Feed and Milk Program Director, University of Kentucky Division of Regulatory Services, 103 Regulatory Services Building, Lexington, Kentucky 40546, phone (859) 257-2785, fax (859) 323-9931, email alan.harrison@uky.edu.

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Agriculture Experiment Station

12 KAR 5:030. Test samples.

RELATES TO: KRS 260.775-260.845, 260.992
STATUTORY AUTHORITY: KRS 260.825(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 260.825(1) ***requires[~~authorizes~~]*** the Director of the Agricultural Experiment Station to promulgate administrative regulations necessary for the efficient enforcement of KRS 260.775 ***through[~~to~~]*** 260.845 regarding milk. This administrative regulation establishes criteria and procedures for the physical handling and storage of milk samples that will be tested for payment purposes.

Section 1. Producers' milk samples to be tested for payment purposes shall at all times be under the care of, and only be physically handled by, a licensed sampler-weigher or a licensed tester.

(1) The license requirement for the physical handling of milk samples to be tested for payment purposes excludes the shipping of samples via a commercial carrier. In ***these[~~such~~]*** cases, the samples shall be packaged, the shipping container sealed, and unpacked by licensed sampler-weighers or licensed testers; and

(2) Milk samples shall be physically handled, stored, and shipped in a manner to maintain their integrity. The sample shall be maintained in a temperature range of 0.5-4.4^{0}C (33-40^0 F).

Section 2. Milk-receiving stations, laboratories, transfer stations, and processors shall provide adequate storage for milk samples.

(1) These locations shall provide a minimum storage capacity for samples [~~typically~~] representing at least three (3) days bulk-milk shipments; and

(2) Sample storage refrigerators shall be monitored daily with an accurate thermometer to ensure the proper temperature. The monitoring shall be documented with:

(a) A recording device; or

(b) A licensed sampler-weigher or licensed tester who shall keep a daily record that includes:

1. Date;
2. Time (including a.m. or p.m.);
3. Temperature; and
4. The sampler-weigher's or tester's initials.

CONTACT PERSON: G. Alan Harrison, Feed and Milk Program Director, University of Kentucky Division of Regulatory Services, 103 Regulatory Services Building, Lexington, Kentucky 40546, phone (859) 257-2785, fax (859) 323-9931, email alan.harrison@uky.edu.

11/18/2020 10:02 AM
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UNIVERSITY OF KENTUCKY
Agriculture Experiment Station

12 KAR 5:040. Sampling and weighing.

RELATES TO: KRS 260.775-260.845, 260.992
STATUTORY AUTHORITY: KRS 260.825(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 260.825(1) ***requires[~~authorizes~~]*** the Director of the Agricultural Experiment Station to promulgate administrative regulations necessary for the efficient enforcement of KRS 260.775 ***through[~~to~~]*** 260.845 regarding milk. This administrative regulation establishes procedures for milk sampler-weighers for accurately sampling and weighing milk in farm bulk tanks.

Section 1. Each bulk farm tank ***shall[~~is required to~~]*** be separately sampled and weighed. If a producer has multiple bulk farm tanks, samples and weights shall be obtained for each tank and the information recorded separately in the sampler-weigher's records.

Section 2. Sampler-weigher Equipment. A sampler-weigher shall use the following equipment in his sampling and weighing procedures:
(1) A sample case shall:
(a) Be rigidly constructed and insulated for safe transportation of the samples;
(b) Have ample space to hold samples;
(c) Maintain a refrigerant that is needed to cool and maintain the samples at a temperature range of 0.5-4.4^0 C (33-40^0 F);
(d) Contain a rack or float to keep the samples in an upright position and to keep the neck and the top of each sample container above the surface of the cooling medium; and
(e) Maintain a refrigerant at the level of the milk in the sample containers***;[.]***
(2) Sample containers shall be clean, dry, and sterile. Sample vials shall have leak-proof caps and may be made of glass or molded, rigid plastic. ***[~~Approved~~]***Plastic bags may also be used ***if approved based on sterility***. The sample containers shall hold a minimum of one (1) ounce of milk and provide sufficient air space for processing the sample in the laboratory;
(3) A sample dipper or other sampling device of sanitary construction. The sampling device shall be stored in a receptacle containing a sanitizing solution. ***To be used,*** both the sampling device and the sanitizing solution shall be approved by the Milk Safety Branch of the Cabinet for Health Services ***based on sterility and efficacy***;
(4) An accurate dial or digital thermometer;
(5) A waterproof, indelible marker to write information on sample containers;
(6) A watch or other device to time the agitation of the milk in the bulk tank prior to sampling;
(7) An indelible pen to complete the necessary paperwork; and
(8) An adequate supply of bulk milk delivery tickets.

Section 3. Weighing Procedures. ***While[~~When~~]*** measuring milk volume in farm bulk tanks with a gauge rod inside the tank or an external scale plate with gauge tube on the outside of the tank, the milk shall be motionless. A sampler-weigher shall:

(1) Use the following procedures for measuring milk with a gauge rod on the inside of a bulk tank:

(a) Remove any milk foam from the measurement area by pushing it aside with the rod;

(b) Remove any milk residue from the rod by wiping the rod with a clean, single-service towel. If the milk residue cannot be removed by this method, rinse the rod in warm (not hot) water and again wipe the rod with a single-service towel;

(c) Lower the gauge rod slowly straight down until it reaches a point approximately one-quarter (1/4) inch above its base. Hold the rod in this position for a moment and then ease it down until it seats firmly and naturally in its base;

(d) Raise the gauge rod and immediately read it in a well-lighted area at eye level;

(e) The gauge rod shall be read to the nearest graduation mark on the rod. If the reading is exactly half-way between two (2) graduation marks, read to the nearest even mark; and

(f) Repeat the gauge rod reading until two (2) readings are in agreement and record the reading***;[.]***

(2) Use the following procedures for measuring milk with an external scale plate and gauge tube on the outside of a bulk milk tank:

(a) If milk is in the external scale plate's gauge tube, it shall be drained and refilled with cold milk. The tube shall be clean and dry prior to filling it with milk;

(b) To fill the gauge tube, open the outlet valve slowly to prevent foaming of milk as it fills the tube;

(c) After the milk from the bottom of the tank fills the tube, read the highest point of the center of the milk's meniscus as the measuring point to compare to the scale plate;

(d) The scale plate shall be read to the nearest graduation mark. If the reading is exactly half-way between two (2) graduation marks, read to the nearest even mark; and

(e) Repeat the scale plate and gauge tube reading until two (2) readings are in agreement and record the reading***;[.]***

(3) Promptly convert the volume reading of the bulk milk tank to milk weight using the tank's conversion chart. The conversion ***shall[~~should~~]*** be repeated until two (2) conversions are in agreement. Record the milk weight***; and[.]***

(4) Procedures for weighing farm bulk milk in tanks that are not equipped with a gauge shall be approved by the director.

Section 4. Sampler-weigher Records. A sampler-weigher shall prepare and account for records pertaining to milk he samples and weighs.

(1) Sampler-weigher records shall include;

(a) Bulk milk delivery tickets;

(b) Producer barn charts;

(c) Information recorded on sample containers; and

(d) Any other record relating to bulk milk sampling and weighing activities.

(2) All records relating to sampler-weigher's daily activities shall be legible and written in indelible ink. Changes or corrections to records shall be made by drawing a single line through the entry and writing the correction nearby. Any changes or corrections shall be dated and initialed.

(3) Bulk milk delivery tickets shall accompany all loads of milk to milk-receiving stations, transfer stations, and processors and shall include ***[~~the following information~~]***:

(a) Identification of the handler;

(b) Identification of the milk-receiving station, transfer station, or processor;

(c) Date of collection;

(d) Producer identification (and tank identification if the producer has multiple tanks);

(e) Time of pickup (including a.m. or p.m.);

(f) Temperature of the milk;

(g) Milk volumetric reading;

(h) Converted milk weight;

(i) Any comments related to unusual circumstances; and

(j) Sampler-weigher's signature.

(4) A sampler-weigher shall record the following information on producer barn charts for each tank sampled and weighed:

(a) Date;

(b) Time (including a.m. or p.m.);

(c) Milk temperature;

(d) Milk volumetric reading;

(e) Converted milk weight; and

(f) Sampler-weigher's signature or initials.

(5) If more than one (1) sampler-weigher samples and weighs producers' milk for one (1) truckload, each sampler-weigher shall sign the bulk milk delivery ticket, regardless of who delivers the load to the milk-receiving station, transfer station, or processor.

Section 5. Sampling Procedures. A sampler-weigher shall use the following procedures to obtain a representative sample from a producer's standard farm bulk tank:

(1) Each sample container shall be permanently marked with waterproof, indelible ink and shall be identified with the following information:

(a) Producer identification (and tank identification if the producer has multiple tanks);

(b) Date;

(c) Time (including a.m. or p.m.);

(d) Milk temperature; and

(e) Sampler-weigher's initials***;[.]***

(2) Milk in the bulk tank shall be agitated sufficiently to provide a homogenous blend and to obtain a representative sample. A minimum of five (5) minutes of agitation time ***shall be[~~is~~]*** required for tanks with less than a 1000 gallon capacity. Tanks with a 1000 gallon capacity or larger shall be agitated a minimum of ten (10) minutes;

(3) To eliminate moisture and sanitizing solutions, the sampling device shall be rinsed with milk at least twice prior to taking samples;

(4) The milk shall be transferred from the sampling device to the sterile sample container away from the opening of the farm bulk tank. The container shall be filled to approximately

three-fourths (3/4) full or to the container's "fill line." Enough air space shall be left in the container to allow the sample to be adequately mixed at the laboratory. After the milk has been transferred to the sample container, the container shall be tightly sealed and immediately placed in the sample case with appropriate refrigerant;

(5) At the time of sampling the first bulk milk tank on the sampler-weigher's route, an additional sample shall be collected for temperature determination. This sample's container shall be identified with the information ***established~~[outlined]~~*** in subsection (1) of this section and with adequate information to identify the sample as the temperature control;

(6) Any additional or special samples obtained on the sampler-weigher's route shall be clearly and specifically identified with waterproof, indelible markings stating the purpose of the sample;***~~[and]~~***

(7) Sampling procedures for nonstandard or sealed farm bulk milk tanks shall be approved by the director ***based on accuracy and sanitation; and~~[.]~~***

(8) Milk samples shall be under a sampler-weigher's immediate care at all times until the samples are delivered to the milk-receiving station, transfer station, or processor.

Section 6. Load Sample. A sampler-weigher shall obtain a load sample from the tank on ***the~~[his]~~*** truck immediately after the last producer's milk is pumped into the truck's tank.

(1) The load sample shall be taken from the porthole at the top of the tank on the truck using a sanitized sampling device. Care shall be taken to prevent any foreign material from entering the porthole. The load-sample container shall be identified with***~~[the following information]~~***:

(a) Adequate information to identify the sample as the load-sample;

(b) Date;

(c) Time (including a.m. or p.m.);

(d) Sampler-weigher's initials; and

(e) The milk truck's assigned tanker number.

(2) The load sample ***shall~~[is to]~~*** be used for comparisons of the load sample and individual producer's samples for the purpose of grading and evaluation of the sampler-weigher's competency in sampling***~~[; and]~~***

(3) The load sample ***shall~~[is to]~~*** be taken by all bulk sampler-weighers in addition to, not in lieu of, any other load samples required by the milk handler, transfer station, receiving station, or processor.

Section 7. Sample Set. A sample for each producer bulk milk tank, a temperature control sample, and a load sample shall accompany each load of milk to its final receiving station, transfer station, or processor. A sampler-weigher ***might~~[may]~~*** need to obtain multiple samples for his bulk milk route to meet this requirement.

Section 8. Milk Sample Transfer Procedures. To expedite the transport of samples to the appropriate laboratory, a sampler-weigher shall follow these procedures:

(1) For bulk milk deliveries to locations where producers' milk samples are routinely transported from the receiving station, transfer station, or processor to the appropriate laboratory; a sampler-weigher shall properly place ***the~~[his]~~*** samples in the location's sample storage refriger-

ator or refrigerated sample storage case after the bulk load of milk has been determined to be acceptable; or

(2) For bulk delivery ***if[~~when~~]*** producer's milk samples are not routinely transported from the receiving station, transfer station, or processor to the appropriate laboratory, a sampler-weigher shall follow written sample transfer procedures established by the licensed ***handler or handlers who issue[~~handler(s) who issues~~]*** payments to producers on the sampler-weigher's ***route or routes[~~route(s)~~]***. Written sample transfer procedures shall be approved by the director ***based on sanitation***.

CONTACT PERSON: G. Alan Harrison, Feed and Milk Program Director, University of Kentucky Division of Regulatory Services, 103 Regulatory Services Building, Lexington, Kentucky 40546, phone (859) 257-2785, fax (859) 323-9931, email alan.harrison@uky.edu.

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UNIVERSITY OF KENTUCKY
Agriculture Experiment Station

12 KAR 5:050. Inspections.

RELATES TO: KRS 260.775-260.845, 260.992
STATUTORY AUTHORITY: KRS 260.825(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 260.825(1) ***requires[~~authorizes~~]*** the Director of the Kentucky Agricultural Experiment Station to promulgate administrative regulations necessary for the effective enforcement of KRS 260.775 ***through[~~to~~]*** 260.845 regarding milk. This administrative regulation establishes a basis for monitoring licensed milk handlers, laboratories, transfer stations, sampler-weighers, and testers to ensure that these licensees are in compliance with KRS 260.775 ***through[~~to~~]*** 260.845.

Section 1. A milk handler, laboratory, and transfer station shall be inspected and evaluated for compliance with KRS 260.775 ***through[~~to~~]*** 260.845. The director shall provide written notice to the appropriate licensee to correct any observed discrepancies. Unsatisfactory compliance shall be dealt with in accordance with KRS 260.775 ***through[~~to~~]*** 260.845 and 260.992.

Section 2. A sampler-weigher shall be inspected and evaluated for compliance with KRS 260.775 ***through[~~to~~]*** 260.845.

(1) A sampler-weigher's records, equipment, samples, and procedures shall be examined to determine compliance.

(2) Milk samples obtained by a sampler-weigher may be collected and analyzed by the director to assist in the evaluation of the sampler-weigher's activities.

(a) Results of these analyses may be used to make comparisons among and between these samples. These comparisons may include the use of milk-component test results and other test results pertaining to milk quality and composition.

(b) Results of these analyses may be used to determine the amount of milkfat on a load of bulk milk as represented by the individual producer's bulk-tank samples and weights and as represented by the load sample and the sum of individual producers' bulk-tank weights. The deviation of the milkfat on the bulk milk load between these two (2) comparisons may, in part, determine the evaluation of the sampler-weigher.

(c) The deviation between the weight of the load of bulk milk represented by the sum of the individual producer's bulk-tank weights and, if available, the weight of the load of bulk milk as determined by an accurate scale or meter may, in part, determine the evaluation of the sampler-weigher. The scale or meter used in this determination shall be well maintained and approved by an accredited scale maintenance firm or appropriate government agency.

(3)***(a) If there is a deviation between milkfat as represented by the load sample and the sum of the individual producers' bulk tank milkfat weights used in the evaluation of an inspection of a sampler-weigher, a grade shall be assigned. Grades shall be based on the dif-***

ference between sum of milkfat weights from all bulk tanks on the load and pounds of milkfat calculated from the load sample. The grading scale shall be:

1. A: excellent (0.50% or less);

2. B: good (0.51 to 1.00%);

3. C: poor (1.01 to 2.00%); and

4. D: unsatisfactory (above 2.00%).

(b) Noncompliance with KRS 260.775 through 260.845 and 12 KAR Chapter 5 shall[~~An evaluation of an inspection of a sampler-weigher shall be awarded a grade. Grades given shall be A - excellent; B - good; C - poor; D - unsatisfactory. Criteria for awarding grades shall be established by the director and shall be printed on the inspection report. Noncompliance with KRS 260.775 to 260.845 and 12 KAR Chapter 5 may~~] result in a D grade inspection.

(4) A sampler-weigher who receives three (3) "D" grade inspections within a twelve (12) month period shall be required to attend the next scheduled one (1) day sampler-weigher training school and take a written examination administered by the director. This shall not prevent the director from taking other actions under KRS 260.775 ***through[~~to~~]*** 260.845***[~~,~~]*** and 260.992 for a sampler-weigher who receives a D grade inspection or who otherwise is not in compliance with KRS 260.775 ***through[~~to~~]*** 260.845 and 260.992.

Section 3. A tester shall be inspected and evaluated for compliance with KRS 260.775 ***through[~~to~~]*** 260.845.

(1) A tester's records, equipment, and procedures shall be examined, in part, to determine compliance.

(2) The results of a tester's analyses may be compared to results of the director's analyses. The deviation between these results shall, in part, determine compliance. The director shall provide written notice to the tester and to the licensed laboratory employing the tester to correct any discrepancies. Unsatisfactory compliance shall be dealt with in accordance with KRS 260.775 ***through[~~to~~]*** 260.845 and 260.992.

CONTACT PERSON: G. Alan Harrison, Feed and Milk Program Director, University of Kentucky Division of Regulatory Services, 103 Regulatory Services Building, Lexington, Kentucky 40546, phone (859) 257-2785, fax (859) 323-9931, email alan.harrison@uky.edu.

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UNIVERSITY OF KENTUCKY
Agriculture Experiment Station

12 KAR 5:060. Purchases from farm bulk tanks.

RELATES TO: KRS 260.775-260.845, 260.992
STATUTORY AUTHORITY: KRS 260.825(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 260.825(1) ***requires[~~authorizes~~]*** the Director of the Kentucky Agricultural Experiment Station to promulgate administrative regulations necessary for the effective enforcement of KRS 260.775 ***through[~~to~~]*** 260.845 regarding milk. This administrative regulation establishes criteria for recordkeeping and reporting practices to ensure that bulk farm milk is fairly and accurately marketed.

Section 1. A licensed bulk milk handler or licensed transfer station shall review bulk milk delivery tickets to ensure compliance with KRS 260.775 ***through[~~to~~]*** 260.845.

(1) A bulk-milk delivery ticket representing a load of milk for a permitted Kentucky producer shall be examined to ensure that a licensed sampler-weigher sampled and weighed the milk.

(2) A bulk-milk delivery ticket representing a shipment of milk from a producer shall be examined for compliance with 12 KAR 5:040, Section 4(3).

(3) Discrepancies shall be reported to the director.

Section 2. Personnel at a licensed laboratory who test permitted producers' samples for pay purposes shall review the information recorded on sample containers to ensure compliance with 12 KAR 5:040, Section 5(1). An agent of the laboratory shall report discrepancies to the director.

Section 3. Licensed Milk Handler Reporting Requirements. (1) Each licensed milk handler shall submit to the director an accurately-completed Kentucky Farm Milk Handlers Report each quarter with payment of inspection fee as required by KRS 260.821.***[~~The Kentucky Farm Milk Handlers Report form shall be provided to handlers by the director.~~]***

(2) Each licensed milk handler who issues payments to permitted producers shall submit to the director, upon request, a current list of these permitted producers to whom payments are being issued. The list shall be submitted with the ***[~~handler's annual license~~]***Application ***for License to Handle Milk, incorporated by reference in 12 KAR 5:010,*** and shall be updated when the handler submits its quarterly Kentucky Farm Milk Handlers Report. The listing shall include the following information about each permitted producer:

(a) Name;
(b) Identification number issued by the handler if different from permit number; and
(c) Mailing address.

Section 4. A licensed milk handler who issues payments to permitted producers shall submit to the director, upon request, a copy of each permitted producer's bulk-tank conversion ***chart***

or charts[~~chart(s)~~] to whom they issue payments. These charts may be reviewed by the director to determine if a permitted producer's bulk milk has been accurately weighed by sampler-weighers.

Section 5. Incorporation by Reference. (1) The following material is incorporated by reference: "Kentucky Farm Milk Handlers Report", July 2020[~~October 2000~~], Division of Regulatory Services.

(2) This material may be inspected, copied or obtained, subject to copyright law, at the Division of Regulatory Services, College of Agriculture, 103 Regulatory Services Building, University of Kentucky, Lexington, Kentucky 40546-0275, Monday through Friday, 8 a.m. to 4:30 p.m.

CONTACT PERSON: G. Alan Harrison, Feed and Milk Program Director, University of Kentucky Division of Regulatory Services, 103 Regulatory Services Building, Lexington, Kentucky 40546, phone (859) 257-2785, fax (859) 323-9931, email alan.harrison@uky.edu.

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UNIVERSITY OF KENTUCKY
Agriculture Experiment Station

12 KAR 5:070. Uniform standards for payment.

RELATES TO: KRS 260.775-260.845, 260.992
STATUTORY AUTHORITY: KRS 260.825(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 260.825(1) ***requires[~~authorizes~~]*** the Director of the Kentucky Agricultural Experiment Station to promulgate administrative regulations necessary for the effective enforcement of KRS 260.775 ***through[~~to~~]*** 260.845 regarding milk. This administrative regulation establishes criteria for uniform standards of payment for producer milk.

Section 1. Number of Samples Required for Milk Component Testing for Pay Purposes. (1) Grade A milk producers shall be paid based on calculations of component tests from a minimum of five (5) bulk tank samples representative of and [~~fairly evenly~~]spaced throughout the monthly pay period.

(2) Manufacturing grade milk producers shall be paid based on calculations from a minimum of three (3) bulk tank samples representative of and [~~fairly evenly~~]spaced throughout the fifteen (15) day pay period.

(3) Payment calculations for producers with multiple farm bulk tanks shall be made for each tank separately or shall include a weighted-average computation. A daily weighted average shall be based on a test from a sample representing each farm bulk tank and a recorded weight for each farm bulk tank.

Section 2. Pay Records. (1) Written records shall be recorded legibly in ink by an agent of the handler and***[~~include the following information~~]***:

(a) Each page shall be signed and dated by a responsible person; and

(b) Changes or corrections to records shall be made by drawing a single line through the entry and writing the corrected entry nearby. Any changes or corrections shall be dated and initialed.

(2) Persons who use electronic systems to create, modify, maintain, or transmit records relating to milk samples, weights, tests, or payments shall employ procedures and controls designed to ensure the authenticity and integrity of the records. ***[~~Such~~]***Procedures and controls shall include***[~~the following~~]***:

(a) The ability to generate accurate and complete copies of records in printed and electronic form ***that shall be[~~which are~~]*** suitable for inspection, review, and copying by the director;

(b) Protection of records to enable their accurate and ready retrieval throughout the retention period of the records;

(c) Limiting electronic record access only to authorized individuals;

(d) Determination that persons who develop, maintain, or use electronic systems have the training and qualifications to perform assigned tasks;***[~~and~~]***

(e) ***Protection[~~The establishment of and adherence to written policies~~]*** to deter record falsification***; and***

(f) Holding[~~. The policies shall hold~~] a person responsible for ***[~~his tasks relating to~~]***electronic records.

(3) The consolidated pay records shall be compiled from the sampler-weigher's weight records, valid laboratory test records, and other factors affecting the price. All records relating to payments shall be properly documented and retained for ***at least*** a two (2) year period.

(4) A statement that agrees with the pay record shall be provided to each permitted producer with the final payment for each month. The statement shall include***[~~the following~~]***:

(a) Dates covered by payment;

(b) Amount of milk paid for;

(c) Detailed pricing description;

(d) Test ***results[~~result(s)~~]*** and component ***yield[~~yield(s)~~]*** used to calculate payment; and

(e) Any deductions.

CONTACT PERSON: G. Alan Harrison, Feed and Milk Program Director, University of Kentucky Division of Regulatory Services, 103 Regulatory Services Building, Lexington, Kentucky 40546, phone (859) 257-2785, fax (859) 323-9931, email alan.harrison@uky.edu.

KENTUCKY RETIREMENT SYSTEMS

David L. Eager, Executive Director

1260 Louisville Road • Frankfort, Kentucky 40601

kyret.ky.gov • Phone: 502-696-8800 • Fax: 502-696-8822

November 30, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulations Compiler
Legislative Research Commission
029, Capitol Annex
702 Capitol Avenue
Frankfort, KY 40601

RE: 105 KAR 1:149. Quasi-governmental employer cessation window.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 105 KAR 1:149, Kentucky Retirement Systems proposes the attached amendment to 105 KAR 1:149.

Sincerely,

Justin M. McNeil
Staff Attorney

KENTUCKY RETIREMENT SYSTEMS
1260 Louisville Road
Frankfort, Kentucky 40601

Final, 11-16-2020

AGENCY AMENDMENT

FINANCE AND ADMINISTRATION CABINET
Kentucky Retirement Systems

105 KAR 1:149. Quasi-governmental employer cessation window.

Page 2
Section 1(2)
Lines 4-5
After "April 1,", insert "2020".
Delete "2021".

Page 4
Section 3(1)
Line 5
After "April 1,", insert "2020".
Delete "2021".

Page 5
Section 4(1)
Line 17
After "April 1,", insert "2020".
Delete "2021".

Andy Beshear
Governor

KENTUCKY BOARD OF PHARMACY
125 Holmes Street, Suite 300
State Office Building Annex
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
pharmacy.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 2:105. Requirements for wholesalers, medical gas wholesalers, wholesale distributors and virtual wholesale distributors

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:105, the Board of Pharmacy proposes the attached amendment to 201 KAR 2:105.

Sincerely,

Larry A. Hadley, R.Ph.
Executive Director
Kentucky Board of Pharmacy

Final 11-24-2020

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

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, ***315.121,*** 315.350, ***315.400,*** 315.402, ***315.404,*** 315.406, ***315.408, 315.410, 315.412***

STATUTORY AUTHORITY: KRS 315.010, 315.191(1)(a), 315.350, 315.402, 315.406

NECESSITY, FUNCTION, AND CONFORMITY: ***KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations to regulate and control all matters set forth in KRS Chapter 315.*** KRS 315.350, 315.402 and 315.406 ***require[~~authorizes~~]*** the board to promulgate administrative regulations to regulate wholesalers, medical gas wholesalers, wholesale distributors, and virtual wholesale distributors of prescription drugs and ***drug***-related devices. This administrative regulation establishes the requirements for the regulation of wholesalers, medical gas wholesalers, wholesale distributors, and virtual wholesale distributors.

Section 1. Definitions[~~Definition~~].

(1) ***"Component" means any raw material, ingredient, or article intended for use in the manufacture of a drug and drug-related device.***

(2) "Distribution" or "distribute" ***is defined by[~~has the same meaning given in~~]*** KRS 315.400(5).

(3)[~~(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.

(4)[~~(3)~~] "Illegitimate Product" is defined by KRS 315.400(11).

(5) "Medical gas wholesaler" ***is defined by[~~has the same meaning given in~~]*** KRS 315.400(13).

(6) "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, such as capsules, tablets, and lyophilized products before reconstitution.

(7)[~~(4)~~] "Suspect product" means a ***component, prescription drug, or drug-related device[~~product~~]*** for which there is reason to believe that such ***component, prescription drug, or drug-related device[~~product~~]***:

(a) Is potentially counterfeit, diverted, or stolen;

(b) Is potentially intentionally adulterated such that the ***component, prescription drug, or drug-related device[~~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 ***component, prescription drug, or drug-related device[~~product~~]*** would result in serious adverse health consequences or death to humans or animals.

(8)[~~(5)~~] "Wholesale distribution" ***is defined by[~~has the same meaning given in~~]*** KRS 315.400(20).

(9)[~~(6)~~] "Wholesale distributor" ***is defined by[~~has the same meaning given in~~]*** KRS 315.400(21).

(10)[(7)] "Wholesaler" ***is defined by[has the same meaning given in]*** KRS 315.010(28), and includes medical gas wholesalers, wholesale distributors, and virtual wholesale distributors.

(11)[(8)] "Virtual wholesale distributor" has the same meaning given in KRS 315.400(21).

Section 2. Requirements.

(1) A wholesaler[wholesale distributor] engaged in wholesale distribution in the Commonwealth shall apply for a license from the Board[board] of Pharmacy in accordance with KRS 315.350, 315.402, 315.406, and this administrative regulation.

(2) A surety bond ***is required*** 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. ***This shall be used[,]*** 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 ***if[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 ***or[/]***groups ***if[when such]*** separate locations or affiliated companies ***or[/]***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 ***the[such]*** bond or other equivalent means of security until one ***(1)*** year after ***the*** 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)] A separate license shall be required for each wholesaler's [wholesale distributor's] facility that engages in wholesale distribution [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 ***if[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 operational, 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, ***USP Chapter 659, Packaging and Storage 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 ***drug***-related devices;

(b) Separation[Physical separation] and quarantine of deteriorated, damaged, outdated, misbranded, adulterated or otherwise recalled prescription drugs and ***drug***-related devices [merchandise] until they are destroyed or returned;

(c) Providing accurate and precise records of all prescription drugs and ***drug***-related devices sold, purchased, traded, delivered, handled, stored, or received and any other information perti-

nent 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), ***21 U.S.C. 360eee-360eee-4***.

(7) Wholesalers shall establish a system to:

(a)[~~a.~~] Quarantine and investigate suspect product to determine if it is illegitimate; and

(b)[~~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, ***subsection[~~Section~~]*** 2(5)(a) and (b) ***of this Section,*** and Section 5(1)(a) and (b), and (2)(a) and (b) ***of this administrative regulation***.

Section 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 ***drug***-related devices within the Commonwealth:

(a)[~~1.~~] Any convictions of the applicant under any federal, state, or local laws relating to drugs, ***including[~~to include~~]*** 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 ***drug***-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 distribution of prescription drugs and ***drug***-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 ***drug***-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 ***administrative*** 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 the [~~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 315.350, 315.400, 315.402, 315.404, 315.406, 315.408, 315.410, 315.412, or this administrative regulation may result in action under KRS 315.121.

Section 4. Application, Fees, Renewals.

(1) An application for a license shall be submitted to the Board of Pharmacy on ***the*** ***["]***Application for a License to Operate as a Wholesaler [~~Wholesale Distributor (KBP W 9:08)~~]***["]***.

(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 names[~~name~~] 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 and ***drug***-related devices;

(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 and ***drug***-related devices; and[~~.~~]

(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 ***submission of the*** Renewal Application ***to Operate as a Wholesaler*** accompanied by the renewal fee set forth in 201 KAR 2:050 and shall be nontransferable.

Section 5. Standards.

(1) Facilities.

(a) All facilities[~~buildings~~] in which prescription[~~legend~~] drugs and ***drug***-related devices 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) All facilities[~~Buildings~~] shall meet all applicable federal, state, and local standards. The facility shall [~~have a~~] quarantine [~~area for storage of~~] prescription drugs and ***drug***-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 wholesaler[~~wholesale distributor~~] shall be equipped with an alarm system to detect entry after hours.

(b) A wholesaler[~~wholesale distributor~~] 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 ***drug***-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 ***drug***-related devices.

(3) Recordkeeping ***requirements for companies handling prescription drugs and drug-related devices exempt from the DSCSA***.

(a) Inventories and other records [~~of transactions~~] regarding the receipt and distribution or [~~and~~] disposition of prescription[~~legend~~] drugs and ***drug***-related devices shall be maintained and readily available for inspection or photocopying by the Board of Pharmacy and authorized law enforcement officials for a period of six (6) 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.~~]

1. The proprietary and established name of the prescription drug and***[/~~or~~]*** related device, ***if applicable***;

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 ***readily retrievable within forty-eight (48) hours[~~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.

(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 ***drug***-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 ***pursuant to KRS 217.182(1)***;

8. A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes ***pursuant to KRS 217.182(1)***; or

9. Any other appropriately licensed or permitted facility in the jurisdiction in which it is located.

(e) A wholesaler may acquire prescription drugs and ***drug***-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 ***if[~~where~~]*** applicable, the FDA and DEA.

(4) Written policies and procedures, ***requirements for companies handling prescription drugs and drug-related devices exempt from the DSCSA***.

(a) A wholesaler[~~Wholesaler Distributor distributors~~] shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, [~~and~~] distribution, and disposition of prescription drugs and ***drug***-related devices[~~:, 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 wholesaler's[~~wholesale distributor's~~] 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 wholesaler[~~wholesale distributor~~] 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, ***if[~~where~~]*** applicable.

(5) Returned, damaged, and outdated prescription drugs and ***drug***-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 ***drug***-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 wholesaler[~~wholesale distributor~~] shall establish, maintain, and adhere to a[~~follow~~] written policy and procedure for handling recalls and withdrawals of [~~products~~] prescription drugs and ***drug***-related devices. The policy and procedure shall cover all recalls and withdrawals of drugs[~~drug products~~] and ***drug***-related devices due to:

(a) Any voluntary action on the part of the manufacturer;

(b) The direction of the FDA[~~Food and Drug Administration~~], 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) 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 expiration date is taken into consideration when distributing inventory[~~the oldest inventory is distributed first~~].

(c) A wholesaler[~~wholesale distributor~~] shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug and related device[~~product~~] 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 wholesaler[~~wholesale distributor~~] shall not distribute prescription[~~legend~~] drugs and ***drug***-related devices directly to a consumer or a patient, except as provided in KRS 315.0351(2). [~~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)~~] Violations of any of these provisions shall be grounds for action under KRS 315.121[~~the suspension or revocation of the license~~].

Section 7[~~8~~]. Incorporation by Reference. (1) ***The following material is incorporated by reference:***

(a) "Application for a License to Operate as a Wholesaler", May 2020***;***

(b)[~~,~~] [Wholesale Distributor (KBP-W-9:08)] ***[~~is incorporated by reference.~~***

~~***(2)]***~~ "Renewal Application to Operate as a Wholesaler", May 2020***; and***

(c) "USP Chapter 659 Packaging and Storage Requirements", November 1, 2020[~~, is incorporated by reference~~].

(3) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601-8024,[~~Spindletop Administration Building Suite 302, 2624 Research Park Drive, Lexington, Kentucky 40511~~], Monday through Friday, 8 a.m. to 4:30 p.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.

MATERIAL INCORPORATED BY REFERENCE

The agency needs to file one (1) clean copy of "USP Chapter 659 Packaging and Storage Requirements" at the time that it files this staff suggested substitute with the edition date 11-1-2020.

Andy Beshear
Governor

KENTUCKY BOARD OF PHARMACY
125 Holmes Street, Suite 300
State Office Building Annex
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
pharmacy.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 2:106. Licensed or permitted facility closures

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:106, the Board of Pharmacy proposes the attached amendment to 201 KAR 2:106.

Sincerely,

Larry A. Hadley, R.Ph.
Executive Director
Kentucky Board of Pharmacy

Final 11-23-2020

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:106. Licensed or permitted facility closures [~~Pharmacy, manufacturer, or distributor closures~~].

RELATES TO: KRS 315.035, 315.0351, 315.036, ***315.121***, 315.340, 315.342, 315.350, 315.402, 315.4102

STATUTORY AUTHORITY: KRS [~~315.036],~~ 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) ***authorizes[~~requires~~]*** the board to promulgate administrative regulations relating to subject matters governed by KRS Chapter 315. This administrative regulation establishes requirements relating to closure of business by licensees and permit holders.

Section 1. Definitions. ***[~~As used in this administrative regulation:~~]***

(1) ***"Involuntary closure" means an interruption of formal business activity resulting from:***

(a) Acute illness or incapacitation;

(b) Death;

(c) Fire, flood, or other natural disaster;

(d) Bankruptcy proceedings; or

(e) Court, government, or Board of Pharmacy action.

(2) "Non-use" means a failure to engage in formal business activity within one (1) year of initial licensing or permitting, or renewal of license or permit.

(3) "Permanent voluntary closure" means a licensee or permit holder:

(a) Ceases to do business and permanently closes; and

(b) Does not file application for a license [~~pharmacy license~~] or permit for the same location.

(4) "Temporary closure" means a licensee or permit holder whose hours of operation have deviated over a period of five (5) consecutive working days from those of record at the Board of Pharmacy office for a reason other than permanent voluntary closure or involuntary closure.

[~~; (2) "Voluntary closure" means a closing or abandonment of premises resulting from:~~

~~(a) Chronic mental or physical deterioration; or~~

~~(b) A deviation from the business hours listed on the current permit application or amendments filed thereto; or~~

~~(c) Cessation of the practice of pharmacy at the licensed location for a reason other than permanent or involuntary closure.~~]

[~~(2)[(3)] "Involuntary closure" means an interruption of formal business activity resulting from:~~

~~(a) Acute illness or incapacitation;~~

~~(b) Death;~~

~~(c) Fire, flood, or other natural disaster;~~

~~(d) Bankruptcy proceedings; or~~

~~(e) Court, government, or Board of Pharmacy action.~~

~~(3) "Temporary closure" means a licensee or permit holder whose hours of operation have deviated over a period of five (5) consecutive working days from those of record at~~

~~***the Board of Pharmacy office for a reason other than permanent voluntary closure or involuntary closure.***~~

~~***(4) "Non-use" means a failure to engage in formal business activity within one (1) year of initial licensing or permitting or renewal of license or permit.]***~~

Section 2. Procedures for Closure Applicable to All Licensees and Permit Holders. (1) Permanent voluntary closure.[

~~(a) A licensee shall conspicuously place a sign notifying the public thirty (30) days in advance of the:~~

~~1. Termination date of business; and~~

~~2. Name and address of the licensee to which prescription files or other pertinent records will be transferred.~~

~~(b) Except when prevented by the exercise of another party's legal rights:~~

~~1. The sign shall remain in place for a period of thirty (30) days after the closure; and~~

~~2. All efforts shall be undertaken to assure a smooth transition of uninterrupted service to those affected by the closure.~~]

(a) [~~(c)~~] A licensee or permit holder shall inform the Board of Pharmacy, and if applicable, the Drug Enforcement Administration (DEA), and the Cabinet for Health and Family Services [~~Human Resources~~] by written notice fifteen (15) days prior to the anticipated [~~closing~~] closure and include the following information:

1. Date of business termination; ~~and~~

2. Name, address, and DEA number of registrant to whom the prescription drugs and ***drug***-related devices including [~~or~~] controlled substances [~~drugs~~] are to be transferred; and

3. Name, address, and DEA number of registrant to whom the records including inventories, acquisition records, purchase records, and disposition records are to be transferred.

(b) [~~(d)~~] In the absence of directives to the contrary from the DEA[~~Drug Enforcement Administration~~], the Board of Pharmacy, or the Cabinet for Health and Family Services[~~Human Resources~~], the transfer shall be effected on the assigned date.

(c) [~~(e)~~] The transferor and the transferee shall each maintain copies of the following records [~~documents~~] relating to transferred controlled substances for at least two (2) years following closure:

1. U.S. Official Order Forms, DEA-222 Schedule II; ~~and~~

2. Schedules III, IV, and V Invoices***[)]***; and [~~for a period of at least two (2) years~~]

3. Controlled substances inventory.

(d) The transferee shall maintain copies of the following records relating to prescription drugs and ***drug***-related devices for at least two (2) years following closure:

1. Inventories;

2. Acquisition records;

3. Purchase records; and

4. Disposition records.

(e) The records in ***paragraph[~~subsection~~]*** (d) ***of this subsection*** may be stored on ***a*** computer or ***by*** other electronic means and ***shall[~~must~~]*** be readily retrievable.

(f) Upon termination, a licensee or permit holder shall:

1. Remove all signs pertinent to pharmacy or drugs from the building and premises; and

2. Return the voided permits, the DEA [~~Drug Enforcement Administration~~] registration, and unused Schedule II Order Forms to their respective office of issue.[

~~(g) The posting of the sign required by paragraph (a) of this subsection shall not be required if:~~

~~1. An application for a pharmacy license for the same location is filed; or~~

~~2. During a sale of a pharmacy, prescription records are transferred to another permitted pharmacy that is within five (5) miles of the location of the pharmacy that is sold and owned by the purchasing entity. (2) Voluntary closure.~~

~~(a) A pharmacy or distributor licensed by the Kentucky Board of Pharmacy whose hours of operation have deviated over a period of five (5) consecutive working days from those of record at the Board of Pharmacy office shall immediately notify the board, verbally and in writing of the reason for the deviation and the anticipated period of continuance.~~

~~(b) Upon receipt of the notice, the Board of Pharmacy, with full cooperation of the licensee, shall make arrangements it deems necessary to provide adequate and continued security and control of all drugs, chemicals, poisons, and devices owned or controlled by the licensee.~~

~~(c) If normal operation cannot resume within sixty (60) days, or if satisfactory agreements cannot be reached between the Board of Pharmacy, the licensee, or his designated representative, the:~~

~~1. Permit shall be revoked; and~~

~~2. Board of Pharmacy shall notify the Cabinet for Human Resources to assume control and responsibility of any drug, chemical, poison, or device deemed necessary in any manner deemed appropriate.~~

~~(d) If the Board of Pharmacy or the Cabinet for Human Resources or its agents liquidate or arrange for the liquidation of items specified in paragraphs (b) and (c) of this subsection, the board or the Cabinet for Human Resources may retain a portion of the proceeds realized from the liquidation equal to the expenses incurred.~~]

(2)[~~(3)~~] Involuntary closure.

(a) Within five (5) days of involuntary closure, a licensee or permit holder, or person authorized to act on [~~his~~] behalf of the licensee or permit holder, shall:

1. Notify the Board[~~board~~] of Pharmacy in writing; and

2. Guarantee the security [~~safety~~] and control of the licensed or permitted premises in a manner that will allow continued storage of prescription drugs and ***drug***-related devices, including controlled substances, and records, including patient records, if applicable, [~~consigned to the board permittees~~] for sixty (60) days after the effective date of the involuntary closure.

(b) Within sixty (60) days after the effective date of the involuntary closure, a licensee or permit holder shall make [~~effect~~] arrangements for the lawful transfer [~~sale~~] or other disposition of prescription drugs and ***drug***-related devices, including controlled substances, and records [~~requiring board licensure~~].

(c) The Board[~~board~~] of Pharmacy may assume control and responsibility of prescription drugs and ***drug***-related devices, including controlled substances, and records, including patient records, if applicable, it deems necessary for disposition, if after the expiration of the sixty (60) day period following the effective date of involuntary closure:

1. A lawful transfer [~~sale~~] or other disposition has not been made [~~effected~~]; or

2. An agreement between the Board[~~board~~] of Pharmacy[~~,~~] and the licensee or permit holder or person authorized to act on behalf of the licensee or permit holder, has not been reached.

(3) Permanent voluntary closure of licensees and permit holders with patient records.

(a) A licensee or permit holder shall conspicuously place a sign notifying the public thirty (30) days in advance of the:

1. Termination date of business; and

2. Name and address of the licensee or permit holder to which prescription files or other patient records will be transferred.

(b) Except when prevented by the exercise of another party's legal rights:

1. The sign shall remain in place for a period of thirty (30) days after the closure; and

2. All efforts shall be undertaken to assure a smooth transition of uninterrupted service to those affected by the closure.

(c) The posting of the sign required by paragraph (a) of this subsection shall not be required if:

1. An application for a pharmacy permit or outsourcing facility license for the same location is filed; or

2. During a sale of a pharmacy or outsourcing facility, prescription records are transferred to another permitted pharmacy or licensed outsourcing facility that is within five (5) miles of the location of the pharmacy or outsourcing facility that is sold and owned by the purchasing entity.

(4) Temporary Closure.

(a) Licensees and permit holders whose hours of operations have deviated over a period of five (5) consecutive working days from those of record at the Board of Pharmacy office shall immediately notify the Board of Pharmacy in writing of the reason for the deviation and the anticipated period of continuance.

(b) The licensee or permit holder shall notify the Board of Pharmacy in writing of the arrangements necessary to provide adequate and continued security and control of all prescription drugs and ***drug***-related devices and records maintained by the licensee or permit holder.

(c) If formal business activity cannot resume within sixty (60) days, or the security and control cannot be maintained, the:

1. License or permit shall be closed; and

2. Procedures for involuntary closure ***shall[~~would~~]*** be followed.

Section 3. Closure of License or Permit Due to Non-use.

(1) The Board of Pharmacy shall close a license or permit due to non-use ***if[~~when~~]***:

(a) The licensee or permit holder fails to notify the Board of Pharmacy of initiation of formal business activity within the first year of issuance;

(b) Inspection reveals a failure to engage in formal business activity within the first year of issuance; or

(c) Inspection reveals a failure to ***engage[~~engaged~~]*** in formal business activity within one ***(1)*** year of renewal.

(2) A licensee or permit holder may request an extension from closure due to non-use. The request ***shall[~~must~~]***:

(a) Be in writing;

(b) Include a legitimate reason for the lack of formal business activity; and

(c) Provide a date by which formal business activity will commence or resume.

(3) Upon closure of a license or permit due to non-use, the Board of Pharmacy shall follow procedures for involuntary closure to secure and dispose of any prescription drugs and ***drug***-related devices and records.

Section 4[~~3~~]. Duties and Responsibilities of Licensee and Permit Holder. A licensee, permit holder or person authorized to act on [~~his~~] behalf of the licensee or permit holder shall:

(1) Fully cooperate with the Board[~~board~~] of Pharmacy to promote the efficient administration of action required by the provisions of this administrative regulation; and

(2) Be financially liable to the Board[~~board~~] of Pharmacy for expenses incurred by the Board[~~board~~] of Pharmacy in its implementation of the provisions of this administrative regulation.

Section 5. Violation. Violations of any of these provisions shall be grounds for the discipline of the license or permit pursuant to KRS 315.121.

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 (RIA)

The agency needs to file one (1) clean copy of a corrected RIA at the time that it files this staff suggested substitute that:

- **Is paginated as Page 11-13**
- **Corrects agency's response for Question 9. on tiering to clarify that tiering is not applied to different types of pharmacy closures.**

As Amended at ARRS 12/8/2020

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

201 KAR 2:106 Pharmacy, Manufacturer, or Distributor Closures

Contact person: Larry Hadley
Contact Phone No.: 502-564-7910
Contact email: larry.hadley@ky.gov

1. Provide a brief summary of:

What this administrative regulation does:

This administrative regulation establishes the requirements relating to closure of business by licensees and permit holders.

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 relating to closure of business by licensees and permit holders.

How this administrative regulation conforms to the content of the authorizing statues:

This administrative regulation establishes the requirements relating to closure of business by licensees and permit holders.

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 other pharmacy permit 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 other pharmacy permit regulations.

The necessity of the amendment to this administrative regulation:

The criteria needed to be updated.

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.

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 other pharmacy permit 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:

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.

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.

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:

Initially:

No costs will be incurred.

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:

No increase in fees or funding will be required because of this new regulation.

8. State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This administrative regulation does not establish fees or directly or indirectly increase any fees.

9. TIERING: Is tiering applied? (Explain why tiering was or was not used)
   Tiering is not applied to different types of pharmacy closures.

Andy Beshear
Governor

KENTUCKY BOARD OF PHARMACY
125 Holmes Street, Suite 300
State Office Building Annex
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
pharmacy.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 2:225. Special limited pharmacy permit – medical gas

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:225, the Board of Pharmacy proposes the attached amendment to 201 KAR 2:225.

Sincerely,

Larry A. Hadley, R.Ph.
Executive Director
Kentucky Board of Pharmacy

Final 11-23-2020

Suggested Amendment

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:225. Special limited pharmacy permit – medical gas.

Page 1
RELATES TO
Line 5
After "KRS 217.015", insert "(11)".
Delete "(5)(a)".

Page 3
Section 4(2)(a)
Line 22
After "Section 1", insert "(8)".
Delete "(9)".

Page 3
Section 4(2)(b)
Line 23
After "Section 1", insert "(9)".
Delete "(10)".

Page 4
Section 5(2)
Line 7
After "This", insert "material".
Delete "form".
After "may be", insert "inspected, copied, or".
After "obtained,", delete "inspected, or copied,".
Line 9
After "8204,", delete "8 a.m. to 4:30 p.m.,".
After "Monday through Friday", insert ", 8 a.m. to 4:30 p.m".

MATERIAL INCORPORATED BY REFERENCE

The agency at the time that it files this staff suggested amendment needs to also file one (1) clean copy of the "Application for Special Limited Pharmacy Permit – Medical Gas Renewal" that includes:

- **The May 2020 edition date**
- **The updated fees as referenced in 201 KAR 2:050 as amended and that includes the permit renewal fee that is now $125, and the updated delinquent renewal penalty for a permit fee that is now $100 with the $25 fee increase.**

Kentucky Permit Number
MG_____

DON'T FORGET!

KENTUCKY BOARD OF PHARMACY
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
e-mail: pharmacy.board@ky.gov
http://pharmacy.ky.gov

APPLICATION FOR SPECIAL LIMITED PHARMACY PERMIT - MEDICAL GAS RENEWAL

Enclose a check or money order for $125.00, made payable to 'Kentucky State Treasurer'. Please print legibly and complete this application; including the required original signature and return to the Board office no later than June 30th. All renewals received after June 30th will be assessed a delinquent fee of $100.00 pursuant to 201 KAR 2:050, Section 1(11).

Facility Name _____ Permit No. _____

Address _____

_____

Email Address _____

Telephone No. _____ Fax No. _____

INCOMPLETE OR UNSIGNED APPLICATIONS WILL BE RETURNED.

OWNERSHIP:

_____Sole Proprietor _____Partnership _____Corporation _____LLC _____Other

Name and title for each owner/officer, including professional designation:

_____

_____

_____

CONSULTANT PHARMACIST*:

Name_____

KY License No. _____

***Consultant Pharmacists are not required for non-resident medicinal gas permits.**

Kentucky Pharmacy Regulation 201 KAR 2:205 requires Consultant Pharmacist to notify the Board within fourteen (14) calendar days of all pharmacist personnel changes.

SCHEDULE OF STORE HOURS:

Consultant Pharmacist must notify the Board within fourteen (14) days of any changes in scheduled hours.

Monday .... _____ to _____ Thursday ... _____ to _____

Tuesday ... _____ to _____ Friday .... _____ to _____

Wednesday _____ to _____ Saturday .. _____ to _____

Sunday .... _____ to _____

Have you had a Pharmacy license/permit surrendered to or fined, suspended, probated, or revoked by any Board of Pharmacy which you have not previously reported to this Board? _____Yes, attach an explanation _____No

The Board may refuse to issue or renew a permit, or suspend, temporarily suspend, revoke, fine or reasonably restrict any permit holder for knowingly making or causing to be made, any false, fraudulent or forged statement in connection with an application for a permit. KRS 315.121.

I hereby certify that the foregoing is true and correct to the best of my knowledge and that I have read and understand Kentucky Revised Statutes Chapters 217, 218A, and 315 and the Regulations of the Kentucky Board of Pharmacy and the Cabinet for Health and Family Services pertaining to the practice of pharmacy and certify that this pharmacy will be conducted in full compliance with all federal and state laws. [If applicable, this pharmacy is currently licensed and in good standing in all states of licensure].

_____ _____

Form 2 – 5/2020 *(Date)* *(Signature of Owner)*

Andy Beshear
Governor

KENTUCKY BOARD OF PHARMACY
125 Holmes Street, Suite 300
State Office Building Annex
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
pharmacy.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 2:240. Special limited pharmacy permit – charitable

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:240, the Board of Pharmacy proposes the attached amendment to 201 KAR 2:240.

Sincerely,

Larry A. Hadley, R.Ph.
Executive Director
Kentucky Board of Pharmacy

Final 11-23-2020

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:240. Special limited pharmacy permit – Charitable.

RELATES TO: KRS 315.035
STATUTORY AUTHORITY: KRS 315.020, 315.030, 315.035, 315.191(1)(a)
NECESSITY, FUNCTION, AND CONFORMITY: KRS ***[315.020, 315.030, and]*** 315.191(1)(a) ***authorizes[requires]***[~~authorizes~~] the board to promulgate administrative regulations to prescribe the criteria for obtaining a pharmacy permit to dispense legend drugs and the procedures for the safe dispensing of legend drugs to citizens of the Commonwealth. This administrative regulation identifies the manner and procedure by which a charitable organization ***may[can be permitted to]***[~~may~~] obtain a pharmacy permit and dispense legend drugs in the Commonwealth.

Section 1. Definitions. (1) "Charitable organization" means an organization qualified as a charitable organization pursuant to Section 501(c)(3) of the Internal Revenue Code.

(2) "Legend drug sample" means an unopened package of a manufacturer's legend drug product that has been distributed to either a practitioner or the charitable pharmacy in accordance with the provisions of the Prescription Drug Marketing Act of 1987.

(3)[~~(3)~~] "Qualified indigent patient" means a patient of the charitable pharmacy that has been screened and approved by the charitable organization as meeting the organization's mission of providing pharmaceutical care to those who are without sufficient funds to obtain needed legend drugs.

(4)[(3)][~~(4)~~] "Special limited pharmacy permit" means a permit issued to a pharmacy that provides ***[miscellaneous]*** specialized pharmacy ***services, such as dispensing legend drugs, and counseling patients[service] [and functions]***.

Section 2. (1) A charitable pharmacy: ***(a)***[~~(a)~~] Shall comply with all pharmacy permit requirements except those specifically exempted by the board pursuant to paragraph (b) of this subsection; and

(b)[(a)][~~(b)~~] May petition the board in writing to be exempted from those pharmacy permit requirements that do not pertain to the operation of that charitable pharmacy.

(2) The charitable pharmacy only shall dispense prescription legend drug samples or prescription legend drugs to qualified indigent patients of the pharmacy.

(3) The charitable pharmacy shall not charge any fee for the dispensing of prescription legend drug samples or prescription legend drugs to qualified indigent patients of the pharmacy.

(4) A charitable pharmacy may accept prescription legend drugs in their unbroken original packaging from pharmacies, wholesalers, or manufacturers, provided appropriate records of receipt and dispensing are maintained.

(5) A charitable pharmacy shall not:

(a) Accept controlled substances from pharmacies, wholesalers, or manufacturers; or

(b) Dispense controlled substances.

(6) A pharmacy that requests a special limited pharmacy permit - charitable shall submit to the board for prior approval, a plan describing the method by which the charitable pharmacy and the pharmacy ***shall[will]*** maintain a separate and distinct prescription drug stock. The failure of

either pharmacy to follow the plan shall result in revocation of the special limited pharmacy permit - charitable and the pharmacy permit.

Section ***3.[2.]***[~~3.~~] License Fees; Renewals. An applicant shall submit:

(1) An initial or renewal application for a special limited pharmacy permit - charitable pharmacy on either the ***["]***Application for Special Limited Pharmacy Permit – Charitable Pharmacy or the ***["]***Application for Special Limited Pharmacy Permit – Charitable Pharmacy Renewal***["]***; and

(2) As appropriate, the:

(a) Initial application fee established by ***[~~Section 1(9),~~]*** 201 KAR 2:050***, Section 1(8)***[~~, Section 1(9)~~]; or

(b) Renewal fee established by ***[~~Section 1(10-11),~~]*** 201 KAR 2:050***, Section 1(9) and (10)***[~~, Section 1(10) and (11)~~].

Section ***4.[3.]***[~~(4)~~] Incorporation By Reference. (1) The following material is incorporated by reference:

(a) ***[~~Effective January 1, 2020~~]*** "Application for Special Limited Pharmacy Permit – Charitable Pharmacy"***, May 2020***[~~, May 2019~~]; and

(b) ***[~~Effective January 1, 2020~~]*** "Application for Special Limited Pharmacy Permit – Charitable Pharmacy Renewal"***, May 2020***[~~, May 2019~~].

(2) This ***material[~~form~~]*** may be ***inspected, copied, or*** obtained, ***subject to applicable copyright law,[~~inspected, or copied~~]***[~~subject to applicable copyright law~~] at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601, ***[~~8 a.m. to 4:30 p.m.,~~]*** Monday through Friday***, 8 a.m. to 4:30 p.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.

MATERIAL INCORPORATED BY REFERENCE

The agency needs to file at the time that it files this staff suggested amendment one (1) clean copy of the "Application for Special Limited Pharmacy Permit-Charitable Pharmacy Renewal" that includes the following changes:

- **Includes May 2020 Edition date**
- **Includes fees updated to $125 for permit renewal and references delinquent renewal penalty of $100**

Kentucky Permit Number
CH_____

DON'T FORGET !

KENTUCKY BOARD OF PHARMACY
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
e-mail: pharmacy.board@ky.gov
http://pharmacy.ky.gov

Application for Special Limited Pharmacy Permit - Charitable Pharmacy Renewal

Enclose a check or money order for $125.00, made payable to 'Kentucky State Treasurer'. Please print legibly and complete this application; including the required original signature and return no later than June 30th. All renewals received after June 30th will be assessed a delinquent fee of $100.00 pursuant to 201 KAR 2:050, Section 1(11).

Name of Facility _____

Physical Address of Facility _____
(Street and Number)

City _____ County _____ State _____ Zip _____

Phone Number _____ Fax Number _____

Email Address _____

Ownership:

☐ Sole Proprietor ☐ Partnership ☐ Unincorporated Business ☐ Incorporated Business

Name and title for each owner/officer, including professional designation *(e.g. Pres. John Jones, PharmD)*

_____

_____

Schedule of Hours:

*P.I.C. must notify the Board within fourteen (14) days of any changes in scheduled hours.

Monday	_____ A.M. to	_____ P.M.	□ 24 Hours
Tuesday	_____ A.M. to	_____ P.M.	□ 24 Hours
Wednesday	_____ A.M. to	_____ P.M.	□ 24 Hours
Thursday	_____ A.M. to	_____ P.M.	□ 24 Hours
Friday	_____ A.M. to	_____ P.M.	□ 24 Hours
Saturday	_____ A.M. to	_____ P.M.	□ 24 Hours
Sunday	_____ A.M. to	_____ P.M.	□ 24 Hours

Please indicate if closed for lunch. _____

Pharmacist in Charge:

Name _____ KY License No. _____

Kentucky Pharmacy Regulation 201 KAR 2:205 requires Pharmacist in Charge to notify the Board within fourteen (14) calendar days of all pharmacist personnel changes.

==========EMPLOYEE INFORMATION==========

Pharmacist-In-Charge(PIC): Name_____ KY License Number_____

Note: 201 KAR 2:205 requires the pharmacist-in-charge to notify the Board within fourteen [14] calendar days of all pharmacist changes.

Employees: Please provide a complete list of all employees licensed/registered with the Board. Use a separate sheet of paper if necessary.

NAME	License/Registration Number (Pharmacist, Pharmacist Intern or Pharmacy Technician)

Name, title and address of each non-pharmacist with keys to the pharmacy:

_____ _____

Have you had a Pharmacy license/permit surrendered to or fined, suspended, probated, or revoked by any Board of Pharmacy which you have not previously reported to this Board?

_____Yes, attach an explanation _____NO

For institutional pharmacies, are there decentralized pharmacy services (i.e. oncology satellite, OR satellite, etc.) where drugs are prepared, stored, and/or compounded in the facility?

_____Yes, how many? _____NO

The Board may refuse to issue or renew a permit, or suspend, temporarily suspend, revoke, fine or reasonably restrict any permit holder for knowingly making or causing to be made, any false, fraudulent or forged statement in connection with an application for a permit. KRS 315.121

I hereby certify that the foregoing is true and correct to the best of my knowledge, that I have read and understand Kentucky Revised Statutes Chapters 217, 218A, and 315 and the regulations of the Kentucky Board of Pharmacy and the Cabinet for Health and Family Services pertaining to the practice of pharmacy and certify that this pharmacy will be conducted in full compliance with all federal and state laws, and that the facility is currently licensed and in good standing in all states of licensure.

_____ _____

(Original Signature of Owner) (Original Signature of Pharmacist in Charge)

_____ _____

(Date) (Date)

Andy Beshear
Governor

KENTUCKY BOARD OF PHARMACY
125 Holmes Street, Suite 300
State Office Building Annex
Frankfort KY 40601
Phone (502) 564-7910
Fax (502) 696-3806
pharmacy.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 2:320. Requirements for manufacturers and virtual manufacturers

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:320, the Board of Pharmacy proposes the attached amendment to 201 KAR 2:320.

Sincerely,

Larry A. Hadley, R.Ph.
Executive Director
Kentucky Board of Pharmacy

Final 11-24-2020

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:320. Requirements *for* [~~Permit~~] *[~~or~~]* manufacturers and virtual manufacturers.

RELATES TO: KRS 315.010, 315.020(2), 315.036, [~~and~~] 315.191(1)(a), 315.400, ***[and]*** 315.404***[.]***

STATUTORY AUTHORITY: KRS 315.020(2), 315.036, 315.191(1), 315.400***[.]***

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.020, 315.036 and 315.191(1)(a) authorize~~s~~ the board to promulgate administrative regulations to regulate the manufacturers and virtual manufacturers of drugs and ***drug***-related devices. [~~KRS 315.036 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 ***drug***-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) ***"Illegitimate Product" is defined by KRS 315.400(11).***

(4) "Manufacturer or virtual manufacturer" ***is defined by KRS 315.010(13)[~~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~~].***

(5) "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, such as capsules, tablets, and lyophilized products before reconstitution.

(6)[~~(4)~~] "Relabeler" means***:***

(a) 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***; and***

(b) [~~. This~~] Does not include establishments that do not change the original labeling, but merely add their own name.

(7)[~~(5)~~] "Repackager" ***is defined by[~~has the same meaning as in~~] KRS 315.400(16).***

(8)[~~(6)~~] "Suspect product" means a ***component, prescription drug, or drug-related device[~~product~~]*** for which there is reason to believe that such ***component, prescription drug, or drug-related device [~~product~~]***:

(a) Is potentially counterfeit, diverted, or stolen;

(b) Is potentially intentionally adulterated such that the ***component, prescription drug, or drug-related device[~~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 ***component, prescription drug, or drug-related device[~~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 operation, maintenance, and storage conditions to ensure proper lighting, ventilation, temperature and humidity control, sanitation, space, and security as per label requirements or official [~~current year~~] United States Pharmacopoeia (USP) compendium requirements, ***USP Chapter 659, Packaging and Storage Requirements as incorporated by reference in 201 KAR 2:105***. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of components and [~~prescription~~] drugs and ***drug-***related devices;

(b) Separation [~~Physical separation~~] and quarantine of deteriorated, damaged, outdated, misbranded, adulterated, or otherwise recalled components and drugs and ***drug-***related devices [~~merchandise~~] until they are destroyed or returned;

(c) Providing accurate and precise records of all components and drugs and ***drug-***related devices [~~goods~~] shipped or received including source ~~or~~ and recipient, date, quantity, itemized description, and any other information pertinent to the [~~transaction~~] receipt and distribution or disposition; ***and***

(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 ***shall[~~must~~]*** comply with all requirements as outlined in the Drug Supply Chain Security Act (DSCSA), ***21 U.S.C. 360eee-360eee-4.***, 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 ***subsection[~~Section~~]*** 2(4)(a) and (b) ***of this Section, and*** Section 5(1)(a) and (b) and (2)(a) and (b) ***of this administrative regulation.***

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 manufacture or virtual manufacture[~~manufacturer~~] of [~~prescription~~] drugs and ***drug-***related devices within the Commonwealth:

(a)[~~1.~~] Any convictions of the officers of the applicant under any federal, state, or local laws relating to drugs, ***including[~~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[~~applicant's~~]*** and its officers' past experience in the manufacture or virtual manufacture of [~~prescription~~] drugs and ***drug***-related devices, including drug samples and 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;

(e)[~~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 ***drug***-related devices, including drug samples and controlled substances;

(f)[~~(e)~~][~~5.~~] Compliance with the requirements under any previously granted license or permit, if any; and

(g)[~~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 ***administrative*** regulation [~~section~~].

(2)[~~(b)~~] 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 based on health and safety considerations [~~for any reason established in KRS 315.121~~].

[~~(2)~~](3) 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 is [~~and its officers are~~] in compliance with all applicable federal, [~~and~~] state, and local laws and regulations relating to drugs and ***drug***-related devices; 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;~~

~~(e) 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 issued pursuant to this administrative regulation [~~holder~~] may be disciplined, suspended, or revoked for failure to comply with the provisions of KRS 315.020, 315.036, 315.400 [~~pursuant to KRS 315.121~~], or this administrative regulation.

(5) No permit shall fail to designate a pharmacist-in-charge.

Section 4[~~3~~]. Application, Fees[~~;~~], Renewals.

(1) An application for a permit shall be submitted to the Board of Pharmacy on ***the [~~"~~]***Application for a Permit to Operate as a Manufacturer or Virtual Manufacturer [~~(KBP M-5:09)~~].***[~~"~~]***

(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 permit holder [~~permittee~~] for the storage, handling, and manufacturing or virtual manufacturing of drugs and ***drug***-related devices [~~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 permit holder [~~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, virtual manufacture or possess [~~prescription~~] drugs and ***drug***-related devices.

(4) All permits shall:

(a) Expire on September 30 following the date of issuance; and

(b) Be:

1. Renewable annually thereafter upon ***completion of the[~~,~~]*** Renewal [~~proper~~] Application ***to Operate as a Manufacturer or Virtual Manufacturer that is*** accompanied by the renewal fee set forth in 201 KAR 2:050; and

2. Nontransferable.

Section [4]5. Standards.

(1) Facilities.

(a) All facilities [~~buildings~~] in which components and [~~legend~~] drugs and ***drug***-related devices are labeled, relabeled, packaged, 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) All facilities [Buildings] shall meet all applicable federal, state, and local standards. The facility shall [~~have a~~] quarantine components and [~~area for storage of prescription~~] drugs and ***drug***-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.

(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 components [~~legend~~] and drugs and ***drug***-related devices 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 or virtual manufacture[~~manufacturer~~] of [~~prescription~~] drugs and ***drug***-related devices.

(e) Lists of officers, directors, managers and other persons in charge of manufacture or virtual manufacture, distribution or disposition, storage, and handling of components and [~~prescription~~] drugs and ***drug***-related devices, including a description of their duties and summary of their qualifications, shall be maintained for purpose of review.

(3) Recordkeeping ***requirements for companies handling prescription drugs and drug-related devices exempt from the DSCSA***.

(a) Inventories and other records [~~of transactions~~] regarding the receipt and distribution or disposition of components [~~legend~~] and drugs and ***drug***-related devices shall be maintained and readily available for inspection or photocopying by the Board of Pharmacy and authorized law enforcement officials for a period six (6) [of ~~two (2)~~] years ~~following disposition of the drugs~~]. These records shall include:

1. The business name and address of the source of the components and drugs and ***drug***-

related devices including the [~~name and principal address of the~~] seller or transferor and the address of the location from which the components and drugs and ***drug***-related devices were shipped;

2. The business name and address to whom components and drugs and ***drug***-related devices were shipped including the purchaser and the address of the location where the components and drugs and ***drug***-related devices were shipped;

3[~~2~~]. The identity and quantity of the components and drugs and ***drug***-related devices received and distributed or disposed of; and

4~~3~~[4]. The dates of receipt and distribution or disposition [~~other distribution~~] of the components and drugs and ***drug***-related devices.

(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 ***readily retrievable within forty-eight (48) hours[~~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 ***drug***-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 ***pursuant to KRS 217.182(1); [~~or~~]***
9. A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes ***pursuant to KRS 217.182(1); or[~~.~~]***

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 ***drug***-related device to the Board of Pharmacy and ***if[~~where~~]*** applicable the FDA and DEA.

(4) Written policies and procedures, ***requirements for companies handling prescription drugs and drug-related devices exempt from the DSCSA***.

(a) A manufacturer or virtual manufacturer shall establish, maintain, and adhere to written policies and procedures for [~~the~~] all operations including production, process controls, receipt, security, storage, inventory, and distribution or disposition of components and [~~prescription~~] drugs and ***drug***-related devices.~~, [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 ***drug***-related devices or any [~~stock~~] components or drugs or ***drug***-related devices with an expiration date that, in the manufacturer's or virtual manufacturer's 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 or virtual manufacturer exercises control over the shipping and receiving of all [~~stock~~] components and drugs and ***drug***-related devices 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 ***drug***-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 ***drug***-related devices [~~goods~~]. If conditions under which a [~~prescription~~] drug or ***drug***-related device has been returned cast doubt on the drug's ~~s~~ or ***drug***-related device's safety, identity, strength, quality, or purity, then the drug or ***drug***-related device shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug or ***drug***-related device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug or ***drug***-related device has been returned cast doubt on the drug [~~drug's~~] or ***drug***-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 ***drug***-related device has been held, stored, or shipped before or during its return and the condition of the drug or ***drug***-related device and its container, carton, or labeling, as a result of storage or shipping.

(6) Handling recalls. A manufacturer or virtual manufacturer shall adopt, maintain, and follow a written policy and procedure for handling recalls and withdrawals of [~~products~~] components or drugs or ***drug***-related devices. 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 FDA [~~Food and Drug Administration~~], or any other federal, state, or local government agency; and

(c) Replacement, relabeling, or repackaging of existing component or drug or ***drug***-related devices [~~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 and ***drug***-related devices salvaging or reprocessing.

Section 6[~~5~~]. Pharmacist-in-charge. A manufacturer or virtual manufacturer 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 and documenting an on-site inspection not less than quarterly.

Section 7[~~6~~]. Violations.

(1) A drug manufacturer or virtual manufacturer shall not distribute [~~legend~~] prescription drugs and ***drug***-related devices 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 8[~~7~~]. Incorporation by Reference. (1) ***The following material is incorporated by reference:***

(a) "Application for a Permit to Operate as a Manufacturer or Virtual Manufacturer", ***May 2020; and***

(b) ***"Renewal Application to Operate as a Manufacturer or Virtual Manufacturer", May 2020***[~~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, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601-8024, [~~Spindletop Administrative Building, Suite 302, 2624 Research Park Drive, Lexington, Kentucky 40511,~~]Monday through Friday, 8 a.m. through 4:30 p.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.

MATERIAL INCORPORATED BY REFERENCE

The agency needs to file one (1) clean copy of the following at the time it files this staff suggested amendment:

- **The "Renewal Application to Operate as a Manufacturer or Virtual Manufacturer"**
    - **Updates the edition date to May 2020**
    - **Updates the Renewal fee from $100 to $125**

KENTUCKY BOARD OF PHARMACY
State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601
Phone (502) 564-7910 Fax (502) 696-3806

RENEWAL APPLICATION TO OPERATE AS A MANUFACTURER OR VIRTUAL MANUFACTURER

Enclose a check or money order for $125.00, made payable to 'Kentucky State Treasurer'. Please print legibly and complete this application; including the required original signature and return no later than September 30th. All renewals received after September30th will be assessed a delinquent fee of $100.00 pursuant to 201 KAR 2:050, Section 1(11).

Incomplete applications will be returned.

TYPE: ☐ MANUFACTURER ☐ VIRTUAL MANUFACTURER

LICENSE/PERMIT NUMBER: _____

NAME OF FACILITY: _____

PHYSICAL ADDRESS: _____

CITY: _____ STATE: _____ COUNTY _____ ZIP _____

PHONE NUMBER: _____ FAX NUMBER: _____

EMAIL ADDRESS: _____

MAILING ADDRESS:

_____

_____

_____

REGISTRATION NO.: **EXP DATE:**

DEA:_____ ___/___/_____

FDA:_____ ___/___/_____

1. Name and title of facility contact person:

Name: _____ Title: _____

Email: _____

2. Identify the Pharmacist-in-Charge:

Name: _____ License No:_____

3. Ownership:

☐ Sole Proprietor ☐ Partnership ☐ Unincorporated Business ☐ Incorporated Business ☐ Other

Pursuant to 201 KAR 2:105, Section 4, on a separate sheet of paper, please provide the following information for each owner/officer, including professional designation (e.g. Pres. John Jones, M.D.):

- ❖ Name and Title
- ❖ Address (Business and Home)
- ❖ Phone Number (Business and Home)
- ❖ Social Security Number[XXX-XX-____]
- ❖ Date of Birth[Month and Year only]

4. Has applicant, or any owner [s], partner [s], officer [s], agent or employee of the applicant, ever been convicted of any felony under federal, state, and/or local laws not previously reported to the Board?

◯ Yes, attach explanation ◯ No

Has applicant, or any owner [s], partner [s], officer [s], agent or employee of the applicant, ever had a license or permit related to drugs revoked or suspended by any federal, state, or local government not previously reported to the Board?

◯ Yes, attach explanation ◯ No

Has applicant, or any owner [s], partner [s], officer [s], agent or employee of the applicant, ever been convicted under federal, state and/or local laws relating to drugs, including drug samples and controlled substances not previously reported to the Board?

◯ Yes, attach explanation ◯ No

5. Schedule of Hours:

Monday: _____ A.M. to _____ P.M. Friday: _____ A.M. to _____ P.M.

Tuesday: _____ A.M. to _____ P.M. Saturday: _____ A.M. to _____ P.M.

Wednesday: _____ A.M. to _____ P.M. Sunday: _____ A.M. to _____ P.M.

Thursday: _____ A.M. to _____ P.M.

The Board may refuse to issue or renew a license/permit or suspend, temporarily suspend, revoke, fine or reasonably restrict the license/permit holder for knowingly making or causing to be made any false, fraudulent or forged statement in connection with an application for a permit. See KRS 315.121.

I hereby certify that the foregoing is true and correct to the best of my knowledge. If the registration herein applied for is granted, I certify that this business will be conducted in full compliance with all applicable federal and state laws and that I will make available any or all records required by law to the extent authorized by law.

_____ _____

Signature and Title of Owner / Manager Date

Changes in the above information must be submitted in writing with the appropriate application fee to the Board office within thirty (30) days.

KENTUCKY BOARD OF OPTOMETRIC EXAMINERS

Andy Beshear
Governor

2365 Harrodsburg Road, Suite A240
Lexington, Kentucky 40504-3333
Phone: (859) 246-2744
Fax (859) 246-2746
http://optometry.ky.gov

Jonathan Shrewsbury, OD, President
Lee Peplinski, OD, Vice President
Freddie Mayes, OD, Secretary/Treasurer
William Reynolds, OD
Harold Corder

Carson Kerr, Executive Director

November 20, 2020

Ms. Emily Caudill
Regulations Compiler
Legislative Research Commission
700 Capitol Avenue
Frankfort, KY 40601

Re: New Administrative Regulation of the Kentucky Board of Optometric Examiners- Staff Suggested Amendments Accepted

Dear Regulations Compiler:

After discussions with Administrative Regulation Review Subcommittee staff of proposed non-substantive revisions identified in 201 KAR 5:140, the Kentucky Board of Optometric Examiners proposes the attached amendment to 201 KAR 5:140.

Thank you for your time and consideration.

Respectfully submitted,

/s/ *Carson F. Kerr*

Carson Kerr
Executive Director

Staff-suggested Amendment

Final Version 11/16/2020 11:38 a.m.
BOARD OF OPTOMETRIC EXAMINERS

201 KAR 5:140. Dispensing.

Page 1
RELATES TO paragraph
Line 4

After "TO: KRS" insert "217.015(35), 217.182(3),".
Delete "217.182(3); KRS 217.015(35); KRS".

Page 1
NECESSITY, FUNCTION, AND CONFORMITY
Line 6

After "NECESSITY, FUNCTION", insert ",".

Page 1
Section 2(2)
Line 18

After "professional practice; and", delete ",".

Page 2
Section 3
Lines 1 and 2

After "An optometrist", insert "shall".
Delete "must".

After "and the optometrist", insert "shall".
Delete "must".

Page 2
Section 4
Lines 3 and 4

After "by an optometrist,", insert "he or she shall".
Delete "an optometrist must".

Page 2
Section 4(2)
Line 6

After "strength, quantity", insert ",".

Page 2
Section 6
Line 11

After "pharmaceutical agent", insert "shall".
Delete "must".

After "possessed, labeled", insert ",".

KENTUCKY BOARD OF BARBERING
312 Whittington Parkway Suite 110
Louisville, KY 40222
(502) 429-7148

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: Board of Barbering Regulations, 201 KAR 14:035, 070, 095, 100, 105, 130, 135, 140

Dear Co-Chairs:

After discussions with Administrative Regulation Review Subcommittee staff concerning the issues raised by the administrative regulations listed below, the Board of Barbering proposes the attached amendments to those same regulations.

201 KAR 14:035	201 KAR 14:070	201 KAR 14:095
201 KAR 14:100	201 KAR 14:105	201 KAR 14:130
201 KAR 14:135	201 KAR 14:140	

Sincerely,

Christopher D. Hunt
Board Attorney
Board of Barbering
312 Whittington Parkway Suite 110
Louisville, KY 40222

Staff-suggested Amendment

Final Version 12/1/2020 2:20 p.m.
GENERAL GOVERNMENT CABINET
Board of Barbering

201 KAR 14:035. Public identification of and access to barber shops and schools.

Page 1
RELATES TO paragraph
Line 5

After "317.410,", insert "317.420".
Delete "317.400".

Page 1
NECESSITY, FUNCTION, AND CONFORMITY paragraph
Line 7

After "AND CONFORMITY:", insert the following:

KRS 317.440 requires the board to promulgate administrative regulations governing the location and housing of barber shops or schools. This administrative regulation establishes

Lowercase "Public".

Page 1
Section 1
Line 10

After "barber shop, barber school", insert ",".

Staff-suggested Amendment

Final Version 12/1/2020 2:23 p.m.
GENERAL GOVERNMENT CABINET
Board of Barbering

201 KAR 14:070. Shop license applications.

Page 1
NECESSITY, FUNCTION, AND CONFORMITY paragraph
Line 7

After "AND CONFORMITY:", insert the following:

KRS 317.440 requires the board to promulgate administrative regulations governing the location and housing of barber shops or schools. This administrative regulation establishes the requirements for the

Lowercase "Application".

Page 1
Section 1
Line 9

After "city, county", insert ",".

After "health regulations and", insert "shall".
Delete "must".

Page 1
Section 2
Line 12

After "A new license", insert "shall".
Delete "must".

Staff-suggested Amendment

Final Version 12/1/2020 2:24 p.m.
GENERAL GOVERNMENT CABINET
Board of Barbering

201 KAR 14:095. Accredited school.

Page 1
NECESSITY, FUNCTION, AND CONFORMITY paragraph
Line 7

After "AND CONFORMITY:", insert the following:

KRS 317.450 requires the board to issue a license to operate a school of barbering to any person, firm, or corporation who or which has complied with its statutory requirements. This administrative regulation establishes the requirements for an

Lowercase "Accredited".

Page 1
Section 1
Line 9

After "addition to all", delete "the".

After "Kentucky laws," insert "shall".
Delete "will".

Page 1
Section 2
Line 12

After "A new license", insert "shall".
Delete "must".

Staff-suggested Amendment

Final Version 12/1/2020 2:26 p.m.
GENERAL GOVERNMENT CABINET
Board of Barbering

201 KAR 14:100. School advertising.

Page 1
NECESSITY, FUNCTION, AND CONFORMITY paragraph
Line 7

After "AND CONFORMITY:", insert the following:

KRS 317.420 requires the board to promulgate administrative regulations to protect the public against misrepresentation, deceit, or fraud in the practice or teaching of barbering. This administrative regulation establishes the requirements for

Lowercase "School".

Page 1
Section 1
Lines 8, 9, and 10

After "knowingly false", insert "or".
Delete "such as".

After "deceptive statements", insert "or".
Delete "and".

After "effort to get", delete "the".

After "to enter", insert "the".
Delete "said".

Page 1
Section 2
Lines 11 and 12

After "and books may", delete ", or may not,".

After "but school advertisements", insert "shall".
Delete "must".

After "show what", insert "shall".
Delete "is to".

Page 1
Section 3
Lines 14 and 16

After "school of barbering", insert "shall".
Delete "must".

After "on this sign", insert "shall".
Delete "must".

Page 1
Section 4
Line 18

After "Section 4.", insert "A school shall not".
Delete "No school is permitted to".

Page 1
Section 5
Line 20

After "A school", insert "may".
Delete "is allowed to".

Page 2
Section 6
Line 1

After "6. Schools", insert "shall not".
Delete "are forbidden to".

Staff-suggested Amendment

Final Version 12/1/2020 2:27 p.m.
GENERAL GOVERNMENT CABINET
Board of Barbering

201 KAR 14:105. Barbering school enrollment and postgraduate requirements.

Page 1
NECESSITY, FUNCTION, AND CONFORMITY paragraph
Lines 12 and 15

After "but not more than", delete ",".

After "(GED) certificate or", insert "its".
Delete "it's".

Page 3
Section 3
Line 10

After "barber school or", delete "a person".

Staff-suggested Amendment

Final Version 12/1/2020 2:29 p.m.
GENERAL GOVERNMENT CABINET
Board of Barbering

201 KAR 14:130. School fees for services.

Page 1
NECESSITY, FUNCTION, CONFORMITY paragraph
Line 7

After "AND CONFORMITY:", insert the following:

KRS 317.440 requires the board to promulgate administrative regulations to protect the public against misrepresentation, deceit, or fraud in the practice or teaching of barbering and to establish fees by administrative regulation.

Page 1
Section 1
Lines 9 and 10

After "A copy of", insert "the".
Delete "such".

After "prices", insert "shall".
Delete "must".

After "Price lists", insert "shall".
Delete "must".

Page 1
Section 2
Lines 14 and 15

After "fees for", delete "such".

After "Barber schools", insert "shall".
Delete "may".

After "or manufacturer for", insert "the".

Staff-suggested Amendment

Final Version 12/1/2020 2:30 p.m.
GENERAL GOVERNMENT CABINET
Board of Barbering

201 KAR 14:135. School attendance hours.

Page 1
NECESSITY, FUNCTION, CONFORMITY paragraph
Line 7

After "AND CONFORMITY:", insert the following:

KRS 317.440 requires the board to promulgate administrative regulations governing the hours and courses of instruction at barber schools. This administrative regulation establishes the

Lowercase "Hours".

Page 1
Section 1
Line 9

After "Section 1.", insert "A".
Delete "No".

After "shall", insert "not".

Staff-suggested Amendment

Final Version 12/1/2020 2:31 p.m.
GENERAL GOVERNMENT CABINET
Board of Barbering

201 KAR 14:140. School license.

Page 1
NECESSITY, FUNCTION, CONFORMITY paragraph
Line 7

After "AND CONFORMITY:", insert the following:

KRS 317.440 and 317.540 require the board to promulgate administrative regulations governing barber school licensing.

Page 1
Section 1
Lines 9, 10, and 11

After "a barber school", insert "shall".
Delete "is required to".

After "interested in operating", insert "the".
Delete "such a".

Page 1
Section 2
Line 15

After "school of barbering", insert "shall".
Delete "must".

Page 1
Section 3
Line 18

After "a barber school", insert "shall be".
Delete "is".

Page 1
Section 4
Line 20

After "establishment, firm", insert ",".

Page 2
Section 4
Line 1

After "barber school and", insert "shall".
Delete "will".

Page 2
Section 5
Line 4

After "barbers", insert "shall".
Delete "must".

Page 2
Section 6
Line 7

After "school,", insert "shall".
Delete "will".

502-429-3300
800-305-2042
Fax: 502-429-3353

KENTUCKY BOARD OF NURSING

312 Whittington Parkway, Suite 300
Louisville, Kentucky 40222-5172
kbn.ky.gov

Andy Beshear
Governor

November 20, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulations Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 20:390 (Nursing Incentive Scholarship Fund)

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised regarding 201 KAR 20:390, the Kentucky Board of Nursing proposes the attached amendments to 201 KAR 20:390.

Sincerely,

Morgan G. Ransdell

Morgan G. Ransdell, General Counsel
Kentucky Board of Nursing
Direct dial: (502) 429-3339
Mobile: (502) 415-3964
Fax: (502) 429-3353
E-mail: morgan.ransdell@ky.gov

cc: Ms. Carrie Nichols

Final 11-17-2020

SUGGESTED AMENDMENT

BOARDS AND COMMISSIONS
Board of Nursing

201 KAR 20:390. Nursing Incentive Scholarship Fund.

Page 2
Section 2(2)(a)
Line 17

After "Scholarship", insert "Fund".
After "Application", insert the following:
form for agency receipt on or before
Delete "by".

Page 3
Section 2(2)(d)
Line 2

After "institution in which", insert "the".

Page 5
Section 6(1)(b)
Line 10

After "form", insert the following:
for agency receipt on or before
Delete "by".
After "June", insert "8".
Delete "1".

Page 7
Section 8(5)(b)
Line 3

After "practice registered nurse", insert a comma.

Page 7
Section 8(9)
Line 14

After "Contract and", insert "Nursing Incentive Scholarship Fund".

KENTUCKY BOARD OF CHIROPRACTIC EXAMINERS

Andy Beshear
Governor

P. O. Box 1360
Frankfort, Kentucky 40602
Phone (502) 892-4250
Fax (502) 564-4818
http://kbce.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 21:00\

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 21:00\, the Kentucky Board of Examiners of Chiropractic proposes the attached amendment to 201 KAR 21:00\.

Sincerely,

Jeff Smith, DC

Chair, Kentucky Board of Examiners of Chiropractic
500 Mero Street
P.O. Box 1360
Frankfort, KY 40601

Final 11/19/2020 10:08 AM
SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Chiropractic Examiners

201 KAR 21:001. Definitions for 201 KAR Chapter 21.

RELATES TO: KRS 312.015, 312.200
STATUTORY AUTHORITY: KRS 312.019(9)
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[sets forth]*** the definitions for 201 KAR Chapter 21.

Section 1. Definitions. (1) "Accepted standards" means those standards of review, care, skill, and treatment that are recognized by a reasonably prudent chiropractor as being acceptable under similar conditions and circumstances.

(2) "Accredited chiropractic college or university" means a chiropractic college or university fully accredited by the Council on Chiropractic Education or its successor and that:

(a) Maintains a standard and reputability approved by the board pursuant to 201 KAR 21:055; and

(b) Meets all educational standards for preceptorship programs as established by the Council on Chiropractic Education.

(3) "Adjacent tissues" means all structures and joints contained within the upper and lower extremity.

(4) "Advertisement of free or discounted services" means any advertisement or solicitation, by any medium, offering free or discounted examinations, consultation, treatment, goods, or other services.

(5)[~~(4)~~] "Appropriate chiropractic treatment" means a determination made of treatment and other services performed which, by virtue of a substantiated and properly diagnosed condition, appear to be of a type consistent with that diagnosis.

(6)[~~(5)~~] "Bill for treatment" means all services provided to a patient, regardless of the monetary consideration paid to the chiropractor.

(7) [~~(6)~~] "Board" is defined by KRS 312.015(1).

(8) [~~(7)~~] "Committee" means the peer review committee established by KRS 312.200.

(9) [~~(8)~~] "Complaint" means an allegation alleging misconduct that might constitute a violation of KRS Chapter 312 or 201 KAR Chapter 21.

(10)[~~(9)~~] "Complete notice of right of rescission" means a conspicuous statement, of not less than ten (10) point font in any advertisement of free or discounted services that reads substantially as follows: "You have the right to rescind, within seventy-two (72) hours, any obligation to pay for services performed in addition to this free or discounted service."

(11)[~~(10)~~] "Conviction" means a finding of guilt resulting from a plea of guilty or nolo contendere, the decision of a court, or the finding of a jury, irrespective of a pronouncement of judgment, or the sentence being deferred or suspended.

(12)[~~(11)~~] "Hearing officer" is defined by KRS 13B.010(7).

(13)[~~(12)~~] "Licensee" means a person who performs chiropractic and who is licensed under KRS 312.015 ***through***~~***to***~~***]*** 312.991***[,]*** and 201 KAR Chapter 21, as a chiropractor.

(14)[~~(13)~~] "Notice of rescission" means notice by the consumer rescinding any agreement to pay for unadvertised additional services performed or to be performed in addition to the free or discounted service.

(15) "Ownership or operation of a chiropractic facility" as ***established***~~***[set forth]***~~ in KRS 312.145(3), means continued, ongoing ownership by a licensee, or in the event of the death or permanent disability of the licensee, ownership or operation of the facility by the licensee's spouse, heirs, successors, or assigns as ***can***~~***[may]***~~ be designated by or in the licensee's estate, for up to twelve (12) months.

(16)[~~(15)~~] "Patient" means an individual who receives treatment from a chiropractor.

(17)[~~(16)~~] "Peer review" is defined by KRS 312.015(4).

(18)[~~(17)~~] "Preceptor" means a licensed doctor of chiropractic, who, after approval of the board, pursuant to 201 KAR 21:085, and an accredited chiropractic college or university, provides an opportunity for an undergraduate intern to work in the doctor's office.

(19)[~~(18)~~] "Promotional items" means small tangible items such as pens, magnets, pads, cups, and ***similar.***~~***[the like given to existing or potential customers;]***~~ These are not considered advertising unless the item contains an offer for free or discounted services.

(20)[~~(19)~~] "Properly utilized services" means appropriate treatment services rendered, including the frequency and duration of those services and that are substantiated as being necessary and reasonable by clinical records and reports prepared by the treating chiropractor.

(21)[~~(20)~~] "Seventy-two (72) hour right of rescission" means the right of a consumer to rescind within seventy-two (72) hours any agreement to pay for services if performed the same day in addition to the advertised free or discounted service at an additional unadvertised cost, or any agreement entered into on the same date to submit to a series, or course of treatments at an additional unadvertised cost.

(22)[~~(21)~~] "Unconscionable fees" means charges or bills for treatment submitted for services performed that are unreasonable charges for those services as compared to the usual and customary charges by a chiropractor or by a health care provider other than a chiropractor for the same or similar services in the locality where the services were performed.

(23)[~~(22)~~] "Undergraduate intern" means an individual studying at an accredited chiropractic college or university and who is in the final academic year prior to receiving a degree in chiropractic.

(24)[~~(25)~~] "Unlawful solicitation" means offering money or something of value to a potential patient or patient in exchange to seek treatment from the licensee.

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.

KENTUCKY BOARD OF CHIROPRACTIC EXAMINERS

Andy Beshear
Governor

P. O. Box 1360
Frankfort, Kentucky 40602
Phone (502) 892-4250
Fax (502) 564-4818
http://kbce.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 21:015

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 21:015, the Kentucky Board of Examiners of Chiropractic proposes the attached amendment to 201 KAR 21:015.

Sincerely,

Jeff Smith, DC

Chair, Kentucky Board of Examiners of Chiropractic
500 Mero Street
P.O. Box 1360
Frankfort, KY 40601

Final 11/19/2020 11:01 AM
SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Chiropractic Examiners

201 KAR 21:015. Code of ethical conduct and standards of practice.

RELATES TO: KRS 312.019(9)(a)
STATUTORY AUTHORITY: KRS 312.019(9)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 312.019(9)(a) authorizes the board to promulgate and amend administrative regulations for the practice of chiropractic, including adopting a code of ethical conduct. This administrative regulation establishes the minimum standards of professional and ethical conduct and practice that a licensee shall maintain.

Section 1. Each licensee shall comply with the minimum standards of professional and ethical conduct established in subsections (1) through ***(10)*** ~~[(9)]~~ of this section.

(1) A licensee shall not advertise the licensee's services except as provided by 201 KAR 21:065.

(2) A licensee shall not commit an act of sexual misconduct, sexual harassment, or any act punishable as a sexual offense.

(3) A licensee shall refrain from chemical or substance abuse. The chemical or substance abuse shall not have to take place in a chiropractic office for the board to take action against a licensee.

(4)(a) Division of a professional fee shall not be made, except upon the basis of actual services rendered.

(b) Unless prohibited by law, each licensed chiropractor of a business entity shall be allowed to pool or apportion fees received in accordance with a business agreement.

(5)(a) A licensee shall not pay or receive compensation for the referral or unlawful solicitation of patients.

(b) A licensee, employee of a licensee, agent of a licensee, contractor of a licensee, or anyone acting in concert with the licensee shall not provide monetary compensation or other consideration of value to an individual in order to induce or entice the individual to commence a chiropractor-patient relationship or continue as a patient of the licensee.

(6)(a) Telemarketing shall be permitted only if the telemarketing is nontargeted, taken from a general list of phone numbers, and if not violating the state's no-call provisions.

(b) The licensee shall be held responsible for the content of any contact made by a telemarketer, agent, employee, or contractor representing the chiropractor.

(7) A licensee shall report to the board any reasonably suspected violation of KRS Chapter 312 or 201 KAR Chapter 21 by another licensee or applicant within thirty (30) days.

(8) A licensee shall report to the board any guilty plea, criminal conviction other than minor traffic violations, civil judgment, settlement, or civil claim made against the licensee within thirty (30) days.

(9) A licensee shall report to the board any discipline from another state licensing board within thirty (30) days of receiving notice of final disciplinary action.

(10) A licensee shall report to the board any malpractice settlement over $10,000 within thirty (30) days of the settlement of the claim.

Section 2. Each licensee shall comply with the minimum standards of practice established in subsections (1) through (6) of this section. (1) A licensee shall keep in confidence whatever the licensee may learn about a patient in the discharge of professional duties. Information shall be divulged by the licensee only if required by law or authorized by the patient.

(2) A licensee shall render care to each patient that is consistent with treatment and care that would be rendered by a reasonably prudent chiropractor licensed in the Commonwealth of Kentucky and shall give a candid account of a patient's condition to the patient, or to those responsible for the patient's care.

(3) A licensee shall inform the patient of the licensee's clinical diagnosis, treatment plan, and expected outcome of treatment prior to the onset of care.

(4) A licensee shall give timely notice to the licensee's patient or to those responsible for a patient's care if the licensee withdraws from a case so that the patient may obtain another chiropractor.

(5) A licensee shall not abandon a patient.

(6) A licensee shall practice the licensee's profession in accordance with the provisions of KRS Chapter 312 and 201 KAR Chapter 21.

Section 3. (1) Each licensee shall cooperate with the board by:

(a) ***Submitting*** ~~***[Furnishing]***~~ germane documents requested by the board;

(b) ***Submitting*** ~~***[Furnishing]***~~ in writing a complete explanation covering the matter contained in the complaint filed with the board;

(c) Appearing before the board at the time and place designated; ~~***[and]***~~

(d) Properly responding to a subpoena issued by the board; ***and***

(e) The board ***shall*** ~~***[will]***~~ in each renewal cycle, audit a minimum of fifteen (15) percent of renewals to assure compliance with continuing education requirements. Licensees, if selected for audit, shall cooperate and provide requested information so the audit may be conducted.

(2) A licensee shall comply with an order issued by the board.

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.

KENTUCKY BOARD OF CHIROPRACTIC EXAMINERS

Andy Beshear
Governor

P. O. Box 1360
Frankfort, Kentucky 40602
Phone (502) 892-4250
Fax (502) 564-4818
http://kbce.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 21:025

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 21:025, the Kentucky Board of Examiners of Chiropractic proposes the attached amendment to 201 KAR 21:025.

Sincerely,

Jeff Smith, DC

Chair, Kentucky Board of Examiners of Chiropractic
500 Mero Street
P.O. Box 1360
Frankfort, KY 40601

Final 11/19/2020 11:39 AM
SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Chiropractic Examiners

201 KAR 21:025. Board; officers, duties, and compensation.

RELATES TO: KRS 312.019, 312.055
STATUTORY AUTHORITY: KRS 312.019
NECESSITY, FUNCTION, AND CONFORMITY: KRS 312.055 requires the election of certain officers by the board. KRS 312.019(6) authorizes the board to employ personnel and incur expenses necessary for the performance of its duties. This administrative regulation establishes the duties of the officers, field personnel, and administrative staff, establishes the terms and procedure for election of officers, and establishes compensation.

Section 1. The officers of the board shall perform the duties established in this section.

(1) The president shall be the chief executive of the board. The president shall preside over all meetings of the board.

(2) The vice president shall perform the duties of the president during the president's absence or inability to serve. The vice president shall perform other reasonable duties delegated to him by the president or by the board.

(3) The executive secretary shall, if necessary or upon the discretion of the board***[, perform the following duties]***:

(a) Record and present the minutes of a meeting to the board at the next scheduled meeting;

(b) ***Supervise[Oversee]*** the administrative functions of the board; and

(c) Perform other reasonable duties delegated to the [secretary or] executive secretary by the [president or the] board.

Section 2. The board may employ a field coordinator as a part of the regular staff of the board. The field coordinator shall be paid a salary as the board may determine.

(1) The field coordinator may be a member of the board, except that the president or executive secretary, as referenced in KRS 312.055(1), shall not serve as field coordinator.

(2) The field coordinator shall:

(a) Investigate complaints against licensees referred ***[to him]***by the board for investigation and report ***[his]***findings to the board;

(b) Not vote on any matter relative to formal or informal complaints against any licensee if:

1. Any of the charges were investigated by him in the capacity of field coordinator; and

2. The field coordinator is a board member; and

(c) Perform other reasonable duties as are delegated ***[to him]***by the [president or by the] board.

(3)(a) If the field coordinator is a member of the board, following ***the[his]*** appointment as field coordinator, he ***or she*** shall serve until the conclusion of his term of appointment as a member of the board.

(b) A member who has been appointed to the position of field coordinator, who is reappointed to the board following the expiration of ***the[his]*** original term, shall continue in the position of field coordinator until a successor is appointed, and accepts and assumes the duties of the position.

(c) A person appointed as field coordinator may be reappointed by the board to the position.

(4) The administrative staff shall assist the board in the performance of its duties and shall:

(a) Keep an accurate and up-to-date file of all licensees of the board, including:

1. Addresses, e-mail addresses, and telephone numbers;

2. Status as to whether or not they are in active practice or are inactive;

3. Whether a licensee is in practice in this state or out of it;

4. Documents establishing attendance at educational programs if ***these[same]*** have been requested by the board;

5. All fees paid by licensees; and

6. Providing to the board, at least once each year, the names of licensees who are delinquent in the payment of fees or attendance of educational programs;

(b) Transmit notices for renewal of licenses as provided by KRS 312.175(2);

(c) Transmit notices of special meetings of the board; and

(d) Attend to the correspondence and communications of the board.

Section 3. A member elected as president, vice president, [secretary,] or executive secretary shall serve in office for one (1) year. An officer may be reelected by the board. Officer elections shall take place at the last meeting of the calendar year and shall take effect the first meeting of the following calendar year.

Section 4. Salary and Per Diem Compensation. (1) [The executive secretary, if elected, shall receive a salary of $1,100 per month.

(2)] Board members shall receive $100 per day for each day of actual service to the board.

Section 5. Financial Audit of Board Accounts. (1) The board shall cause, on a biennial basis, an independent financial audit of board accounts to be conducted and a report made to the board of the results***[of same]***.

(2) The annual financial audit shall be conducted by the Kentucky Auditor of Public Accounts, or by an independent auditor qualified and licensed as a certified public accountant, and retained by the board***.[to perform the audit,]*** If the Auditor of Public Accounts declines to perform the audit***, the board shall perform the audit***.

(3) The audit shall be of the previous year's accounts, unless the board finds ***[in its judgment]***that a broader audit ***is necessary[should be conducted]***, and votes to conduct a broader audit by a majority of the board. The board vote shall define the scope of the audit sought.

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.

KENTUCKY BOARD OF CHIROPRACTIC EXAMINERS

Andy Beshear
Governor

P. O. Box 1360
Frankfort, Kentucky 40602
Phone (502) 892-4250
Fax (502) 564-4818
http://kbce.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 21:045

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 21:045, the Kentucky Board of Examiners of Chiropractic proposes the attached amendment to 201 KAR 21:045.

Sincerely,

Jeff Smith, DC

Chair, Kentucky Board of Examiners of Chiropractic
500 Mero Street
P.O. Box 1360
Frankfort, KY 40601

Final 12/1/2020 2:57 PM
SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Chiropractic Examiners

201 KAR 21:045. Specialties.

RELATES TO: KRS ***312.015, 312.017,*** 312.019, 312.021
STATUTORY AUTHORITY: KRS 312.019, 312.021
NECESSITY, FUNCTION, AND CONFORMITY: KRS 312.021 requires the board to identify by administrative regulation those specialties of chiropractic for which certification may be granted and to establish by administrative regulation the procedure for obtaining and maintaining certification and the fees therefor. This administrative regulation ***establishes requirements for obtaining specialty certification*** ***[~~implements KRS 312.021~~]***.

Section 1. (1) A licensee in active practice and in good standing with the board who makes a written request to the board, provides proof of education, and pays the fee established in Section 3 of this administrative regulation shall be certified as a specialist in the licensee's field of certification, if the licensee holds certified or diplomate status with a certification granting entity.

(2) The certification or diplomate program shall be:

(a) Recognized by the American Chiropractic Board of Specialties or comparable authority with a comparable education level; and

(b) Within the scope of practice as ***established*** ***[~~defined~~]*** by KRS 312.015 and 312.017.

(3) Specialties certified ***shall*** include those such as radiology, nutrition, orthopedics, neurology, and pediatrics as approved by the American Board of Chiropractic Specialties.

(4) The complete list of approved and certified specialties is available on the board's current Web site [~~at www.kbce.ky.gov~~].

Section 2. The applicant for certified status under Section 1 of this administrative regulation shall submit with the applicant's written request proof of current status with the specialty certificate issuing board. Certification by the board shall be for a stated period of time not exceeding one (1) year.

Section 3. ***[~~The board may charge a reasonable fee for certification of specialties.~~]***The fees currently charged by the board are $100 for certification of each specialty and thirty (30) dollars for annual renewal.

Section 4. Advertisement of Designation of Chiropractic Certifications. (1) Advertisement of chiropractic specialties shall include the word "chiropractic" with any specialty designation and conform to the standards established in ***201 KAR Chapter 21*** ***[~~these administrative regulations~~]***.

(2) Any designation or certification not recognized by the board may only be advertised if:

(a) The designation or certification is not abbreviated, but is written out;

(b) The certifying or conferring college, university, or organization is named; and

(c) Proof of attainment of the advertised designation or certification is on file at the board office.

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.

KENTUCKY BOARD OF CHIROPRACTIC EXAMINERS

Andy Beshear
Governor

P. O. Box 1360
Frankfort, Kentucky 40602
Phone (502) 892-4250
Fax (502) 564-4818
http://kbce.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 21:051

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 21:051, the Kentucky Board of Examiners of Chiropractic proposes the attached amendment to 201 KAR 21:051.

Sincerely,

Jeff Smith, DC

Chair, Kentucky Board of Examiners of Chiropractic
500 Mero Street
P.O. Box 1360
Frankfort, KY 40601

Final 12/1/2020 2:58 PM
SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Chiropractic Examiners

201 KAR 21:051. Board hearings.

RELATES TO: KRS 312.150, 312.160, 312.163
STATUTORY AUTHORITY: KRS 312.019(5), (9)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 312.109(5) authorizes the board to enforce and investigate violations. KRS 312.019(9) authorizes the board to promulgate administrative regulations consistent with KRS Chapter 312, governing the practice of chiropractic. KRS 312.150 authorizes disciplinary action to be taken against a licensee. KRS 312.160 requires a right to an appeal for a licensed person disciplined after a hearing. This administrative regulation establishes procedural guidelines for board hearings and the processing of complaints against a licensee.

Section 1. Complaints and Investigations. (1) A complaint may be made by any person, organization, or entity. A complaint made by a person, organization, or entity shall be in writing and shall be signed by the person offering the complaint. The complaint shall contain:

(a) The name, phone number, and address of the person making the charge and the name and address of the place of business of the person or persons against whom charges are made; and

(b) A clear and concise description of the issues of fact.

(2) Upon receipt of a complaint against a licensee, the board shall send a copy of the complaint to the licensee for a response.

(a) The complaint shall be sent to the last known address of the licensee that the board has on file. Proof of mailing of the complaint to the licensee's last address on file shall constitute proof of service of the complaint.

(b) The licensee shall file a response within twenty (20) days from the date of the board's letter.

(c) The board shall review the complaint and the licensee's response before it determines if the nature and quality of the charges warrant dismissal, further investigation, or the initiation of a hearing.

(d) In making its determination, the board shall consider if the charges if proven would warrant sanction by the board.

(e) If the licensee fails to file a response within twenty (20) days of service of the complaint, the board may, ***based on lack of good cause*** ~~***[in its discretion]***~~, treat such failure as a default by the licensee, which in this case shall be equivalent to a finding that the factual allegations of the complaint may be taken as true. The board shall also have the authority to grant extensions of time for filing of a response ***based on the reason***.

(3) The board may proceed against a licensee on its own initiative either on the basis of information contained in its own records or on the basis of information obtained through its own investigation.

(4) The filing of formal charges shall require the affirmative vote of a majority of the board.

(5)(a) If the board finds that allegations against a licensee are insufficient for initiation of a formal disciplinary procedure, it shall dismiss the matter and notify all interested parties.

(b) If the board determines that disciplinary proceedings are appropriate, the board shall issue a notice of disciplinary action and inform the licensee of the specific reason for the board's action, including the:

1. Statutory or regulatory violation;
2. Factual basis on which the disciplinary action is based; and
3. Penalty to be imposed.

(c) The licensee, or the complainant may appeal the disciplinary action ***established~~[set forth]~~*** in the notice of disciplinary action to the board. An appeal shall be made within twenty (20) days of the date of the board's notice.

1. A written request for an administrative hearing shall be filed with the board within twenty (20) calendar days of the date of the board's notice. This request shall be sent to the Board of Chiropractic Examiners by mail or delivery to [~~P.O. Box 183, Glasgow, Kentucky 42142 or by delivery to 905 South Green Street, Glasgow, Kentucky 42141.~~] the board's address as shown on the board's notice of disciplinary action.

2. If the request for a hearing is not timely filed, the notice of disciplinary action shall be effective upon the expiration of the time for the licensee to request a hearing.

(d) The board may resolve the matter informally through mediation or negotiation. Any agreed order reached through mediation or negotiation shall be approved by the board and signed by the individual who is the subject of the complaint, the individual's attorney, and the chair of the board.

Section 2. (1) The hearing shall be held in accordance with KRS Chapter 13B.

(2) The respondent ***shall~~[may]~~*** be entitled to a reasonable continuance of the hearing date, for good cause, as recommended to the board by the hearing officer.

(3) The board shall keep a record of the hearing ***at least for as long as the matter is pending for a decision or appeal, and for the duration of the disciplinary action*** .

(4) It shall take a majority of the board to sustain the charges against the respondent licensee. The hearing officer shall issue a recommended order pursuant to KRS Chapter 13B, which the board shall consider, along with any exceptions filed by the parties, before issuing a final order.

(5) If the board sustains some or all of the charges, the board shall by majority vote establish the sanction under law ***that~~[which]~~*** it finds warranted. The order of the board shall be mailed to the parties [~~respondent~~] by certified mail, return receipt requested.

Section 3. Pursuant to KRS 312.160, the respondent may, within thirty (30) days of receipt of the order, appeal to the Franklin Circuit Court. In the absence of an appeal, the order of the board shall be final at the expiration of the thirty (30) day period.

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.

KENTUCKY BOARD OF CHIROPRACTIC EXAMINERS

Andy Beshear
Governor

P. O. Box 1360
Frankfort, Kentucky 40602
Phone (502) 892-4250
Fax (502) 564-4818
http://kbce.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 21:055

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 21:055, the Kentucky Board of Examiners of Chiropractic proposes the attached amendment to 201 KAR 21:055.

Sincerely,

Jeff Smith, DC

Chair, Kentucky Board of Examiners of Chiropractic
500 Mero Street
P.O. Box 1360
Frankfort, KY 40601

Final 11/19/2020 3:26 PM
SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Chiropractic Examiners

201 KAR 21:055. Colleges and universities; accreditation, approval.

RELATES TO: KRS 312.019(2), (9)(b), 312.085
STATUTORY AUTHORITY: KRS 312.019(9)(b)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 312.019 ***requires~~[provides that]~~*** the board ***to~~[shall]~~*** pass upon the qualifications of applicants for a license. KRS 312.085 ***requires~~[provides that]~~*** each applicant ***to~~[shall]~~*** be a graduate of a chiropractic college or university ***that~~[which]~~*** maintains a standard and reputability approved by the board. ***This administrative regulation establishes the requirements for board approval of educational institutions~~[The purpose of this administrative regulation is to delineate the characteristics of institutions which are approved by the board]~~***.

Section 1. A person who makes application to the board to practice chiropractic shall be a graduate of a chiropractic college or university ***that shall be~~[which is]~~*** accredited as required by KRS 312.085. In addition to accreditation, the chiropractic college or university shall offer a course of study, provide a faculty, and have a physical plant and facility ***~~[which are]~~***approved by the board. The following minimum standards shall apply:

(1)(a) The chiropractic college or university shall have ***well-stated~~[well-stated]~~*** goals and purposes to prepare the doctor of chiropractic as a competent health care provider, well-educated to diagnose and treat ***~~[his]~~***patients and to render the augmentative treatment provided for by KRS 312.015.

(b) It shall have a course of study, an administration, teaching staff, a physical plant and facility capable of achieving these objectives.

(2)(a) The chiropractic college or university shall offer courses of instruction to teach and train its graduates ,as ***established~~[set forth]~~*** by the Council on Chiropractic Education.~~[.]~~ as doctors of chiropractic to diagnose and treat their patients and to render augmentative care.[

~~(b) Courses offered shall include:~~

~~1. Anatomy;~~
~~2. Physiology;~~
~~3. Pathology;~~
~~4. Neurology;~~
~~5. Histology;~~
~~6. Hygiene;~~
~~7. Bacteriology;~~
~~8. Chemistry;~~
~~9. Chiropractic orthopedics;~~
~~10. Diagnoses;~~
~~11. Argumentative procedures, and use and effects of x-rays; and~~

~~12. Chiropractic principles and practices.~~]

(c) It shall require for graduation and completion the amount and quality of classroom instruction ***and[;]*** laboratory and clinical experience required of chiropractic colleges or universities by the Council on Chiropractic Education.

(d) The college or university shall also offer courses of continuing education on a postgraduate level.[

~~(3)(a) Seventy-five (75) percent of the members of the full-time faculty of the chiropractic college or university shall hold graduate degrees in the field of chiropractic or graduate degrees in the allied field in which they teach.~~

~~(b) A course for which credit is given shall be taught by a person who holds a degree in chiropractic or in the allied field in which he teaches.~~

~~(4)(a) The chiropractic college or university shall have exclusive possession of buildings adequate to accommodate the student body, faculty and administration, with classrooms, laboratories, clinic, library, research facilities and offices.~~

~~(b) The plant, grounds, equipment and facilities shall be maintained in a safe, sanitary, efficient and attractive condition.~~

~~(c) The chiropractic college or university shall fully comply with all applicable statutes, administrative regulations, ordinances and codes pertaining to health and safety.~~

~~Section 2. (1) Each chiropractic college or university shall engage in a comprehensive, active and ongoing self-evaluation program conducted by representatives from its administration, faculty and student body.~~

~~(2) A report of that evaluation shall be submitted to the board from the college or university upon written request of the board.~~

~~(3) The college or university shall also submit, upon written request by the board;~~

~~(a) Its catalog and supplemental materials and information sufficient to advise the board of the courses offered and the instructors thereof;~~

~~(b) The faculty and staff of the college or university, the courses they teach and the duties they perform, their educational attainment, professional memberships and professional positions held by them;~~

~~(c) The physical plant of the college or university, including the number and size of buildings, classrooms, libraries, laboratories, offices and clinic; the extent of laboratory training and clinical experience available to its students; the books and materials available in its library;~~

~~(d) The number of students at each level of educational attainment;~~

~~(e) The calendar of the college or university showing the beginning and ending dates of its terms, the vacation periods, the holidays observed, and the examination periods; and~~

~~(f) Any other information as may be requested by the board to assist it in evaluating the college or university and its ability to produce graduates qualified to diagnose and treat patients as doctors of chiropractic.~~

~~Section 3. (1) The board and any designees of the board shall have the right to inspect and observe any aspect of the educational program, plant and facilities of any chiropractic college or university which has a graduate or graduates to apply to be licensed by the board.~~

~~(2) Upon request of a college or university, the board shall designate an inspection team consisting of not more than five (5) members to inspect the college or university and to observe operations and to report its observations to the board with respect to the manner in which the college or university is complying with the standards set forth or alluded to in this administrative regulation.~~

~~(3) The expenses of the inspection team and reasonable compensation for members of the inspection team who are not members of the board shall be paid by the requesting college or university.~~]

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.

KENTUCKY BOARD OF CHIROPRACTIC EXAMINERS

Andy Beshear
Governor

P. O. Box 1360
Frankfort, Kentucky 40602
Phone (502) 892-4250
Fax (502) 564-4818
http://kbce.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 21:065

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 21:065, the Kentucky Board of Examiners of Chiropractic proposes the attached amendment to 201 KAR 21:065.

Sincerely,

Jeff Smith, DC

Chair, Kentucky Board of Examiners of Chiropractic
500 Mero Street
P.O. Box 1360
Frankfort, KY 40601

Final 12/1/2020 3:02 PM
SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Chiropractic Examiners

201 KAR 21:065. Professional advertising; seventy-two (72) hour right of rescission.

RELATES TO: KRS 312.019(9)(g), 312.021, 312.991
STATUTORY AUTHORITY: KRS 312.019(9), 312.021(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 312.021(1) ***requires that[~~prohibits~~]*** advertising ***shall not be[~~that is~~]*** false, deceptive, or misleading. KRS 312.019(9)(g) authorizes the board to promulgate administrative regulations to regulate forms of advertising and authorizes the board to establish a seventy-two (72) hour rescission period for a consumer responding to certain forms of solicitation or advertising. This administrative regulation establishes limits of permissible professional advertising to safeguard the public from false or misleading statements and nuisance type advertising. This administrative regulation also ***establishes[~~defines~~]*** the forms of solicitation or advertising ***in which[~~wherein~~]*** the responding consumer shall be granted a seventy-two (72) hour rescission period.

Section 1. ***[~~Interpretation, application, and any disciplinary action taken pursuant to this regulation shall be at the sole discretion of the board as part of its statutory function of regulating the profession of chiropractic.~~***

~~Section 2.~~] A licensee may advertise chiropractic services through any medium if the advertisement is not false, deceptive, or misleading. (1) An advertisement shall include:

(a) If the business name used in the advertisement has the word "chiropractic" in it, then ***[~~no~~]***additional information ***shall not be[~~is~~]*** required***; or[.]***[~~Business name and address;~~

~~(b) Chiropractor's name;~~

~~(c) Telephone number;~~

~~(d) Expiration date of the advertisement, if any; and~~]

(b)[~~(e)~~] If the word "chiropractic" is not included in the name of the business, then the advertisement ***shall[~~must~~]*** contain the name of at least one (1) doctor in the office and clearly identify them as a doctor of chiropractic, or clearly state in some manner that the office is a chiropractic office. Words or letters designating the particular doctor degree held by the chiropractor. "D.C." shall designate a doctor of chiropractic.

(2) Deviation from these requirements shall first be approved by the board.[

~~(3) An advertisement offering a free or discounted service shall include complete a notice of the right of rescission, which notice shall not be smaller than ten (10) point font.~~]

Section 2. Consumer Rights, Notice. (1) The board may choose***, in accordance with this administrative regulation[~~in its sole discretion~~]***, to require a licensee to place a consumer notice of a seventy-two (72) hour right of rescission on any advertisement offering a free or discounted service.

(a) A chiropractor advertising free or discounted services shall in any advertisement or solicitation provide the consumer with notice, in print of no less than ten (10) point font, of the seventy-two (72) hour right of rescission. ***The~~[Such]~~*** notice shall include information on the form and manner in which the patient ***shall~~[must]~~*** exercise the right of rescission.

(2)(a) Within ten (10) days of a notice of rescission, the chiropractor shall tender to the consumer any payment made by the consumer prior to the rescission for an unadvertised service performed.

(b) If payment had not yet been made by the consumer for an unadvertised service, the consumer's account shall not be billed for that service.

(3)(a) In order to be effective, the notice of rescission shall be given by the consumer to the chiropractor within seventy-two (72) hours of the completion of the advertised free or discounted service or agreement to submit to a series or course of treatments.

(b) The notice shall be:

1. In writing; and
2. Express the intention of the consumer to rescind his or her obligation.

(c) If notice of rescission is given by mail, it shall be effective if it:

1. Is properly addressed;
2. Has sufficient postage affixed; and
3. Is postmarked.

Section 3. (1) A written advertisement may be sent or delivered to an individual addressee only if [~~(a) That addressee is one (1) of a class of persons, other than a family, to whom it is also sent or delivered at or about the same time; and (b)~~] it is not prompted or precipitated by a specific event or occurrence involving or relating to the addressee or addressees as distinct from the general public.

(2) A licensee who advertises a fee for routine services and accepts the employment shall perform the services for the amount advertised, and a statement to that effect shall be included in every advertisement in which a fee is listed.

Section 4. If a complaint is filed with the board regarding an advertisement of a licensee, the board shall request, and the licensee shall ***submit~~[furnish]~~***, a copy of the advertisement, including audio or video if the advertisement is in ***audio or video~~[such]~~*** medium.[

~~Section 5. Advertisement of Designation of Chiropractic Certifications.~~

~~(1) Advertisement of chiropractic specialties as established in 201 KAR 21:045 shall include the word "chiropractic" with any specialty designation and conform to the standards established in this administrative regulation.~~

~~(2) Any designation or certification not recognized by the board may only be advertised if:~~

~~(a) The designation or certification is not abbreviated, but is written out;~~

~~(b) The certifying or conferring college, university, or organization is named; and~~

~~(c) Proof of attainment of the advertised designation or certification is on file at the board office.~~]

Section 5[~~6~~]. A licensee shall post his or her name on the premises where a chiropractic service is being offered, and the name(s) of all associate licensees who practice chiropractic on the premises. [~~and the posted name~~] The posted names shall be clearly visible to the public at the entrance to the premises, or on a sign visible outside of the premises, that offers the delivery of chiropractic services

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.

KENTUCKY BOARD OF CHIROPRACTIC EXAMINERS

Andy Beshear
Governor

P. O. Box 1360
Frankfort, Kentucky 40602
Phone (502) 892-4250
Fax (502) 564-4818
http://kbce.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 21:075

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 21:075, the Kentucky Board of Examiners of Chiropractic proposes the attached amendment to 201 KAR 21:075.

Sincerely,

Jeff Smith, DC

Chair, Kentucky Board of Examiners of Chiropractic
500 Mero Street
P.O. Box 1360
Frankfort, KY 40601

Final 12/1/2020 3:05 PM
SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Chiropractic Examiners

201 KAR 21:075. Peer review committee procedures and fees.

RELATES TO: KRS 312.200
STATUTORY AUTHORITY: KRS 312.015, 312.019, 312.200
NECESSITY, FUNCTION, AND CONFORMITY: KRS 312.200 requires the board to appoint a peer review committee and establish procedures and fees for the review of submitted claims. This administrative regulation establishes fees and procedures pertaining to the peer review committee.

Section 1. Peer Review Committee. (1) The board shall appoint a Peer Review committee of up to four (4) members. ***[~~Subject to the below regulation,~~]***All members of the peer review committee ***may[~~shall~~]*** serve a three (3) year term.

(a) Each member of the Peer Review committee shall serve until their successor is appointed and qualified.

(b) Appointments to fill vacancies shall be for the unexpired term.

(c) Applicants for appointment to the Peer Review committee shall make application on the same form utilized by applicants for appointment to the board, except filed with the board and not the Governor's office, and shall include a cover letter stating that the application is for the Peer Review Committee.

(2) Members of the Peer Review committee shall be doctors of chiropractic of integrity and ability who at the time of their appointment have been actual residents of the Commonwealth of Kentucky for at least two (2) years next preceding their appointment, and have been engaged in the actual practice of chiropractic for at least five (5) years next preceding their appointment.

(3) Any member of the peer review committee shall not hold an elected position in any state organization or association relating to or consisting of licensees of this board***[,]*** or the practice of chiropractic.

(4)***(a)*** Beginning ***on March 1,[~~in~~]*** 2021, the longest-serving member on the Peer Review committee shall be replaced by a member with a three (3) year appointment.

(b)[;] In 2022, the next longest-serving member of the Peer Review committee shall be replaced by a member with a three (3) year appointment.

(c)[;] In 2023, the next longest-serving member on the Peer Review committee shall be replaced by a member with a three (3) year appointment.

(d)[~~; and~~] In 2024, the next longest-serving member shall be replaced by a member with a three-year appointment.

(e) Thereafter, each appointee to the Peer Review committee shall be appointed to a three (3) year term.

(f) This ***subsection shall[~~provision does~~]*** not prohibit any member of the peer review committee from serving consecutive terms.

Section 2. Procedures and Fees of Peer Review Committee. (1) Peer review shall not take place until the patient has submitted a release permitting photocopies of the applicable treatment or billing records prepared by the chiropractor in the regular course of business.

(a) Treatment records shall not be released for peer review without the patient's authorization.

(b) The acceptance of, or the request for, payment by a chiropractor shall constitute the consent of the chiropractor to the submission of all necessary records and other information concerning the treatment or the cost to the peer review committee.[

~~(c) Six (6) copies of all records or other data shall be submitted to the committee.~~]

(2)(a) Each claim shall be assigned to an individual member of the committee who shall review the submitted records and response from the charged party and report his findings to the full committee, which shall review the findings and either adopt those findings or modify them as determined by majority vote.

(b) A copy of the findings shall be forwarded to the board, the patient, the chiropractor, and insurer or other third party payor.

(3)(a) The peer review committee shall elect a chair.

(b) The committee may recommend for the board's approval a contract with or employment of third parties to perform administrative functions or to aid in obtaining records necessary for appropriate review of claims.

(c)1. The peer review committee shall recommend to the board that a complaint be filed against a chiropractor if it appears from the review of a claim that reasonable cause exists to believe that the chiropractor has violated any portion of KRS Chapter 312 or 201 KAR Chapter 21 for which a chiropractor may be disciplined.

2. The peer review committee shall transmit all complaint information the committee possesses to the board.

(4)(a) A chiropractor, insurer, or other third party payor requesting review shall submit with the request a service fee of fifty (50) dollars payable to "B.C.E. Peer Review."

(b) An additional fee shall be charged for claims requiring more than one (1) hour of review by the committee calculated at fifty (50) dollars per hour, which sum shall be due prior to the delivery of committee findings to all parties.

(c) All fees shall be paid by the chiropractor, insurer, or other third party payor requesting the review.

(5) Each member of the peer review committee shall comply with the requirements and standards established in 201 KAR 21:095.

Section 3. [~~2.~~] Annual Report. (1) An annual summary of the findings of the peer review committee shall be prepared by the committee and submitted to the board.

(2) The report shall be made available to interested persons upon request and upon payment of the cost of reproduction.

(3) A report or summary submitted to the public by the board shall not disclose the name or identity of any patient without the patient's consent.

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.

KENTUCKY BOARD OF CHIROPRACTIC EXAMINERS

Andy Beshear
Governor

P. O. Box 1360
Frankfort, Kentucky 40602
Phone (502) 892-4250
Fax (502) 564-4818
http://kbce.ky.gov

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 21:085

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 21:085, the Kentucky Board of Examiners of Chiropractic proposes the attached amendment to 201 KAR 21:085.

Sincerely,

Jeff Smith, DC

Chair, Kentucky Board of Examiners of Chiropractic
500 Mero Street
P.O. Box 1360
Frankfort, KY 40601

Final 12/1/2020 3:33 PM
SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Chiropractic Examiners

201 KAR 21:085. Preceptorship Program.

RELATES TO: KRS 312.019(9)(h), 312.085(2)
STATUTORY AUTHORITY: KRS 312.019(9), 312.085(2)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 312.019(9)(h) and 312.085(2) authorize the board to establish a preceptorship program through which students at accredited colleges and universities may work at the direction and under the supervision of a licensed doctor of chiropractic prior to graduation. This administrative regulation establishes the preceptorship program.

Section 1. Requirements of Preceptor. A preceptor shall:
(1) Be approved by the Kentucky State Board of Chiropractic Examiners for participation;
(2) Have a current Kentucky license that is active and in good standing;
(3) Have been in practice for five (5) years or more in Kentucky;
(4) Provide evidence of malpractice insurance;
(5) Be of good moral character, proof of which shall be evidenced by ***at least*** three (3) letters of reference from persons outside the licensee's family;
(6) Not practice while impaired by alcohol or narcotics;
(7) Have not been found in violation of a requirement of 201 KAR Chapter 21, other than for a minor advertising violation, for the preceding two (2) years and have no present investigations (including during a term as preceptor) for possible violations; and
(8) Comply and be qualified as applicable. The board shall encourage development of extension faculty designation for all preceptors approved by the colleges or university.

Section 2. Preceptor Relationship with College or University and Intern. (1) The preceptor shall make a joint application to the board and the college or university.
(2) The preceptor shall arrange or confer with the college or university representative prior to the beginning date of each session to plan the program duration, organization, and substance.
(3) The preceptor ***shall[is required to]*** maintain any records and reports related to the student's performance in compliance with the standards ***established[set forth]*** by the Council on Chiropractic Education and the college or university the student attends. [~~Upon assignment, the preceptor shall maintain complete records and reports of each student's performance and provide an evaluation to the college or university on forms provided by the college or university.~~
~~(a) Any incident reports related to the operation of the practicum education experience shall be maintained by the preceptor and shall be the sole property of the preceptor.~~
~~(b) Upon receipt of written consent by the college or university, board, or student, the preceptor shall provide a copy of the report.~~]

(4)(a) The preceptor may request the college or university to withdraw any student whose performance is unsatisfactory or whose health status prevents the student's successful completion of the practicum education assignment.

(b) A statement, in writing, of the reason for that action shall be provided by the preceptor to the college, university, or student upon request.

(5) The preceptor shall not be liable for the payment of any wage, salary, or compensation of any kind for services properly required of and performed by an intern.

(6) The preceptor shall provide the college or university with a written code of ethics that applies to the preceptor's office.

(7)(a) The preceptor shall ensure that interns ***shall be*** ~~***[are]***~~ allowed to perform only those duties that are lawful and ethical in the practice of chiropractic.[

~~(b) An intern shall not make a final diagnosis or perform an adjustment.~~]

(8)(a) The preceptor shall assume the risk of any accident or injury to any intern while on preceptor's premises, which shall include working areas.

(b) The preceptor shall maintain premises liability insurance.

Section 3. Requirements of Intern. (1) The intern shall submit a fee of $200 to the board for each semester he or she is participating in the preceptorship program.

(2) The intern shall remain in good standing academically and demonstrate an acceptable level of performance, both quantitatively and qualitatively, in the college or university outpatient clinic.

(3) The intern shall complete, sign, and submit all application materials ***from the internship program*** to the college or university clinic director for verification and approval.

(4) The intern shall serve in the preceptorship program for a term established by the college or university for the purpose of augmenting his competence in all areas of chiropractic practice.

(5) The intern shall provide both the college or university and the preceptor with a current telephone number and address.

(6) The intern shall be responsible for following all reasonable and lawful policies and procedures of the preceptor's office.

(7) The intern shall be responsible for providing and wearing professional attire.

(8) The intern shall be responsible for his own transportation and living arrangements.

(9) The intern shall report to the preceptor on time.

(10) The intern shall not submit for publication any material relating to his preceptorship without prior written approval of the preceptor and the college or university.

(11) The intern shall make ~~***[such]***~~reports as required by the Council on Chiropractic Education and the college or university under which the preceptorship is conducted. [~~ensure that biweekly reports shall be submitted by the preceptor to the college or university on his or her activities and progress.~~

~~(12) At the completion of the preceptorship, the intern shall present to the college or university clinic director a paper describing his or her experiences and summarizing the acquisition of knowledge during the preceptorship.~~]

(12[~~13~~]) The intern shall provide evidence of professional liability insurance from the college or university.

(13[~~14~~]) The intern shall respond to any inquiry by the board within twenty (20) days.

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.

PUBLIC PROTECTION CABINET
OFFICE OF CLAIMS AND APPEALS
500 Mero Street, 2SC1
Frankfort, KY 40601
Phone: (502) 782-8255
Fax: (502) 573-4817
http://kycc.ky.gov/

Andy Beshear
Governor

Ray Perry
Deputy Secretary

Kerry B. Harvey
Secretary

Edith Halbleib
Executive Director

December 1, 2020

Senator Stephen West, Co-Chair
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c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601
Via email RegsCompiler@LRC.KY.GOV

RE: Office of Claims and Appeals Regulations
Board of Tax Appeals – 802 KAR 1:010

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 802 KAR 1:010, the Office of Claims and Appeals proposes the attached amendment to 802 KAR 1:010.

Sincerely,

Edith Halbleib

Edith Halbleib
Executive Director
Office of Claims and Appeals
Public Protection Cabinet
500 Mero Street 2SC1
Frankfort, Kentucky 40601
(502) 782-8240 (Phone)
(502) 573-4817 (FAX)
Edith.halbleib@ky.gov

Subcommittee Substitute

PUBLIC PROTECTION CABINET
Office of the Secretary
(As Amended at ARRS)

802 KAR 1:010. Tax appeal procedures.

RELATES TO: KRS 12.027, Chapter 13B, 49.220, 49.230, 49.240, 49.250, EO 2020-708
STATUTORY AUTHORITY: KRS 49.020, 49.220(1)
NECESSITY, FUNCTION, AND CONFORMITY: Executive Order 2020-708 ("Order") requires that the Kentucky Claims Commission be abolished and the Office of Claims and Appeals be immediately established within the Public Protection Cabinet, and to include the Board of Tax Appeals. The Order also sets forth the powers and duties of the Board of Tax Appeals, and authorizes the board to promulgate regulations necessary to immediately carry out the provisions and purposes of the Order and the board's statutory authority. KRS 49.020(5) authorizes the board [~~commission~~] to promulgate administrative regulations that are necessary to carry out the provisions and purposes of the board's[~~commission's~~] statutory authority. KRS 49.220(1) authorizes the board[~~commission~~], with exclusive jurisdiction, to hear and determine appeals from final rulings, orders, and determinations of any agency of state or county government affecting revenue and taxation. This administrative regulation establishes the procedures governing tax appeals.

Section 1. Definitions. (1) "Board" means the Board of Tax Appeals.
(2) "Office" means the Office of Claims and Appeals.

Section 2. Rules for Filing Tax Appeals with the Board. (1) Initiation of tax appeal. A party wishing to appeal a final ruling, order, or determination of any agency of state or county government affecting revenue or taxation shall file a petition with the board for a formal hearing in accordance with KRS Chapter 13B.
(2) Timing. The initial petition of appeal shall be received by the board within thirty (30) days of the date of mailing of the final ruling, order, or determination of the agency of state or county government that is the subject of the appeal. If the determination is not mailed, then the initial petition shall be considered as received by the board within (30) days of the date of issuance.
(a) An untimely appeal shall be dismissed.
(b) If the appeal is timely filed, but deficient, the board, office, or hearing officer shall notify the petitioner of deficiencies and allow fifteen (15) business days to amend the petition.
(3) Format and content. A petition of appeal shall be legibly written, typed, or printed and contain ***[~~the following~~]***:
(a) A statement of all relevant issues of fact and law;
(b) A statement certifying that the information contained in the petition of appeal is true and correct to the best knowledge of the petitioner or counsel, if represented by an attorney;
(c) The signature of the petitioner or the signature of counsel, if represented by an attorney;
(d) The petitioner's mailing address, telephone number, and email address;

(e) If represented by an attorney, the petitioner's attorney's name, mailing address, telephone number, and email address; and

(f) A copy of the final ruling, order, or determination to be reviewed.

(4) Upon receiving a petition of appeal, the board shall provide notice to:

(a) The appellee that an action has been filed;

(b) The petitioner that the petition of appeal has been received; and

(c) The petitioner's counsel, if represented by an attorney.

(5) Upon receiving a Petition of Appeal, the appellee or the appellee's attorney shall file an entry of appearance within thirty (30) days of the date of the notice of appeal provided by the board. The entry of appearance shall contain the mailing address, telephone number, and email address of the appellee and the appellee's attorney, if applicable.

Section 3. Rules Applicable to All Filings. (1) Filings. All documents may be filed:

(a) In person or by private delivery to Board of Tax Appeals, 500 Mero Street, 2 SC1, Frankfort, Kentucky 40601;

(b) ***By*** mail to the address listed above; or

(c) ***By*** electronic mail to taxappeals@ky.gov if the document can be sent in one (1) electronic message.

(2) Service.

(a) Any party who files a pleading or motion with the board or hearing officer shall notify all other parties to the appeal by serving upon each party a copy of the pleading or motion filed. A filed pleading or motion shall be accompanied by a certification stating:

1. That a copy has been served on each party, or if the party is represented by counsel, on the party's counsel; and

2. The method of service used.

(b) Service upon a party shall be made by delivering a copy to the attorney or party, ***by*** electronic mail, or by mailing it to the attorney or party at the last known address. Service is complete upon mailing, unless the serving party learns or has reason to know that it did not reach the person to be served. Service by electronic mail shall be considered complete when sent if properly addressed. Documents filed by electronic mail shall be considered received when sent if properly addressed.[~~Rules Applicable to All Filings. (1) Filings. All documents shall be filed by mail, electronic mail to taxappeals@ky.gov, or in person. Documents filed by electronic mail shall be considered received when sent if properly addressed.~~

~~(2) Service. Any party who files a document with the commission or hearing officer shall serve to all other parties to the appeal a copy of the document filed. A filed document shall be accompanied by a certification stating: (a) That a copy has been served on each party; and (b) The method of service used.~~

~~Section 2. Rules for Filing Tax Appeals with the Commission. (1) Initiation of tax appeal. A party wishing to appeal a final ruling, order, or determination of any agency of state or county government affecting revenue or taxation shall file a petition of appeal with the commission.~~

~~(2) Timing. The initial petition of appeal shall be received by the commission within thirty (30) days of the date of mailing of the final ruling, order, or determination of the agency of state or county government that is the subject of the appeal.~~

~~(a) An untimely appeal shall be dismissed.~~

~~(b) If the appeal is timely filed, the commission or hearing officer shall notify the petitioner of deficiencies and allow fifteen (15) days to amend the petition.~~

~~(3) Format and content. A petition of appeal shall be legibly written, typed, or printed and contain the following:~~

~~(a) A statement of all relevant issues of fact and law;~~

~~(b) A statement certifying that the information contained in the petition of appeal is true and correct to the best knowledge of the petitioner or counsel, if represented by an attorney;~~

~~(c) The signature of the petitioner or counsel, if represented by an attorney;~~

~~(d) The petitioner's mailing address, telephone number, and email address;~~

~~(e) If represented by an attorney, the petitioner's attorney's name, mailing address, telephone number, and email address; and~~

~~(f) A copy of the final ruling, order, or determination to be reviewed.~~

~~(4) Upon receiving a petition of appeal, the commission shall provide notice to:~~

~~(a) The appellee that an action has been filed;~~

~~(b) The petitioner that the petition of appeal has been received; and~~

~~(c) The petitioner's counsel, if represented by an attorney.~~]

Section 4[~~3~~]. Representation in Proceedings before the Board [~~Commission~~]. (1) If the appeal is by an individual, the individual may proceed without an attorney or engage counsel to provide representation.

(2) An individual who is not an attorney shall not be permitted to represent any other individual or legal entity who is a party to an appeal.

(3) In accordance with Supreme Court Rule 3.020, if the appealing party is a corporation, joint venture, partnership, LLC, estate, or any entity other than ***an [~~in~~]*** individual as identified in subsection (1) of this section, the entity shall be represented by an attorney on all matters before the board, including the filing of the appeal.

(4) An attorney licensed to practice in another state, but not the Commonwealth of Kentucky, shall be permitted to represent a party before the board if the attorney complies with Supreme Court Rule 3.030(2).[~~The appellee or the appellee's attorney shall file an entry of appearance within thirty (30) days of the date of the notice of appeal provided by the commission. The entry of appearance shall contain the mailing address, telephone number, and email address of the appellee and the appellee's attorney, if any. (2) An individual who is not an attorney shall not represent any other individual or an entity or other individual who is a party to an appeal.~~]

Section 5[4]. Discovery. (1) Discovery may be obtained without prior order of the board [~~commission~~] or hearing officer. ***Except to the extent the provisions of this section differ,*** [~~pursuant to the~~] the Kentucky Rules of Civil Procedure (CR) governing depositions and discovery shall apply ***[~~except to the extent the provisions of this section differ~~]***.

(2) In addition to the provisions of CR 26 addressing opinions and use of expert witnesses:

(a) ***Absent a stipulation between the parties or an order issued by the board providing otherwise, and at least ninety (90) days before the date set for the hearing,*** a party shall disclose to the other party or parties the identity of any witness qualified as an expert by knowledge, skill, experience, training, or education the party may use at the hearing to provide

expert testimony ~~***[at least ninety (90) days before the date set for the hearing, absent a stipulation between the parties or an order issued by the board providing otherwise]***~~; or

(b) If the evidence is intended solely to contradict or rebut evidence on the same subject matter of a witness identified by another party, within thirty (30) days after the other party's disclosure.

(3)[~~(2)~~] The board [~~commission~~] or hearing officer may deny, limit, or require discovery.

(4)[~~(3)~~] If a party fails to comply with an order regarding discovery, the board [~~commission~~] or hearing officer may order that the:

(a) Matters that the requesting party was seeking to establish through discovery shall be taken as having been established for the purposes of the hearing;

(b) Noncomplying party shall be prohibited from introducing related documents or testimony at the hearing;

(c) Appeal be dismissed or relief be granted as requested by the opposing party;

(d) Appeal be stayed until the order is obeyed; or

(e) Noncomplying party, the advising attorney, or both pay the reasonable costs, including attorney's fees, caused by the failure to comply.

(5)[~~(4)~~] A response to discovery under subsection (1) of this section shall not be filed with the board [~~commission~~] unless required by order of the board or hearing officer.[~~or used as evidence.~~]

Section 6. Prehearing or Status Conference and Hearing Schedule. (1) In any appeal assigned to a board member or hearing officer, the board or hearing officer may schedule a prehearing or status conference. The prehearing or status conference may be conducted by telephone or other electronic means upon reasonable notice to all parties, which consists of prior notice of not less than five (5) days, unless otherwise agreed to by the parties.

(2) A prehearing or status conference may be used to set a hearing date, discuss jurisdictional matters, settlement possibilities, discovery, preparation of stipulations, clarification of issues, rulings on witnesses, taking of evidence, issuance of subpoenas, mediation, and other matters that will promote the orderly and prompt conduct of the hearing.

(3) If the board member or hearing officer and parties cannot agree upon a hearing date, the board member or hearing officer shall set the matter for hearing no later than six (6) months from the date of the conference.

(4) Upon conclusion of the prehearing or status conference, the board member or hearing officer shall issue an order including all matters determined at the prehearing or status conference.

Section 7[~~5~~]. Prehearing Filings. (1) At least thirty (30) days prior to the hearing, a party shall file with the board [~~commission~~] or hearing officer a:

(a) [~~(1)~~] Prehearing summary that contains a:

1.[~~(a)~~] Summary of the party's position on any issue of fact in dispute;

2.[~~(b)~~] Summary of the party's position on any issue of law raised by the appeal; and

3.[~~(c)~~] Written statement of facts to which the party agrees and any facts which [~~that~~] a party does not dispute;

(b)[~~(2)~~] List of the names, addresses, and phone numbers (if known) of all witnesses the party expects to call to testify as a witness at the hearing; [~~and~~]

(c)[~~(3)~~] Copy of all exhibits that the party intends to introduce at the hearing;

(d) Proposed findings of fact and conclusions of law; and

(e) Proposed final order if the appeal is heard by the board, or a proposed recommended order if the appeal is heard by a hearing officer.

(2)The prehearing filings required by ***this [~~the~~]*** section shall satisfy the requirements under KRS 13B.090(3) establishing a party's right to inspect a list of witnesses and documentary or tangible evidence at least five (5) days prior to the hearing. The board may issue a prehearing order modifying discovery procedures or deadlines, or mandating additional requirements for prehearing filings.

Section 8[~~6~~]. Motion Practice. (1) Any party may file a motion. Any party affected by a motion or pleading may file a response to the motion or pleading within thirty (30) [~~fifteen (15)~~] days from the date on which the motion or pleading was [~~originally~~] served.

(2) A moving party may file a reply to another party's response. The reply shall be filed within fifteen (15) days from the date the response was served. Other replies or responses shall not be filed, unless prior approval is granted by the board [~~commission~~] or hearing officer.

Section 9. Briefs. A party shall file with the board or hearing officer any brief required by order of the board or hearing officer. The board or hearing officer may require a party to file a post-hearing brief or to supplement at any time a brief already filed to assist in adjudicating the hearing. A brief shall include the signature of the party, or the party's counsel.

Section 10[~~7~~]. Summary Disposition. (1) At any time after the commencement of an appeal [~~has begun~~], a party may move for a summary disposition of the whole or a part of the appeal by filing a motion that:[~~, in which event the procedure established in subsections (1) through (4) of this section shall apply.~~

~~(1) The moving party shall file a motion that:~~]

(a) Asserts that there are no disputed material facts as to one (1) or more of the issues before the board [~~commission~~] or hearing officer;

(b) Includes a statement specifying which material facts are undisputed. Assertions of a material undisputed fact or facts may be submitted to the board or hearing officer through affidavits or responses made by another party to any discovery request, including answers to interrogatories, admissions, and depositions. Facts stated in the petition of appeal, including exhibits attached to the petition, may be relied upon as undisputed material facts by the appellee; and[~~A material undisputed fact may be submitted to the commission or hearing officer through affidavits, discovery responses, or deposition testimony;~~]

(c) States that any issue before the board [~~commission~~] or hearing officer for which summary disposition is sought is a matter of legal, and not factual, interpretation.[~~; and~~

~~(d) Attaches a copy of any legal authority that supports the moving party's position on any legal issue before the board [commission] or hearing officer.~~]

(2)(a) Within twenty (20) days after a party moves for summary disposition, any other party may file a response presenting the party's position on issues of law and fact, which shall include any affidavit, written response to discovery requests, deposition testimony, or statements in the Petition of Appeal, demonstrating the party's assertion that a material fact or facts are disputed.[~~shall:~~

~~1. Submit an~~ An ~~acknowledgment that there are no disputed material facts;~~

~~2. Submit a response stating that a material fact is in dispute, along with any affidavit, discovery response, or deposition testimony that shows the material fact in dispute. Facts stated in the petition of appeal and any document or exhibit attached thereto may be relied upon as undisputed material facts by the appellee; and~~

~~3. Attach all legal authorities that support the opposing party's position on any legal issue.~~]

(b) Failure of a nonmoving party to respond within twenty (20) days to the motion for summary disposition or to request additional time to respond to the motion may result in the board [~~commission~~] or hearing officer finding there are no disputed factual issues to be considered in deciding the legal issues.

(3) If the nonmoving party files a response to the motion for summary disposition, the moving party shall have ten (10) days to file a reply to the response.

(4) The board [~~commission~~] or hearing officer may grant a motion for summary disposition in whole or in part. If the board [~~commission~~] or hearing officer grants a summary disposition as to one (1) or more issues, but not all issues, then the remaining issues shall be heard by the board [~~commission~~] or hearing officer in accordance with this administrative regulation and KRS Chapter 13B.

Section 11[~~8~~]. Other. Except as otherwise stated in KRS Chapter 49 or this administrative regulation, the conduct of hearings shall be governed by the procedures established in KRS Chapter 13B.

CONTACT PERSON: Leah Cooper Boggs, Executive Advisor, 500 Mero Street 218NC, phone +1 (502) 352-8095, fax +1 (502) 564-3969, email LBoggs@ky.gov.

PUBLIC PROTECTION CABINET
OFFICE OF CLAIMS AND APPEALS
500 Mero Street, 2SC1
Frankfort, KY 40601
Phone: (502) 782-8255
Fax: (502) 573-4817
http://kycc.ky.gov/

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December 1, 2020

Senator Stephen West, Co-Chair
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c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601
Via email RegsCompiler@LRC.KY.GOV

RE: Office of Claims and Appeals Regulations
Board of Claims – 802 KAR 2:010

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 802 KAR 2:010, the Office of Claims and Appeals proposes the attached amendment to 802 KAR 2:010.

Sincerely,

Edith Halbleib

Edith Halbleib
Executive Director
Office of Claims and Appeals
Public Protection Cabinet
500 Mero Street 2SC1
Frankfort, Kentucky 40601
(502) 782-8240 (Phone)
(502) 573-4817 (FAX)
Edith.halbleib@ky.gov

TEAM KENTUCKY

Subcommittee Substitute

PUBLIC PROTECTION CABINET
(As Amended at ARRS)

802 KAR 2:010. Negligence claims before the Board of Claims [~~Kentucky Claims Commission~~].

RELATES TO: KRS 12.027, 49.020, 49.040, 49.090, 49.120, EO 2020-708
STATUTORY AUTHORITY: KRS 49.020(5)
NECESSITY, FUNCTION, AND CONFORMITY: Executive Order 2020-708 ("Order") requires that the Kentucky Claims Commission be abolished and that the Board of Claims, and the Office of Claims and Appeals be established. The Order also sets forth the powers and duties of the Board of Claims and the Office ***of Claims and Appeals*** and authorizes the board to promulgate emergency regulations necessary to carry out the provisions and purposes of the Order and the board's statutory authority. KRS 49.020(5) authorizes the board [~~commission~~] to promulgate administrative regulations that are necessary to carry out the provisions and purposes of the board's statutory authority. KRS 49.220(1) authorizes the board [~~commission.~~], with exclusive jurisdiction, to investigate, hear proof, and to compensate persons for damages sustained to either person or property as a proximate result of negligence on the part of the Commonwealth, any of its cabinets, departments, bureaus, or agencies, or any of its officers, agents, or employees while acting within the scope of their employment by the Commonwealth or any of its cabinets, departments, bureaus, or agencies. This administrative regulation establishes the [~~requirements and~~] procedures [~~for filing and adjudicating negligence~~] governing these claims[~~under the jurisdiction of the commission and the method of pleading and practice before the commission~~].

Section 1. Definition. (1) "Board" means the Board of Claims.
(2) "Office" means the Office of Claims and Appeals.

Section 2[~~1~~]. Filing Claims. Form and content. A claim shall be legibly written, typed, or printed and contain ***[~~the following~~]***:
(1) The name, address, telephone number, and email address of the claimant;
(2) The amount of the claim; and
(3) A statement of the facts that:
(a) ***Show [~~Shows that~~]*** the claimant may be entitled to relief pursuant to KRS 49.010 through 49.180; and
(b) Enables the agency against which a claim is made to investigate the claim and prepare its defense; and
(4) ***The signature of [~~Is signed by~~]*** the claimant and counsel for claimant, if any. [
~~(1) A claim shall:~~
~~(a) Be legibly written, typed, or printed;~~
~~(b) Contain:~~
~~1. The name, address, telephone number, and email address of the claimant;~~
~~2. The amount of the claim; and~~

~~3. A statement of the facts that:~~

~~a. Shows that the claimant may be entitled to relief pursuant to KRS 49.010 through 49.180; and~~

~~b. Enables the respondent agency to investigate the claim and prepare its defense; and~~]

Section 3. Rules Applicable to All Filings. (1) Filings. All documents may be filed:

(a) In person or by private delivery to the Board of Claims, 500 Mero Street, 2 SC1, Frankfort, Kentucky 40601;

(b) ***By*** mail to the address listed above; or

(c) ***By*** electronic mail to mailto:negligenceclaims@ky.gov, if the document can be sent in one (1) electronic message. [

~~(c) Be filed by mail, electronic mail at mailto:negligenceclaims@ky.gov, or delivered in person to the commission's office.~~]

(2) Service.

(a) Any party who files a pleading or motion with the board or hearing officer shall notify all other parties to the claim by serving upon each party a copy of the pleading or motion filed. A filed pleading or motion shall be accompanied by a certification stating:

1. That a copy has been served on each party, or if the party is represented by counsel, on the party's counsel; and

2. The method of service used.

(b) Service upon a party shall be made by delivering a copy to the attorney or party, electronic mail, or by mailing it to the attorney or party at the last known address. Service is complete upon mailing, unless the serving party learns or has reason to know that it did not reach the person to be served. Service by electronic mail shall be considered complete when sent if properly addressed. Documents filed by electronic mail shall be considered received when sent if properly addressed.

(3) Extension of time. An extension of time to file a response, motion, other pleading, brief, proposed finding of fact, or conclusion of law shall be granted:

(a) On agreement of the parties; or

(b) Upon a showing of good cause.

Section 4. Representation in Proceedings before the Board [~~Commission~~]. (1) If the claim is by an individual, the individual may proceed without an attorney or engage counsel to provide representation.

(2) An individual who is not an attorney shall not be permitted to represent any other individual or legal entity who is a party to the claim.

(3) In accordance with Supreme Court Rule 3.020, if the claimant is a corporation, joint venture, partnership, LLC, estate, or any entity other than an individual as identified in subsection (1), the entity shall be represented by an attorney on all matters before the board, including filing the claim.

(4) An attorney admitted to practice in another state, but not the Commonwealth of Kentucky, shall be permitted to represent a party before the board if the attorney complies with Supreme Court Rule 3.030(2).

(5) If an attorney is not identified in the claim form or is later retained to represent a claimant after the filing of the claim form, the attorney shall enter an appearance in the record within ten (10) days of being retained. [

~~(2) An attorney representing a claimant before the commission shall enter an appearance the time the complaint is filed or as soon thereafter as possible.~~

~~(3) Any orders related to the claim and copies shall be served on the opposing party and the hearing officer presiding over the claim.~~

~~(4) An individual who is not an attorney shall not represent any other individual or an entity party to a claim.~~]

Section 5[~~2~~]. Response to Claims. (1) Upon receipt of a completed claim, the board [~~commission~~] shall submit a copy of each claim to the head of the agency against which the claim is filed, or the attorney representing the agency against which the claim is filed.

(2) The agency against which a claim has been filed shall respond [~~answer the claim or file a responsive motion in writing~~] to the board [~~commission~~] and the claimant within thirty (30) days of receiving the claim.

(3) If the agency against which a claim is filed admits liability in its response, a final order shall be entered.[

~~(3) The commission shall consider the claim at its next regular or special meeting if:~~

~~(a) The response filed by the affected agency admits liability; or~~

~~(b) The respondent agency fails to respond to the commission concerning its investigation within thirty (30) days.~~

~~(4) If the agency denies negligence in a claim requiring a hearing pursuant to KRS 49.090(3), a hearing officer shall be assigned, and the commission shall notify the claimant and the head of the affected agency of the assignment.~~

~~(5) The commission may grant an extension of time to file the answer or response to the claim upon:~~

~~(a) Agreement of the parties; or~~

~~(b) A showing of good cause demonstrating that the purpose of the request is not to delay proceedings.~~]

Section 6. Claims Not Requiring a Hearing Under KRS 49.090(3). (1) If the agency against which a claim is filed fails to respond within thirty (30) days, the board or a board member assigned by the chair shall ***[~~do one of the following~~]***:

(a) Enter a show cause order;

(b) ***Recommend an [~~A recommended~~]*** order of dismissal***;[~~,~~]*** or

(c) Deem the facts contained in the claim admitted and render an award.

(2) If the response filed by the agency denies negligence in a claim not requiring a hearing pursuant to KRS 49.090(3), the board or board member shall decide the claim and render a decision.

(3) Within fourteen (14) days of the decision, any party may request a full board review by written notice to the board.

Section 7. Claims Requiring a Hearing under KRS 49.090(3). (1) If the agency fails to respond within thirty (30) days, the board shall issue a show cause order or the matter shall be assigned to a hearing officer.

(2) If the response filed by the agency denies negligence in a claim requiring a hearing pursuant to KRS 49.090(3), a hearing officer shall be assigned, and notice of ***the [~~such~~]*** assignment shall be provided to the parties.

Section 8[~~3~~]. Prehearing or Status Conference and Hearing Schedule. (1) The hearing officer shall schedule a [~~telephonic~~] prehearing or status conference, which may be conducted by telephone or other electronic means:

(a) Within thirty (30) days of the assignment of the claim; and

(b) Upon reasonable notice to all parties, which consists of prior notice of not less than five (5) days, unless agreed to otherwise by the parties.

(2) The hearing officer may convene the [~~telephonic~~] prehearing or status conference or order the affected state agency to convene the conference.

(3) A prehearing or status conference may be used to discuss jurisdictional matters, settlement possibilities, discovery, preparation of stipulations, clarification of issues, rulings on witnesses, taking of evidence, issuance of subpoenas, mediation, and other matters that will promote the orderly and prompt conduct of the hearing.

(4) The hearing officer and the parties shall set an agreed date for the hearing at the prehearing or status conference. If the hearing officer and parties cannot agree upon a hearing date, the hearing officer shall set the matter for hearing no later than six (6) months from the date of the conference, unless the parties have otherwise agreed to hold the claim in abeyance.

(5) Upon conclusion of the prehearing or status conference, the hearing officer shall issue an order including all matters determined at the prehearing or status conference.

(6) The hearing officer shall notify the board [~~commission~~] of the date and time for the hearing. The office[~~executive director, or his or her designee,~~] shall:

(a) Reserve a place within the proper venue to conduct the hearing;

(b) Select a court reporter to be present at the hearing to record the proceedings; and

(c) Notify the parties and the court reporter of the date, time, and place of the hearing.

Section 9. Motion Practice. (1) Any party may file a motion.

(2) Any party affected by a motion or pleading may file a response to the motion or pleading within thirty (30) days from the date on which the motion or pleading was served.

(3) A moving party may file a reply to another party's response. The reply shall be filed within fifteen (15) days from the date the response was served. Other replies or responses shall not be filed, unless prior approval is granted by the board or hearing officer.

(4) If a response is not filed within thirty (30) days, the board or hearing officer shall issue an order on the motion within sixty (60) days of the date the response was due.

Section 10. Discovery. (1) Discovery may be obtained without prior order of the board or hearing officer. ***Except to the extent the provisions of this Section differ,*** the Kentucky Rules of Civil Procedure (CR) governing depositions and discovery shall apply ***[~~except to the extent the provisions of this Section 10 differ~~]***.

(2) In addition to the provisions of CR 26 addressing opinions and use of expert witnesses:

(a) ***Absent a stipulation between the parties or an order issued by the board providing otherwise, and at least ninety (90) days before the date set for the hearing,*** a party shall disclose to the other party or parties the identity of any witness qualified as an expert by knowledge, skill, experience, training, or education the party may use at the hearing to provide expert testimony ***[~~at least ninety (90) days before the date set for the hearing, absent a stipulation between the parties or an order issued by the board providing otherwise~~]***;or

(b) If the evidence is intended solely to contradict or rebut evidence on the same subject matter of a witness identified by another party, within thirty (30) days after the other party's disclosure.

(3) The board or hearing officer may deny, limit, or require discovery.

(4) If a party fails to comply with an order regarding discovery, the board or hearing officer may order that the:

(a) Matters that the requesting party was seeking to establish through discovery shall be taken as having been established for the purposes of the hearing;

(b) Noncomplying party shall be prohibited from introducing related documents or testimony at the hearing;

(c) ***[~~The~~]*** Claim be dismissed or relief be granted as requested by the opposing party;

(d) ***[~~The~~]*** Claim be stayed until the order is obeyed; or

(e) Noncomplying party, the advising attorney, or both pay the reasonable costs, including attorney's fees, caused by the failure to comply.

(5) A response to discovery under subsection (1) of this section shall not be filed with the board unless required by order of the board or hearing officer.

Section 11. Briefs. A party shall file with the board or hearing officer any brief required by order of the board or hearing officer. The board or hearing officer may require a party to file a post-hearing brief or to supplement at any time a brief already filed to assist in adjudicating the hearing. A brief shall include the signature of the party, or the party's counsel.

Section 12. Summary Disposition. At any time after the commencement of the claim, a party may move for a summary disposition of the whole or a part of the claim by filing a motion that:

(1) Asserts that there are no disputed material facts as to one (1) or more of the issues before the board or hearing officer;

(2) Includes a statement specifying which material facts are undisputed. Assertions of a material undisputed fact or facts may be submitted to the board or hearing officer through affidavits or responses made by another party to any discovery request, including answers to interrogatories, admissions, and depositions. Facts stated in the claim, including exhibits, may be relied upon as undisputed material facts by the appellee; and

(3) States that any issue before the board or hearing officer for which summary disposition is sought is a matter of legal, and not factual, interpretation.

(4) Within twenty (20) days after a party moves for summary disposition, any other party may file a response presenting the party's position on issues of law and fact, which shall include any affidavit, written response to discovery requests, deposition testimony, or statements in the claim, demonstrating the party's assertion that a material fact or facts are disputed.

(5) If the nonmoving party files a response to the motion for summary disposition, the moving party shall have ten (10) days to file a reply to the response.

(6) The board or hearing officer may grant a motion for summary disposition in whole or in part. If the board or hearing officer grants a summary disposition as to one (1) or more issues, but not all issues, then the remaining issues shall be heard by the board or hearing officer in accordance with this administrative regulation and KRS Chapter 13B.

Section 13[4]. Conduct of Hearing. Except as otherwise established in KRS Chapter 49 or this administrative regulation, the conduct of hearings shall be governed by the procedures established in KRS Chapter 13B.

Section 14. Board Decision. (1)(a) Each contested claim shall be submitted to the board at its next meeting following the submission of the recommended order, except for Agreed Orders.

(b) The board shall issue its final order in accordance with KRS 49.080.

(c) The stated deadlines within which the board shall render a final order shall commence upon the last filing of any exceptions to the recommendation.

(2) The board, or a majority of its members, shall render a decision on each contested claim requiring a hearing pursuant to KRS 49.090(3) and each request for a full board review of a claim decided by an individual member.

(3) In rendering the final order, the board shall consider the record including the recommended order and any exceptions duly filed to the recommended order.

(4) The board may accept the recommended order of the hearing officer and adopt it as the final order of the board, or it may reject or modify, in whole or in part, the recommended order, or it may remand the matter, in whole or in part, to the hearing officer for further proceedings as appropriate.

(5) If the final order differs from the recommended order, it shall include separate statements of findings of fact and conclusions of law. The final order shall also include the date the board rendered the order, the date it was served on the parties, and to whom it was served, and a statement advising the parties fully of available appeal rights.

(6) Unless waived by the party, a copy of the final order shall be transmitted to each party or to his attorney of record.

(7) The matter shall be deemed finally adjudicated if:

(a) In a claim under $2,500, no full board review has been requested; or

(b) The claim has been the subject of full board review; or

(c) No judicial appeal has been filed.

Section 15. Payment of Awards. Within thirty (30) days after an order of the Board of Claims making an award has become final, the agency making payment of ***the*** ~~***[such]***~~ award shall furnish to the Board of Claims a copy of any check reflecting ***the*** ~~***[such]***~~ payments.

CONTACT PERSON: Leah Cooper Boggs, Executive Advisor, 500 Mero Street 218NC, phone +1 (502) 352-8095, fax +1 (502) 564-3969, email LBoggs@ky.gov.

PUBLIC PROTECTION CABINET
OFFICE OF CLAIMS AND APPEALS
500 Mero Street, 2SC1
Frankfort, KY 40601
Phone: (502) 782-8255
Fax: (502) 573-4817
http://kycc.ky.gov/

Andy Beshear
Governor

Ray Perry
Deputy Secretary

Kerry B. Harvey
Secretary

Edith Halbleib
Executive Director

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601
Via email RegsCompiler@LRC.KY.GOV

RE: Office of Claims and Appeals Regulations
Crime Victims Compensation Board – 802 KAR 3:010

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 802 KAR 3:010, the Office of Claims and Appeals proposes the attached amendment to 802 KAR 3:010.

Sincerely,

Edith Halbleib

Edith Halbleib
Executive Director
Office of Claims and Appeals
Public Protection Cabinet
500 Mero Street 2SC1
Frankfort, Kentucky 40601
(502) 782-8240 (Phone)
(502) 573-4817 (FAX)
Edith.halbleib@ky.gov

Subcommittee Substitute

PUBLIC PROTECTION CABINET
(As Amended at ARRS)

802 KAR 3:010. Crime victims compensation.

RELATES TO: KRS 12.027, 49.260 - 49.490, 216B.015, 216B.400, EO 2020-708
STATUTORY AUTHORITY: KRS 49.020, 49.300(1)
NECESSITY, FUNCTION, AND CONFORMITY: Executive Order 2020-708 ("Order") requires that the Kentucky Claims Commission be abolished and the Office of Claims and Appeals be established to include the Crime ***Victims [~~Victim's~~]*** Compensation Board. The Order also sets forth the powers and duties of the Crime Victims Compensation Board and authorizes the board to promulgate regulations necessary to immediately carry out the provisions and purposes of the Order and the board's statutory authority. KRS 49.300(1) authorizes the Crime Victims Compensation Board [~~commission~~] to promulgate administrative regulations that are necessary to carry out the provisions of KRS 49.270 through 49.490. This administrative regulation establishes procedures for crime victims to file claims for compensation.

Section 1. Definition. "Board" means the Crime Victims Compensation Board.

Section 2[~~1~~]. Filing Claims. (1) A claim shall be:
(a) Legibly written, typed, or printed on the Crime Victim Compensation Form;
(b) Signed by the claimant and the counsel representing the claimant, if any.
(2) A claim shall be filed ***[~~by~~]***:
(a) In person or by private delivery to the Crime ***Victims [~~Victim's~~]*** Compensation Board, 500 Mero Street, 2 SC1, Frankfort, Kentucky 40601;
(b) ***By*** mail to the address listed above; or
(c) ***By*** electronic mail to crimevictims@ky.gov, if the document can be sent in one (1) electronic message[~~; and~~
~~(c) Filed by mail, electronic mail to crimevictims@ky.gov, or delivered in person to the commission~~].
(3) [~~(2)~~] If applying for lost wages or loss of support, a claim shall be supplemented by:
(a) A notarized Employment Verification form; and
(b) If requested by ***[~~the~~]*** board [~~commission~~] staff:
1. A Physician Statement form; or
2. A Mental Health Counselor's Report form.

Section 3[~~2~~]. Kentucky Medical Assistance Program. (1) The board [~~commission~~] shall cross-reference every claim with those claims that appear in the Kentucky Medical Assistance Program (KMAP) database maintained by the Cabinet for Health and Family Services.
(2) If a crime victim is covered by Medicare or Medicaid, the board's [~~commission's~~] staff will provide the board [~~commission~~] a list of:
(a) All itemized medical charges for which ***the [~~that~~]*** victim seeks compensation; and

(b) The victim's services covered by medical assistance as reported in KMAP.

(3) Upon making an award to a Medicaid-eligible crime victim, the board [~~commission~~] shall not consider any medical bills submitted by or on behalf of the victim for any KMAP-covered services.

(4) If the board [~~commission~~] makes an award to a victim who received medical assistance for a KMAP-covered service, the KMAP as final payor shall not be responsible for the payment of any portion of ***the [~~that~~]*** claim awarded by the board [~~commission~~].

Section 4. Attorney's Fees. If a claimant is represented by an attorney and the attorney so requests, the board, may, as a part of any award or by separate order subsequent to the award, allow a reasonable attorney's fee for the filing of a claim and any subsequent proceedings. ***The [~~Such~~]*** fee shall not exceed fifteen (15) percent of the amount of the award, and shall be paid out of the award and not in addition to the award. ***An [~~No~~]*** attorney, representing a claimant, shall ***not*** contract for or receive as a fee any sum larger than fifteen (15) percent of the amount of the award. Any fee contract in violation of this provision shall be void.

Section 5[~~3~~]. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Crime Victim Compensation Form", August 2020[~~February 2018~~];

(b) "Employment Verification", August 2020[~~February 2018~~];

(c) "Physician Statement", August 2020[~~February 2018~~]; and

(d) "Mental Health Counselor's Report", August 2020[~~February 2018~~].

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of Claims and Appeals [~~Kentucky Claims Commission~~], 500 Mero St 2SC1, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. and is available online at http://cvcb.ky.gov/Pages/default.aspx.

CONTACT PERSON: Leah Cooper Boggs, Executive Advisor, 500 Mero Street 218NC, phone +1 (502) 352-8095, fax +1 (502) 564-3969, email LBoggs@ky.gov.

Andy Beshear
Governor

Ray A. Perry
Deputy Secretary

PUBLIC PROTECTION CABINET
Department of Insurance
P.O. Box 517
Frankfort, Kentucky 40602-0517
1-800-595-6053
http://insurance.ky.gov

Kerry B. Harvey
Secretary

Sharon P. Clark
Commissioner

November 19th, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: **806 KAR 9:030. Adjuster licensing restrictions.**

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by **806 KAR 9:030**, the Department of Insurance proposes the attached amendment to **806 KAR 9:030**.

Sincerely,

DJ Wasson

DJ Wasson, Deputy Commissioner
Department of Insurance
Mayo-Underwood Building, 500 Mero St.
Frankfort, KY 40601

Final 11-18-2020

Suggested Amendment
PUBLIC PROTECTION CABINET
Department of Insurance
Agency Licensing Division

806 KAR 9:030. Adjuster licensing restrictions.

Page 1
Section 1(1)
Lines 14-15
After "licensed pursuant to" insert "KRS 304.9-430".
Delete "the Kentucky Insurance Code".

Page 2
Section 3
Line 8
After "to the commissioner", delete "the".
Line 9
After "Representing", insert "an".

Page 2
Section 4(1)
Line 10
After "Request for", capitalize the first letter of "unlicensed", "adjuster", and "representing".
Line 11
After "an", capitalize the first letter of "insurer".
After "to", capitalize the first letter of "adjust", "losses", and "resulting".
After "from a", capitalize the first letter of "catastrophe".
After the closing quotation marks, insert a comma
After "(", insert "05/2019".
Delete "07/2020".

Andy Beshear
Governor

Ray A. Perry
Deputy Secretary

PUBLIC PROTECTION CABINET
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P.O. Box 517
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Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: **806 KAR 9:190. Disclosure requirements for financial institutions authorized to engage in insurance activities.**

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by **806 KAR 9:190**, the Department of Insurance proposes the attached amendment to **806 KAR 9:190**.

Sincerely,

DJ Wasson

DJ Wasson, Deputy Commissioner
Department of Insurance
Mayo-Underwood Building, 500 Mero St.
Frankfort, KY 40601

Final 11-18-2020

SUGGESTED SUBSTITUTE

PUBLIC PROTECTION CABINET
Department of Insurance
Agent Licensing Division

806 KAR 9:190. Disclosure requirements for financial institutions authorized to engage in insurance agency activities.

RELATES TO: KRS 286.3-030(4), 304.9-135
STATUTORY AUTHORITY: KRS 304.9-135(2)(g)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.9-135(2)(g) requires the Commissioner to promulgate administrative regulations to specify the disclosure forms required by KRS 304.9-135(2)(b), (c), and (f). This administrative regulation specifies the disclosure forms for use by financial institutions authorized to engage in insurance agency activities.

Section 1. A financial institution authorized by law to engage in insurance agency activities shall provide to an insurance consumer the disclosure forms:
(1) Notice of Free Choice of Agent and Insurer; and
(2) Financial Institution Disclosures.

Section 2. ***The disclosure form, Model Privacy Forms and General Instructions as incorporated by reference in 806 KAR 3:210, may be used to provide the disclosure required under KRS 304.9-135(2)(c).***

Section 3. Incorporation by Reference. (1) The following material is incorporated by reference:
(a) FI-02, "Notice of Free Choice of Agent and Insurer", (***12[8]***/2020 edition) [~~(7/2002 edition)~~]; and
(b) FI-03, "Financial Institution Disclosures", (***7/2002[8/2020]*** edition) [~~(7/2002 edition)~~].
(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department of Insurance, Mayo-Underwood Building, 500 Mero Street[~~215 West Main Street~~], Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

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.

MATERIAL INCORPORATED BY REFERENCE

The agency at the time that it files this staff suggested amendment needs to file one (1) clean copy of the FI-02, "Notice of Free Choice of Agent and Insurer" form that:

- **Includes a comma after "loan" in the first sentence**
- **Updates the edition date to 12/2020**

NOTICE OF FREE CHOICE OF AGENT AND INSURER

The Kentucky Insurance Code, KRS 304.12-150, provides that when insurance is required according to the terms of a debt or loan, you have the right to choose the agent and insurer through or by which your insurance is to be placed. Your free choice of an agent and insurer and an adequate insurance policy cannot be refused. If you, as a consumer, are denied your right to choose, or if an adequate insurance policy is refused, you should notify the Commissioner of Insurance at 500 Mero Street, P.O. Box 517, Frankfort, Kentucky 40602 or 1-800-595-6053.

Andy Beshear
Governor

Ray A. Perry
Deputy Secretary

PUBLIC PROTECTION CABINET
Department of Insurance
P.O. Box 517
Frankfort, Kentucky 40602-0517
1-800-595-6053
http://insurance.ky.gov

Kerry B. Harvey
Secretary

Sharon P. Clark
Commissioner

November 19th, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: **806 KAR 9:370. Preneed funeral agent license.**

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by **806 KAR 9:370**, the Department of Insurance proposes the attached amendment to **806 KAR 9:370**.

Sincerely,

DJ Wasson

DJ Wasson, Deputy Commissioner
Department of Insurance
Mayo-Underwood Building, 500 Mero St.
Frankfort, KY 40601

Final 11-18-2020

SUGGESTED SUBSTITUTE

PUBLIC PROTECTION CABINET
Department of Insurance
Agent Licensing Division

806 KAR 9:370. Preneed funeral agent license.

RELATES TO: KRS ***304.1-050[~~204.1-050~~]***(2), 304.4-010, 304.9-020(1), ***304.9-080, 304.9-150,*** 304.9-230, 304.9-260 304.12-240(1)(a).

STATUTORY AUTHORITY: KRS 304.2-110, 304.9-230.

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110 authorizes the commissioner to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code. KRS 304.9-230 authorizes the commissioner to issue an agent's license with the limited line of authority for other limited lines of authority, and requires the commissioner to promulgate administrative regulations to establish the requirements, if any, for pre-licensing courses of instruction and examination for each limited line of authority. This administrative regulation establishes the preneed funeral limited line of authority and the requirements for licensure.

Section 1. Definitions.

(1) "Agent" is defined ***by[~~in~~]*** KRS 304.9-020(1).

(2) "Department" is defined ***by[~~in~~]*** KRS 304.1-050(2).

(3) "Preneed funeral contract or prearrangement" is defined ***by[~~in~~]*** KRS 304.12-240(1)(a).

(4) "Preneed funeral insurance" means a life insurance or annuity contract used solely to fund a preneed funeral contract or prearrangement.

Section 2. An agent license with a limited line of authority for preneed funeral insurance shall only sell, solicit, or negotiate preneed funeral insurance with a face amount that does not exceed $25,000.

Section 3. License Application. To apply for an agent license with a preneed funeral ***[~~insurance~~]*** limited line of authority, an applicant shall submit to the department the following information:

(1) (a) For individual applicants, Form 8301, incorporated by reference in 806 KAR 9:025, including all applicable attachments; and

(b) For business entity applicants, Form 8301-BE, incorporated by reference in 806 KAR 9:025, including all applicable attachments; ***[~~and~~]***

(2) ***A completed background check through the Kentucky Administrative Office of the Courts; and***

(3) The corresponding fees established by 806 KAR 4:010.

Section 4. Pre-licensing training. An applicant for an agent license with a preneed funeral ***[~~insurance~~]*** limited line of authority shall not be required to complete pre-licensing training.

Section 5. Examination. An applicant for an agent license with a preneed funeral ***[~~insurance~~]*** limited line of authority shall not be required to complete an examination.

Section 6. License renewal. An agent with a preneed funeral ***[~~insurance~~]*** limited line of authority shall renew in accordance with KRS 304.9-260.

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.

Andy Beshear
Governor

Ray A. Perry
Deputy Secretary

PUBLIC PROTECTION CABINET
Department of Insurance
P.O. Box 517
Frankfort, Kentucky 40602-0517
1-800-595-6053
http://insurance.ky.gov

Kerry B. Harvey
Secretary

Sharon P. Clark
Commissioner

November 25th, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: **806 KAR 12:170. Life insurance disclosures.**

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by **806 KAR 12:170**, the Department of Insurance proposes the attached amendment to **806 KAR 12:170**.

Sincerely,

DJ Wasson

DJ Wasson, Deputy Commissioner
Department of Insurance
Mayo-Underwood Building, 500 Mero St.
Frankfort, KY 40601

Subcommittee Substitute

PUBLIC PROTECTION CABINET
Department of Insurance
Health and Life Division
(As Amended at ARRS)

806 KAR 12:170. Life insurance disclosures.

RELATES TO: KRS 304.12-010, 304.12-020, 304.12-230
STATUTORY AUTHORITY: KRS 304.2-110
NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110(1) 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, KRS Chapter 304. This administrative regulation establishes requirements for insurers to deliver information to purchasers of life insurance that is designed to improve the buyer's ability to select the most appropriate plan of life insurance for the buyer's needs and improve the buyer's understanding of the basic features of the policy that has been purchased or is under consideration.

Section 1. Definitions. (1) "Buyer's Guide" means the current Life Insurance Buyer's Guide published by the National Association of Insurance Commissioners[~~Commonwealth of Kentucky Department of Insurance~~].

(2) "Current scale of nonguaranteed elements" means a formula or other mechanism that produces values for an illustration as if there is no change in the basis of those values after the time of illustration.

(3)[~~(2)~~] "Generic name" means a short title that is descriptive of the premium and benefit patterns of a policy or a rider.[

~~(3) "In force illustration" means an illustration furnished after the policy has been in force for one (1) year or more.~~]

(4) "Nonguaranteed elements" means the premiums, credited interest rates, including any bonus, benefits, values, non-interest based credits, charges, or elements of formulas used to determine any of these, that are subject to company discretion and are not guaranteed at issue. An element is considered nonguaranteed if any of the underlying nonguaranteed elements are used in its calculation.

(5) "Policy data" means a display or schedule of numerical values, both guaranteed and nonguaranteed, for each policy year or a series of designated policy years of the following information:

(a) Illustrated annual, other periodic, and terminal dividends;

(b) Premiums;

(c) Death benefits; and

(d) Cash surrender values, outstanding policy loans, current policy loan interest rate, and endowment benefits.

(6) "Policy summary" means a separate document describing the elements of the policy and complying with the requirements established in Section 3 of this administrative regulation.

Section 2. Application. (1) Except as provided in subsection (2) of this section ***[~~of this administrative regulation~~]***, this administrative regulation shall apply to:

(a) A solicitation, negotiation, or procurement of life insurance occurring within this state; and

(b) An issuer of life insurance contracts including fraternal benefit societies.

(2) This administrative regulation shall not apply to:

(a) Individual and group annuity contracts;

(b) Credit life insurance;

(c) Group life insurance;

(d) Life insurance policies issued in connection with pension and welfare plans ***that [~~which~~]*** are subject to the federal Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. Section 1001 et seq. as amended; or

(e) Variable life insurance under which the amount or duration of the life insurance varies according to the investment experience of a separate account.

Section 3. Policy Summary. A policy summary shall describe the elements of the policy including the following:

(1) A permanently placed title stating: "STATEMENT OF POLICY COST AND BENEFIT INFORMATION";

(2) The name and address of the insurance agent or, if an agent is not involved, a statement of procedure to be followed in order to receive responses to inquiries regarding the policy summary;

(3) The full name and home office or administrative office address of the life insurance company issuing the policy;

(4) The generic name of the basic policy and each rider;

(5) The following amounts shall be listed in total, not on a per thousand or per unit basis and, if applicable for the first ten (10) policy years and representative policy years thereafter, the amounts shall be listed sufficiently to clearly illustrate the premium and benefit patterns, including at least an age from sixty (60) through sixty-five (65) and policy maturity:

(a) The annual premium of the basic policy;

(b) The annual premium for each optional rider;

(c)1. The amount payable upon death at the beginning of the policy year pursuant to the basic policy with additional benefits for each rider shown separately.

2. If more than one (1) insured is covered pursuant to one (1) policy or rider, death benefits shall be displayed separately for each insured or for each class of insured's if death benefits do not differ within the class;

(d) The total guaranteed cash surrender values at the end of the year with values shown separately for the basic policy and each rider; and

(e) Endowment amounts payable pursuant to the policy that are not included pursuant to the cash surrender values described in this subsection;

(6)(a) The effective policy loan annual percentage interest rate, if the policy contains this provision, specifying whether the rate is applied in advance or in arrears.

(b) If the policy loan interest rate is adjustable, the policy summary shall state that the annual percentage rate shall be determined in accordance with the provisions of the policy and the applicable law; and

(7) The date on which the policy summary was prepared.

Section 4. Duties of Insurers. (1) Requirements for new issues.

(a)1. Except as provided in subparagraph 2. of this paragraph, the insurer shall provide the Buyer's Guide to each prospective purchaser prior to accepting the applicant's initial premium or premium deposit.

2. If the policy for which application is made contains an unconditional refund provision of at least ten (10) days, the Buyer's Guide may be delivered with the policy or prior to delivery of the policy.

(b) The insurer shall provide a policy summary to prospective purchasers in which the insurer shall identify the policy form as not marketed with an illustration.

1. The policy summary shall show guarantees only.

2. The policy summary shall consist of a separate document with all required information set out in a manner that does not minimize or render any portion of the summary obscure.

3. Amounts that remain level for two (2) or more years of the policy may be represented by a single number if it is clearly indicated what amounts are applicable for each policy year.

4. Amounts in Section 3(5) of this administrative regulation shall be listed in total, not on a per thousand or per unit basis.

5. If more than one (1) insured is covered under one (1) policy or rider, death benefits shall be displayed separately for each insured or for each class of insured if death benefits do not differ within the class.

6. Zero amounts shall be displayed as a blank space.

7. Delivery of the policy summary shall be consistent with the time for delivery of the Buyer's Guide as specified in paragraph (a) of this subsection.

(2) Requirements applicable to existing policies.

(a) Upon request by the policy owner, the insurer shall furnish the policy data or an in force illustration as follows:

1. For policies issued prior to January 1, 2008, the insurer shall furnish policy data, or, at its option, an in force illustration meeting the requirements of 806 KAR 12:140.

2. For policies issued on ***or*** ***~~[and]~~*** after January 1, 2008 and declared not to be used with an illustration, the insurer shall furnish policy data, limited to guaranteed values, if it has chosen not to furnish an in force illustration meeting the requirements of 806 KAR 12:140.

3. If the policy was issued on ***or*** ***~~[and]~~*** after January 1, 2008 and declared to be used with an illustration, an in force illustration shall be provided.

4. Unless otherwise requested, the policy data shall be provided for twenty (20) consecutive years beginning with the previous policy anniversary.

~~[5. The insurer may charge a reasonable fee for the policy data, not to exceed ten (10) dollars.]~~

(b)1. If a life insurance company changes its method of determining scales of nonguaranteed elements on existing policies, it shall notify each affected policy owner of the change and its effect on the policy no later than the date of the first payment on the new basis.

2. The requirement established in subparagraph 1. of this paragraph shall not apply to policies for which the death benefit pursuant to the basic policy on the date of notice does not exceed $5,000.

(c) If the insurer makes a material revision in the terms and conditions which will limit its right to change any nonguaranteed factor, it shall notify each affected policy owner of the change no later than the first policy anniversary following the revision.

Section 5. General Rules. (1)(a) Prior to commencing a life insurance sales presentation, an agent shall inform the prospective purchaser that the agent is acting as a life insurance agent.

(b) The agent shall inform the prospective purchaser, in writing, of the full name of the insurance company which the agent represents.

(c) In sales situations in which an agent is not involved, the insurer shall identify the insurer's full name.

(2)(a) An insurance producer marketing insurance products shall not use a title or designation, including "financial planner," "investment advisor," "financial consultant," or "financial counseling" to imply that the insurance producer is engaged in an advisory or consulting business in which compensation is unrelated to sales.

(b) This subsection shall not preclude:

1. A person recognized as having a financial planning or consultant designation from using the designation even if only selling insurance; or

2. Members of a recognized trade or professional association from having these terms as part of the organization's name from citing membership. If authorized only to sell insurance products, a person citing membership shall disclose that fact.

(c) A person shall not charge an additional fee for services customarily associated with the solicitation, negotiation, or servicing of policies.

(3)(a) A reference to nonguaranteed elements shall include a statement that the item is not guaranteed and is based on the company's current scale of nonguaranteed elements.

(b) If a nonguaranteed element would be reduced by the existence of a policy loan, a statement to that effect shall be included in each reference to nonguaranteed elements.

Section 6. Failure to Comply. Failure of an insurer to provide or deliver the Buyer's Guide, an in force illustration, a policy summary, or policy data shall constitute an omission that misrepresents the benefits, advantages, conditions, or terms of an insurance policy.

Section 7. Effective Date. The requirements of this administrative regulation shall not be implemented or enforced prior to the effective date, determined pursuant to KRS 13A.330, or January 1, 2012, whichever is later.

Section 8. Incorporation by Reference. (1) "[~~The~~]Life Insurance Buyer's Guide, "National Association of Insurance Commissioners", 2018[~~Common-wealth of Kentucky", July 2011,~~] is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department of Insurance, Mayo-Underwood Building, 500 Mero Street[~~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 Web site at: http://insurance.ky.gov/.

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.

Andy Beshear
Governor

Ray A. Perry
Deputy Secretary

PUBLIC PROTECTION CABINET
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P.O. Box 517
Frankfort, Kentucky 40602-0517
1-800-595-6053
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Kerry B. Harvey
Secretary

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Commissioner

November 19th, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: **806 KAR 30:010. License procedures.**

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by **806 KAR 30:010**, the Department of Insurance proposes the attached amendment to **806 KAR 30:010**.

Sincerely,

DJ Wasson

DJ Wasson, Deputy Commissioner
Department of Insurance
Mayo-Underwood Building, 500 Mero St.
Frankfort, KY 40601

Final 11-18-2020

SUGGESTED SUBSTITUTE

PUBLIC PROTECTION CABINET
Department of Insurance
Financial Standards Division

806 KAR 30:010. *[~~Application for~~]* License *procedures[~~procedure~~].*

RELATES TO: KRS ***304.3-230,*** 304.30-030
STATUTORY AUTHORITY: KRS 304.30-070***, 304.4-010***
NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.30-070 authorizes the commissioner [~~executive director~~] to make reasonable administrative regulations to effectuate subtitle 30 of the Kentucky Insurance Code and to regulate the manner in which licensed insurance premium finance companies conduct their business. This administrative regulation sets forth ***[~~application for~~]*** license procedures.

Section 1. Application for Original or Renewal License. Each application for an original or renewal license as an insurance premium finance company shall be made on ***the Application for License as an Insurance Premium Finance Company form[~~forms prescribed by the commissioner~~]***[~~executive director~~]. It shall be accompanied by all required documents and the license fee provided by ***806 KAR 4:010[~~KRS 304.4-010~~]*** which shall not be prorated. Each application for renewal of a license as an insurance premium finance company shall be made on or before May 1 of each year and shall be accompanied by the renewal fee provided by ***806 KAR 4:010[~~KRS 304.4-010~~]***.

Section 2. Biographical Questionnaire. ***(1)*** Each application for an original license as an insurance premium finance company shall be accompanied by biographical information for the persons specified in this section on ***the Biographical Questionnaire for Premium Finance Companies form[~~forms prescribed by the commissioner~~]***[~~executive director~~]. A separate form shall be completed and executed:

(a)[~~(1)~~] In the case of a sole proprietor, by the sole proprietor;

(b)[~~(2)~~] In the case of a partnership or limited partnership, by each partner or limited partner;

(c) In the case of a corporation, by each officer, director, and owner of more than ten (10) percent, directly or indirectly, of the outstanding shares of stock; and

(d)[~~(3)~~]*In the case of* ***any other business organization[~~a firm~~]****, by each member or holder of record or beneficial interest therein****[~~; and~~***

~~(4) In the case of a corporation, by each officer, director, and owner of more than ten (10) percent, directly or indirectly, of the outstanding shares of stock~~].

(2)[~~(5)~~] Biographical questionnaires shall[~~need not~~] be filed with an application for renewal of a license if[~~unless~~] changes have taken place in the business organization involving individuals who have not previously filed the[~~such~~] questionnaire.

Section 3. Consent to Jurisdiction and Service of Process. Each applicant for a license and each person required to file the biographical questionnaire shall be deemed to have appointed the Secretary of State as its attorney to receive service of all legal process issued against it in this state upon causes of action arising within this state. Nothing contained herein shall preclude service by any other authorized method. Service upon the Secretary of State shall be made in the same manner as is provided ***under KRS 304.3-230*** for service of process upon authorized foreign or alien insurers.

Section 4. Changes in Condition of Licensee. (1) If any licensee or any person who is a partner, member, supervisory employee, officer, director, or ten (10) percent stockholder of a licensee is convicted, by final judgment of a court, of a felony involving moral turpitude, the ***licensee[~~commissioner~~]***[~~executive director~~] shall, within ten (10) days after such conviction, ***notify the commissioner[~~be advised~~]*** of the facts in detail by letter.

(2) The licensee shall notify the commissioner[~~executive director~~] immediately upon its discovery that it no longer meets the requirements of 806 KAR 30:080.

Section 5. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) Form 106, "Application for License as an Insurance Premium Finance Company", (10/2020); and

(b) Form 503, "Biographical Questionnaire for Premium Finance Companies", (10/2020).

(2) This material may be inspected, copied, or obtained subject to applicable copyright law, at the Kentucky Department of Insurance, Mayo-Underwood Building, 500 Mero Street, Frankfort, KY 40601, Monday through Friday, 8 a.m. to 4:30 p.m.

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.

MATERIAL INCORPORATED BY REFERENCE

At the time that the agency files this staff suggested amendment, it will need to file one (1) clean copy of the following material incorporated by reference:

- **Form 106, "Application for License as an Insurance Premium Finance Company" with the 10/2020 edition date**
- **Form 503, "Biographical Questionnaire for Premium Finance Companies" with the 10/2020 edition date**

Commonwealth of Kentucky • Department of Insurance • 500 Mero Street • P.O. Box 517 • Frankfort, KY 40602
502-564-6082 • FAX 502-564-4604

Application for License as an Insurance Premium Finance Company

1. Company name _____
If conducting business under an assumed business name, so indicate, and attach a certified copy of certificate of assumed business name required under KRS Chapter 365.
Yes_____ No_____

2. Address at which applicant will conduct business under license:

_____

(a) Address of principal place of business within state:

_____

(b) Address at which all books, records, accounts and documents relating to business in this State will be kept.

_____

(c) If applicant is a foreign corporation, address of home office:

_____

3. Applicant is
( ) Individual Proprietor
( ) Partnership or Limited Partnership
( ) Corporation
( ) Other (Specify) _____

4. Attached hereto and made a part hereof are the following:
(Check and complete one)
( ) Certified copy of articles of association for a partnership
( ) Certified copy of articles of association for a limited partnership, and limited partnership statement and affidavit required under KRS Chapter 362 together with proof of publication
( ) Certified copy of articles of incorporation and certificate of incorporation for a domestic corporation
( ) Certified copy of articles of incorporation and Kentucky Certificate of Incorporation for a foreign corporation
( ) Certified copies of organic documents for formation of other firm

5. If applicant has engaged previously in the same or a similar business, provide details including name(s), address(es) and date(s) first commenced:

_____

_____

6. State whether applicant is directly or indirectly under common ownership, control, management or is otherwise affiliated or associated with any insurer, or any person, firm or corporation having or exercising control of an insurer.

Yes_____ No_____

(Supply complete details)

7. If applicant is a partnership

(a) State whether general partnership or limited partnership

_____

(b) Give names and addresses of all partners specifically identifying limited partners, if any:_____

_____

_____

8. If applicant is a corporation, trust or other entity, other than a partnership, of which ownership is manifested by shares, identify each type of share and state:

(a) Number of shares authorized:_____
(b) Number of share outstanding:_____
(c) Par Value_____
(d) Give name, residence address, title, number and percent of shares directly or beneficially owned by every officer, director and every person, firm, or corporation owning or controlling 10% or more of the shares of each type:

Name and residence address Title Number of shares (%)

_____

_____

_____

9. Attach current, certified financial statement which is as of the following date:

_____

10. In addition to an insurance premium finance company, the following additional business will be conducted at the address of the applicant:

_____

_____

11. If applicant, or any subsidiary, affiliated, or associated insurance premium finance company has more than one place of business, give the name and address of each.

_____

_____

_____

12. If the appropriate answer is "Yes" to any of the following questions concerning the applicant, any officer, director, owner or beneficial owner of 10% or more of the shares, complete details must be given, including names, address, disposition of charges, etc. (Omit minor traffic offenses).
Have any of the above:
(a) Applied previously in this state for a license to engage in the business of insurance premium financing?_____
(b) Received a rejection, revocation or suspension of license under laws of this state governing insurance premium or other consumer financing?_____
(c) Received a rejection, revocation or suspension of license under an insurance premium financing law or regulation, or similar law or regulation of any other state?_ _____
(d) Received a revocation or suspension of any license, been convicted or entered a plea of guilty, or nolo contendere, with respect to any law or regulation relating to the business of insurance?_____
(e) Been arrested, indicted, convicted, entered a plea of guilty or nolo contendere with respect to a state or federal offense in this or any other state?_____
(f) Been found by the commissioner of the Department of Insurance to have violated any of the provision of the Kentucky Insurance Code or any Regulation of the commissioner of the Department of Insurance?_____
(g) Been placed in voluntary or involuntary bankruptcy, receivership, trusteeship or conservatorship?_____
(h) Does any of the above now hold a license to engage in the business of insurance premium financing or a similar or related business in any state, district or territory of the United States?_____

13. State whether applicant understands that the commissioner may revoke or suspend the license of any premium finance company upon finding that:

(a) Any license issued to such company was obtained by fraud:
Yes_____ No_____
(b) There was any misrepresentation in the application for license:
Yes_____ No_____
(c) The holder of such license has otherwise shown himself untrustworthy or incompetent to act as a premium finance company:
Yes_____ No_____
(d) Such company has violated any of the provisions of the Kentucky Insurance Code:
Yes_____ No_____
(e) Such company has been rebating part of the service charge as allowed and permitted to any insurance agent or any employee of an insurance agent or to any other person as an inducement to the financing of any insurance policy with the premium finance company:
Yes_____ No_____

14. It is understood that the proposed insurance premium finance company and each person required to file a biographical questionnaire are deemed to have appointed the Kentucky Secretary of State as their agent to receive service of all legal process issued against them in this state upon legal claims arising in the state.
Yes_____ No_____

15. State whether applicant is fully familiar with the laws pertaining to insurance premium finance companies:
Yes_____ No_____

16. State whether applicant is fully familiar with the regulations of the commissioner of the Department of Insurance pertaining to insurance premium finance companies:
Yes_____ No_____

17. Attached is a check in the amount of $500 made payable to Kentucky State Treasurer for the initial license fee.

VERIFICATION

County_____

State_____

I, _____, the undersigned, being

the _____ of the
(Title, if a corporation)

_____
(Name of the insurance premium finance company)

swear, (or affirm) subject to the penalties of perjury, that to the best of my knowledge and belief, the statements contained in this application, including the accompanying statements (if any), are true and complete.

By_____

Subscribed and sworn to before me this _____ day of _____, 20_____

_____
(Notary Public)

Commonwealth of Kentucky • Department of Insurance • 500 Mero Street • P.O. Box 517 • Frankfort, KY 40602
502-564-6082 • FAX 502-564-4604

Biographical Questionnaire for Premium Finance Companies

1. Company name_____

2. Position held_____

3. Individual's name_____

   Date of birth_____

   Place of birth_____

4. Current residential address_____
   _____

5. Current business address_____
   _____

6. Residential addresses for past five (5) years:
   (a)_____
   (b)_____
   (c)_____
   (d)_____
   (e)_____

7. Education (beyond secondary schools and dates:

   _____
   _____
   _____
   _____
   _____

8. Employment history (Beginning with current employer, trace back complete history. Show dates of employment, name and address of company, position held, and duties.)

   _____
   _____
   _____
   _____
   _____

9. List any other companies which you now serve, or within the past five years have served, either as an officer or director. (List company, position and dates.)

_____
_____
_____
_____
_____

10. Have you ever been charged with a criminal violation (other than a traffic offense) at any time? _____ If "Yes" provide complete details:

_____
_____
_____

11. Have you ever held any other license (except a driver's license)?_____
If "Yes" provide details as to any such license which was ever suspended, revoked, or renewal refused.

_____
_____
_____

12. Have you ever been charged by any regulatory agency, city, county, state or federal governments with having violated any laws, rules or regulations?

_____

Has any company been so charged, allegedly as a result of any action or conduct on your part? _____If "Yes" to either, submit full details including disposition of charge.
_____
_____
_____

13. Have you ever been known by any other name? _____
If "Yes" provide complete details. _____
_____
_____

14. If the appropriate answer is "Yes" to any of the following questions, complete details must be given, including name, address, disposition of charges, etc. (Omit minor traffic offenses.)

Have you:

(a) Applied previously in this state for a license to engage in the business of insurance premium financing?_____

(b) Received a rejection, revocation or suspension of license under laws of this state governing insurance premium or other consumer financing?_____

(c) Received a rejection, revocation or suspension under an insurance premium financing law or regulation or similar law or regulation in any other state?_____

(d) Received a revocation or suspension of any license, been convicted or entered a plea of guilty, or nolo contendere, with respect to any law or regulation relating to the business of insurance?_____

(e) Been arrested, indicted, convicted, entered a plea of guilty or nolo contendere with respect to a state or federal offense in this or any other state?_____

(f) Been found by the Commissioner of the Department of Insurance to have violated any of the provisions of the Kentucky Insurance Code or any regulation of the Commissioner of the Department of Insurance?_____

(g) Been placed in voluntary or involuntary bankruptcy, receivership, trusteeship or conservatorship?_____

(h) Do you now hold a license to engage in the business of insurance premium financing or a similar or related business in any state, district or territory of the United States?_____

15. State whether you understand that the Commissioner may revoke or suspend the license of any premium finance company upon finding that:

(a) Any license issued to such company was obtained by fraud?
Yes_____ No_____

(b) Any misrepresentation in the application for the license?
Yes_____ No_____

(c) The holder of such license has otherwise shown himself untrustworthy or incompetent to act as a premium finance company?
Yes_____ No_____

(d) Such company has violated any of the provisions of the Kentucky Insurance Code?
Yes_____ No_____

(e) Such company has been rebating part of the service charge as allowed and permitted to any insurance agent or any employee of an insurance agent or to any person as a inducement to the financing of any insurance policy with the premium finance company?
Yes_____ No_____

16. State whether you are fully familiar with the laws pertaining to insurance premium finance companies?
Yes_____ No_____

17. State whether you are fully familiar with the regulations of the Commissioner of the Department of Insurance pertaining to insurance premium finance companies?
Yes_____ No_____

VERIFICATION

County_____

State_____

I, _____, the undersigned, being

the _____ of the
(Title, if a corporation)

_____
(Name of the insurance premium finance company)

swear, (or affirm) subject to the penalties of perjury, that to the best of my knowledge and belief, the statements contained in this application, including the accompanying statements (if any), are true and complete.

By_____

Subscribed and sworn to before me this _____ day of _____, 20___

_____
(Notary Public)

Andy Beshear
Governor

Ray A. Perry
Deputy Secretary

PUBLIC PROTECTION CABINET
Department of Insurance
P.O. Box 517
Frankfort, Kentucky 40602-0517
1-800-595-6053
http://insurance.ky.gov

Kerry B. Harvey
Secretary

Sharon P. Clark
Commissioner

November 19th, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: **806 KAR 30:070. Books and records subject to inspection.**

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by **806 KAR 30:070**, the Department of Insurance proposes the attached amendment to **806 KAR 30:070**.

Sincerely,

DJ Wasson

DJ Wasson, Deputy Commissioner
Department of Insurance
Mayo-Underwood Building, 500 Mero St.
Frankfort, KY 40601

Final 11-18-2020

SUGGESTED SUBSTITUTE

PUBLIC PROTECTION CABINET
Department of Insurance
Financial Standards and Examination Division

806 KAR 30:070. Books and records subject to inspection.

RELATES TO: KRS ***304.30-030,*** 304.30-060
STATUTORY AUTHORITY: KRS 304.30-070
NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.30-070 authorizes the commissioner [~~executive director~~] to make reasonable administrative regulations to effectuate Subtitle 30 of the Kentucky Insurance Code and to regulate the manner in which licensed insurance premium finance companies conduct their business. This administrative regulation sets forth the records and recorded information subject to inspection by the commissioner [~~Executive Director~~].

Section 1. Books and Records. (1) ***Records shall be preserved for the time period set forth in KRS 304.30-060(2).[~~Until payment under the agreement is made in full,~~]*** Every licensee shall maintain [~~file~~] each premium finance agreement or duplicate originals [~~thereof,~~] and all original documents relating to the premium finance agreement, [~~thereto (~~]except those papers returned to the insured. The premium finance agreement and all original documents relating to the premium finance agreement shall:

(a) Include a common identifying number; and

(b) Be available for inspection by the department at any time. [~~) so as to be readily available for inspection at any time. All such papers and instruments shall bear a common identifying number.~~]

(2) Every licensee shall maintain a register, ledger, or combination of records containing a summary of premium finance agreements acquired, other than pursuant to a pledge, which can readily show:

(a) The date of acquisition;
(b) The name of the insured;
(c) The identifying number;
(d) The principal balance;
(e) The amount of service charge;
(f) The balance payable by the insured;
(g) A distribution of proceeds showing the dates, amounts, purposes, and names of the person to whom any part of the proceeds is distributed; ***and***
(h) The application of any part of the proceeds to an unpaid balance due on an existing premium finance agreement which is terminated by refinance agreement.

(3) Every licensee shall maintain a record which will readily disclose at any time the aggregate number and outstanding time balances of all premium finance agreements held by it, other than pursuant to a pledge.

(4) Every licensee shall maintain an individual ledger card or appropriate combination of records with respect to each premium finance agreement showing:

(a) The name and address of the insured;
(b) The identifying account number;
(c) The name of the agent or broker;
(d) The amount of the principal balance;

(e) The date of acquisition;

(f) The name or names of the insurers and the policy number of the related insurance contracts;

(g) The date from which the service charge is payable and whether the [~~such~~] date is the effective date of the insurance coverage or some other later date;

(h) The service charge;

(i) The balance payable by the insured; ***and***

(j) Schedule of required payments.

(5) The ledger card shall also show all receipts setting forth their application to outstanding balances, delinquency, and other charges, if any, with the type of the [~~such~~] charge clearly specified.

(6) With respect to cancellation of insurance, the licensee shall record:

(a) The [~~the~~] effective date of the [~~such~~] cancellation;

(b) The [~~, the~~] date of notice to the insured; [~~and~~]

(c) The [~~the~~] date of notice to the insurer;

(d) The[~~. There shall also be recorded the~~] amount of return premium received, if any; [~~,~~] and

(e) The[~~the~~] disposition of any return premium received [~~thereof~~].

(7) In connection with the prepayment of a premium finance agreement, the ledger card shall show the amount of service charge refund required to be made and the date such refund is made.

(8) With respect to any premium finance agreement, whether charged off or not, upon which legal proceedings have been taken, every licensee shall clearly indicate in permanent form on the insured's ledger card or on a separate sheet or card or file bearing the identifying account number, the following:

(a) The date of referral to an outside counsel for collection;

(b) The date and terms of any settlement agreed upon or the results of any legal or summary action taken for or against the licensee; and

(c) The nature or any collection expense incurred by the licensee in connection with litigation and charged to or paid by the insured or other obligor.

(9)(a) Except as noted in paragraph (b) of this subsection, records [~~Records~~] bearing any notation made in conformity with subsection (8) of this section shall be kept in a binder or file separate from other records.

(b) The [~~; provided, however, that the~~] record of [~~as to~~] a premium finance agreement which has been paid in full, [~~or~~] which is current as to payments, or concerning which a decision has been officially made to abandon collection efforts of every kind, may be placed elsewhere.

(c) If the licensee engages in any other business, the records relating to the insurance premium finance business shall be kept separate from the records of any other business.

Section 2. Annual Report. Prior to May 1 of each year, each licensee shall furnish to the commissioner[~~Executive Director~~] a completed [~~form, entitled "~~]Annual Report of ***[~~Insurance~~]*** Premium Finance ***Companies[~~Company~~]***[~~," filed herein by reference. Copies may be obtained from the Office of Insurance, 151 Elkhorn Court, P.O. Box 517, Frankfort, Kentucky 40602.~~]

Section 3. Incorporation by Reference. (1) "Annual Report of ***[~~Insurance~~]*** Premium Finance ***Companies[~~Company~~]*** (07/2020) 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, Frankfort, Kentucky 40601, Monday through Friday 8 a.m. to 4:30 p.m.

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.

Andy Beshear
Governor

Ray A. Perry
Deputy Secretary

PUBLIC PROTECTION CABINET
Department of Insurance
P.O. Box 517
Frankfort, Kentucky 40602-0517
1-800-595-6053
http://insurance.ky.gov

Kerry B. Harvey
Secretary

Sharon P. Clark
Commissioner

November 23rd, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: **806 KAR 52:010. Forms for application, security deposits and financial statements.**

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by **806 KAR 52:010**, the Department of Insurance proposes the attached amendment to **806 KAR 52:010**.

Sincerely,

DJ Wasson

DJ Wasson, Deputy Commissioner
Department of Insurance
Mayo-Underwood Building, 500 Mero St.
Frankfort, KY 40601

SUGGESTED SUBSTITUTE

PUBLIC PROTECTION CABINET
Department of Insurance
Financial Standards and Examination Division
(Amendment)

806 KAR 52:010. Forms for application, security deposits and financial statements.

RELATES TO: KRS 304.50

STATUTORY AUTHORITY: KRS 304.50-010(2), 304.50-030(1), 304.50-050(1), (2), 304.50-060(4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.50-010(2) requires the commissioner [~~executive director~~] to promulgate administrative regulations as necessary to govern admission, certification, and regulation of workers' compensation self-insured groups. ***KRS*** 304.50-030(1) requires a workers' compensation self-insured group seeking initial certification to file an application on a form approved by the commissioner [~~Executive Director~~]. KRS 304.50-050(1) requires a workers' compensation self-insured group to provide a security deposit to the commissioner [~~Executive Director~~] on a form prescribed by the commissioner [~~Executive Director~~]. KRS 304.50-050(2) ***authorizes[~~allows~~]*** trustees to file cash, cash equivalents, United States Treasuries or a bank letter of credit in satisfaction of the security deposit requirement, on a form prescribed by the commissioner [~~Executive Director~~]. KRS 304.50-060(4) requires workers' compensation self-insured groups to file statements of financial condition on a form prescribed by the commissioner [~~Executive Director~~]. This administrative regulation prescribes the required forms for application, security deposits, and financial statements.

Section 1. Definitions. (1) Commissioner is defined ***by[~~in~~]*** KRS 304.1-050(1) ["~~Executive Director" means the Executive Director of the Office of Insurance~~].

(2) Department is defined ***by[~~in~~]*** KRS 304.1-050(2) ["~~Office" means the Office of Insurance~~].

(3) "Self-Insured group" is defined ***by[~~in~~]*** KRS 304.50-015(29).

Section 2. (1) Pursuant to KRS 304.50-030(1), Form 100, Initial Application for Certificate of Filing As a Workers' Compensation Self-Insured Group, shall be completed and submitted to the commissioner [~~Executive Director~~] to apply for initial certification as a workers' compensation self-insured group.

(2) Pursuant to KRS 304.50-050(5), Form 141, Election Form for Designation of Custodian Bank for Safekeeping of Securities, shall be completed and submitted to the

commissioner [~~Executive Director~~] to propose designation of a bank or trust company for the safekeeping of securities.

(3) Pursuant to KRS 304.50-050(2), Form 142, Letter of Credit, shall be completed and submitted to the commissioner [~~Executive Director~~] when issuing a letter of credit in satisfaction of the security deposit requirement for a workers' compensation self-insured group.

(4) Pursuant to KRS ***304.50-050(2) [~~304.50(2)~~]***, Form 145, Transaction Sheet for Securities Held Under Safekeeping with Designated Custodian Banks, shall be completed and submitted to the commissioner [~~Executive Director~~] when transferring funds in or out of the Safekeeping Account and shall be approved by the commissioner [~~Executive Director~~] before the bank can complete the transfer.

(5) Pursuant to KRS ***304.50-050(2) [~~304.50(2)~~]***, Form 826, Safekeeping Agreement for Workers' Compensation Self-Insured Groups, shall be completed and submitted to the commissioner [~~Executive Director~~] when the self-insured group initially sets up the security account or when a group transfers the security deposit to another bank.

(6) Pursuant to KRS 304.50-060(4), the Workers' Compensation Self-Insured Group Quarterly Statement (Blank), shall be completed and submitted to the commissioner [~~Executive Director~~] to file a quarterly statement of financial condition. Form 102, Trustee Confirmation of Receipt, shall be completed by each trustee of the workers' compensation self-insured group, acknowledging receipt of a copy of the quarterly statement of financial condition, and submitted to the Department [~~Office~~] of Insurance within ***forty-five (45) [~~seventy-five (75)~~]*** calendar days after the close of each quarterly reporting period.

(7) Pursuant to KRS 304.50-060(4), the Workers' Compensation Self-Insured Group Annual Statement (Blank), shall be completed and submitted to the commissioner [~~Executive Director~~] to file an annual statement of financial condition.

(8) Pursuant to KRS 304.50-050(1), Form 147, Deposit Calculation for Workers' Compensation Self-Insured Groups, shall be completed and submitted annually to the commissioner [~~Executive Director~~] to calculate the correct amount to be placed in the Safekeeping Account.

Section 3. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Form 100 - Initial Application for Certificate of Filing As a Workers' Compensation Self-Insured Group 7/2020[~~(2005)~~]";

(b) "Form 141 - Election Form for Designation of Custodian Bank for Safekeeping of Securities 7/2020[~~(2005)~~]";

(c) "Form 142 - Letter of Credit 7/2020[~~(2005)~~]";

(d) "Form 145 - Transaction Sheet for Securities Held Under Safekeeping with Designated Custodian Banks 7/2020[~~(2005)~~]";

(e) "Form 826 - Safekeeping Agreement for Workers' Compensation Self-Insured Groups ***7/2020***[~~(2005)~~]";

(f) "Workers' Compensation Self-Insured Group Quarterly Statement (Blank) 7/2020[~~(July 15, 2005)~~]";

(g) "Form 102 - Trustee Confirmation of Receipt 7/2020[~~(4/2005)~~]";

(h) "Workers' Compensation Self-Insured Group Annual Statement (Blank) ***7/2020***[~~(July 15, 2005)~~]"; and

(i) "Form 147 - Deposit Calculation for Workers' Compensation Self-Insured Groups 6/2020 [~~(2005)~~]".

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department [~~Office~~] of Insurance, Mayo-Underwood Building, 500 Mero Street, [~~215 West Main Street~~], Frankfort, Kentucky 40601, Monday through Friday, 8:00 a.m. to 4:30 p.m. This material is also available on the Department [~~Office~~] of Insurance Internet Web site at https://insurance.ky.gov [~~http://doi.ppr.ky.gov/kentucky/~~].

Andy Beshear
Governor

Jonathan Rabinowitz
Chairman

Kerry B. Harvey
Secretary

Marc A. Guilfoil
Executive Director

Public Protection Cabinet

KENTUCKY HORSE RACING COMMISSION
Established 1906
4063 Iron Works Pkwy., Bldg. B
Lexington, Kentucky 40511
Telephone: (859) 246-2040 Fax: (859) 246-2039
Website: http://khrc.ky.gov

November 25, 2020

Emily Caudill, Regulations Compiler
Legislative Research Commission
029, Capitol Annex
702 Capitol Aven.
Frankfort, KY 40601

Re: 810 KAR 3:020 Agency Amendment

Via Electronic Mail

Dear Ms. Caudill:

Following the Administrative Regulation Review Subcommittee on November 9, 2020, the Kentucky Horse Racing Commission proposes the attached agency amendment to 810 KAR 3:020. Please do not hesitate to contact me if you have questions or concerns.

Very truly yours,

Jennifer Wolsing

Jennifer Wolsing
General Counsel

Agency Amendment
Public Protection Cabinet
Kentucky Horse Racing Commission

810 KAR 3:020: Licensing of Racing Participants

Page 14
Section 12(2)
Lines 16-20

Delete the following:

"Failure to meet the financial responsibility requirements of KRS 230.310 is defined as a licensee's failure to satisfy a final and unappealable judgment rendered against him or her by any administrative, state or federal court for goods, supplies, services, or fees that are in any way related to the business of horse racing."

Insert the following:

Any licensee who shall accumulate unpaid obligations, default in obligations, issue drafts or checks that are dishonored or payment refused, or otherwise display financial irresponsibility reflecting on his or her experience, character, or general fitness, shall be deemed to have violated the financial responsibility requirements of this Section and may be subject to refusal, suspension, or revocation of license.

Page 14-15
Section 12(3)
Lines 14: 21-23; 15: 1-2

After "a third party with knowledge," insert the following:

of the failure to meet the financial responsibility requirement, through the presentation of a final, unappealable judgment from a state, federal, or administrative court.

Delete the following "of the final judgment."

CABINET FOR HEALTH AND FAMILY SERVICES
Office of the Secretary

Andy Beshear
Governor

275 East Main Street, 5W-A
Frankfort, KY 40621
502-564-7042
502-564-7091
www.chfs.ky.gov

Eric C. Friedlander
Secretary

November 30, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 901 KAR 5:120. Abortion reporting.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 901 KAR 5:120, the Department for Public Health proposes the enclosed suggested amendment to 901 KAR 5:120.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at 564-3970, extension 4069.

Sincerely,

Donna Little

Donna Little
Deputy Executive Director
Office of Legislative and Regulatory Affairs

11/23/2020

SUGGESTED AMENDMENT

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Epidemiology and Health Planning

901 KAR 5:120. Abortion reporting.

Page 2
Section 2(4)(a)
Lines 18-19

After "in writing", insert "including the following".
Delete "as follows".

Page 4
Section 5(1)(b)
Line 9

After "of Abortion",", insert "10/2020".
Delete "4/2020".

VS-913 Rev. 10/2020

COMMONWEALTH OF KENTUCKY
STATE REGISTRAR OF VITAL STATISTICS
REPORT OF ABORTION

****TYPE OR PRINT IN PERMANENT BLACK INK****

Kentucky Public Health
Prevent. Promote. Protect.

1. Facility Name *(if not clinic or hospital, provide address)*	2. County of Abortion	3. Date of Abortion *(MM/DD/YYYY)*	4. Patient's Residence *(State)*

5. Age	6. Married ☐ Yes ☐ No	7. Is Hispanic ☐ Yes ☐ No	8. Hispanic Origin (e.g. Cuban, Mexican, Puerto Rican, etc.) If yes, specify

9. Race	10. Education *(Specify only highest grade completed)*		11. Date Last Normal Menses Began *(MM/DD/YYYY)*
☐ American Indian ☐ Black ☐ White ☐ Other *(Specify)* _____	Elementary/Secondary (0-12)	College (1-4 or 5+)	

12a. Clinical Estimate of Gestation *(Weeks)*	12b. Probable Post-Fertilization Age *(Weeks)*	13. Heartbeat detected ☐ Yes ☐ No

Previous Pregnancies *(Complete each section)*

Live Births		Other Abortions	
14a. Now Living Number _____ ☐ None	14b. Now Dead Number _____ ☐ None	15a. Spontaneous Number _____ ☐ None	15b. Induced *(Do not include this abortion)* Number _____ ☐ None

16a. In the attending physician's reasonable medical judgment, the abortion was necessary to prevent the death of the pregnant woman or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman: ☐ Yes ☐ No

If yes, list medical condition: _____

16b. If the post-fertilization age of the fetus is more than 20 weeks, in the attending physician's reasonable medical judgment, the abortion was necessary to prevent the death of the pregnant woman or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman: ☐ Yes ☐ No

16c. If the post-fertilization age of the fetus is more than 20 weeks, a different physician, not professionally related to the attending physician, made the reasonable medical judgment the abortion was necessary to prevent the death of the pregnant woman or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman: ☐ Yes ☐ No

Name of different physician: _____ **Date judgment received:** _____

17a. If the post-fertilization age of the fetus is more than 20 weeks, certify whether the attending physician certifies that the pregnancy was terminated in a way that provided the best chance for the unborn child to survive.

Was the pregnancy terminated in a way that provided the best chance for the unborn child to survive? ☐ Yes ☐ No

17b. If the answer to (17a) is "no," certify whether terminating the pregnancy in a way that provided the best chance for the unborn child to survive posed a greater risk of death or substantial and irreversible injury to the woman *(Specify below)*:

18 Reason for abortion
Is the abortion being performed because *(Check only one)*

☐ Sex of the unborn child ☐ Race of the unborn child ☐ Color of the unborn child ☐ National origin of the unborn child

☐ Potential diagnosis of Down Syndrome ☐ Potential diagnosis of any other disability

19a. Abortion Procedures
Procedure That Aborted Pregnancy *(Check only one)*

☐ Suction Curettage ☐ Medical (Nonsurgical) ☐ Dilation and Evacuation (D&E) ☐ Intra-Uterine Instillation (Saline or Prostaglandin)

☐ Sharp Curettage (D&C) ☐ Hysterotomy/Hysterectomy ☐ Other/Abortion Drug *(Specify)* _____

19b. If the post-fertilization age of the fetus is more than 20 weeks, certify the attending physician's written certification for the method and reasons for choosing the method that aborted the pregnancy. *(Specify below)*:

20. Were there any abortion complications known to the provider as a result of the abortion? ☐ Yes ☐ No *(If yes, check all that apply)*
Abortion complications to be reported shall include only the following physical or psychological conditions arising from the induction or performance of an abortion:

☐ Allergic reaction to anesthesia or abortion-inducing drugs
☐ Amniotic fluid embolism
☐ Cardiac arrest
☐ Cervical laceration
☐ Coma
☐ Death
☐ Deep vein thrombosis
☐ Failure to terminate the pregnancy
☐ Free fluid in the abdomen
☐ Heavy bleeding that causes symptoms of hypovolemia or the need for a blood transfusion
☐ Hemolytic reaction due to the administration of ABO-incompatible blood or blood products
☐ Hypoglycemia occurring while the patient is being treated at the abortion facility
☐ Incomplete abortion or retained tissue
☐ Infection
☐ Missed ectopic pregnancy
☐ Pelvic inflammatory disease
☐ Placenta Previa in subsequent pregnancies
☐ Pre-term delivery in subsequent pregnancies
☐ Psychological complications including depression, suicidal ideation, anxiety, and sleeping disorders
☐ Pulmonary embolism
☐ Renal failure
☐ Respiratory arrest
☐ Shock
☐ Uterine laceration
☐ Any other adverse event as defined by criteria provided in the Food and Drug Administration Safety Information and Adverse Event Reporting Program.

Name of person completing report *(Type or print)* _____

This form shall be sent to the State Registrar of Vital Statistics within 15 days after the end of the month in which the abortion occurred.
(Each abortion as defined in KRS 311.720 that occurs in the Commonwealth, regardless of the length of gestation, shall be reported to the Office of Vital Statistics by the person in charge of the institution or attending physician within fifteen (15) days after the end of the month in which the abortion occurred.)

Office of Vital Statistics
275 East Main Street, 1E-A
Frankfort, KY 40621

VS-913 Rev. 10[04]/2020

COMMONWEALTH OF KENTUCKY
STATE REGISTRAR OF VITAL STATISTICS
REPORT OF ABORTION

****TYPE OR PRINT IN PERMANENT BLACK INK****

1. Facility Name *(if not clinic or hospital, provide address)*	2. County of Abortion	3. Date of Abortion *(MM/DD/YYYY)*

4. Patient's Residence *(State)*	5. Age	6. Married ☐ Yes ☐ No	7. Is Hispanic ☐ Yes ☐ No	8. Hispanic Origin (e.g. Cuban, Mexican, Puerto Rican, etc.) If yes, specify

9. Race	10. Education *(Specify only highest grade completed)*	
☐ American Indian ☐ Black ☐ White ☐ Other *(Specify)* _____	Elementary/Secondary (0-12)	College (1-4 or 5+)

11. Date Last Normal Menses Began *(MM/DD/YYYY)*	12a. Clinical Estimate of Gestation *(Weeks)*	12b.[13.] Probable Post-Fertilization Age *(Weeks)*	13. Heartbeat detected ☐ Yes ☐ No

Previous Pregnancies *(Complete each section)*

Live Births		Other Abortions	
14a. Now Living	14b. Now Dead	15a. Spontaneous	15b. Induced *(Do not include this abortion)*
Number _____ ☐ None	Number _____ ☐ None	Number _____ ☐ None	Number _____ ☐ None

16a. In the attending physician's reasonable medical judgment, the abortion was necessary to prevent the death of the pregnant woman or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman: Yes No

If yes, list medical condition: _____

16b. If the post-fertilization age of the fetus is more than 20 weeks, in the attending physician's reasonable medical judgment, the abortion was necessary to prevent the death of the pregnant woman or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman: ☐ Yes ☐ No

16c.[16b.] If the post-fertilization age of the fetus is more than 20 weeks, a different physician, not professionally related to the attending physician, made the reasonable medical judgment the abortion was necessary to prevent the death of the pregnant woman or to avoid a serious risk of the substantial and irreversible impairment of a major bodily function of the pregnant woman: ☐ Yes ☐ No

Name of different physician: **Date judgment received:**

17a. If the post-fertilization age of the fetus is more than 20 weeks, certify whether the attending physician certifies that the pregnancy was terminated in a way that provided the best chance for the unborn child to survive.

Was the pregnancy terminated in a way that provided the best chance for the unborn child to survive? ☐ Yes ☐ No

17b. If the answer to (17a) is "no," certify whether terminating the pregnancy in a way that provided the best chance for the unborn child to survive posed a greater risk of death or substantial and irreversible injury to the woman *(Specify below)*:

18 Reason for abortion
Is the abortion being performed because *(Check only one)*

☐ Sex of the unborn child ☐ Race of the unborn child ☐ Color of the unborn child ☐ National origin of the unborn child

☐ Potential diagnosis of Down Syndrome ☐ Potential diagnosis of any other disability

19a.[18a.] Abortion Procedures
Procedure That Aborted Pregnancy *(Check only one)*

☐ Suction Curettage ☐ Medical (Nonsurgical) ☐ Dilation and Evacuation (D&E) ☐ Intra-Uterine Instillation (Saline or Prostaglandin)

☐ Sharp Curettage (D&C) ☐ Hysterotomy/Hysterectomy ☐ Other/Abortion Drug *(Specify)* _____

19b.[18b.] If the post-fertilization age of the fetus is more than 20 weeks, certify the attending physician's written certification for the method and reasons for choosing the method that aborted the pregnancy. *(Specify below)*:

20.[19.] Were there any abortion complications known to the provider as a result of the abortion? ☐ Yes ☐ No *(If yes, check all that apply)*
Abortion complications to be reported shall include only the following physical or psychological conditions arising from the induction or performance of an abortion:

☐ Allergic reaction to anesthesia or abortion-inducing drugs
☐ Amniotic fluid embolism
☐ Cardiac arrest
☐ Cervical laceration
☐ Coma
☐ Death
☐ Deep vein thrombosis
☐ Failure to terminate the pregnancy
☐ Free fluid in the abdomen
☐ Heavy bleeding that causes symptoms of hypovolemia or the need for a blood transfusion
☐ Hemolytic reaction due to the administration of ABO-incompatible blood or blood products
☐ Hypoglycemia occurring while the patient is being treated at the abortion facility
☐ Incomplete abortion or retained tissue
☐ Infection
☐ Missed ectopic pregnancy
☐ Pelvic inflammatory disease
☐ Placenta Previa in subsequent pregnancies
☐ Pre-term delivery in subsequent pregnancies
☐ Psychological complications including depression, suicidal ideation, anxiety, and sleeping disorders
☐ Pulmonary embolism
☐ Renal failure
☐ Respiratory arrest
☐ Shock
☐ Uterine laceration

☐ Any other adverse event as defined by criteria provided in the Food and Drug Administration Safety Information and Adverse Event Reporting Program.

Name of person completing report ***(Type or print)*** _____

This form shall be sent to the State Registrar of Vital Statistics within 15 days after the end of the month in which the abortion occurred. (Each abortion as defined in KRS 311.720 that occurs in the Commonwealth, regardless of the length of gestation, shall be reported to the Office of Vital Statistics by the person in charge of the institution or attending physician within fifteen (15) days after the end of the month in which the abortion occurred.)

Office of Vital Statistics
275 East Main Street, 1E-A
Frankfort, KY 40621

CABINET FOR HEALTH AND FAMILY SERVICES
Office of the Secretary

Andy Beshear
Governor

275 East Main Street, 5W-A
Frankfort, KY 40621
502-564-7042
502-564-7091
www.chfs.ky.gov

Eric C. Friedlander
Secretary

November 30, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 902 KAR 8:160. Local health department operation requirements.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 8:160, the Department for Public Health proposes the enclosed suggested amendment to 902 KAR 8:160.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at 564-3970, extension 4069.

Sincerely,

Donna Little

Donna Little
Deputy Executive Director
Office of Legislative and Regulatory Affairs

Staff-suggested Amendment

Final Version 11/23/2020 9:19 a.m.
CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Administration and Financial Management

902 KAR 8:160. Local health department operations requirements.

Page 12
Section 10
Line 5

After "10. Identification of", capitalize "local needs".

CABINET FOR HEALTH AND FAMILY SERVICES
Office of the Secretary

Andy Beshear
Governor

275 East Main Street, 5W-A
Frankfort, KY 40621
502-564-7042
502-564-7091
www.chfs.ky.gov

Eric C. Friedlander
Secretary

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 902 KAR 8:170. Local health department financial management requirements.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 8:170, the Department for Public Health proposes the enclosed suggested substitute to 902 KAR 8:170.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at 564-3970, extension 4069.

Sincerely,

Donna Little

Donna Little
Deputy Executive Director
Office of Legislative and Regulatory Affairs

Subcommittee Substitute

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Administration and Financial Management
(As Amended at ARRS)

902 KAR 8:170. Local health department financial management requirements.

RELATES TO: KRS 41.240(4), 45A.690, 211.180(1), ***211.185, 211.186, 211.187,*** 212.025, 212.120, 212.245(3), (4), 212.890, 424.110-424.150, ***[Ky. Acts Ch. 21,]*** 2 C.F.R. Part 200

STATUTORY AUTHORITY: KRS 194A.050(1), 211.170(1), (2), (3), (6)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet; or to comply with federal law. KRS 211.170(1), (2), (3), and (6) require the cabinet to establish policies and standards of operation; supervise financial, personnel, program, administrative and other functions; and allocate, modify, or cancel allotments of state funds for Kentucky's local health departments. This administrative regulation establishes minimum fiscal and financial management requirements for Kentucky's county and district local health departments and for all other classes of local health departments, except if a specific Kentucky revised statute requires a more stringent minimum requirement.

Section 1. Definitions. (1) "***Core public health program" is defined by KRS 211.185(4). [***~~***"Agency" is defined by 2020 Ky. Acts ch. 21, sec. 1(1).***~~***]***

(2) ***[***~~***"Core public health program" is defined by 2020 Ky. Acts ch. 21, sec. 1(4).***~~

~~***(3) "Department" is defined by 2020 Ky. Acts ch. 21, sec. 1(5).***~~

~~***(4) "Fee-for-service program" means a program in which service fees, excluding program administration fees, are greater than fifty (50) percent of funding.***~~

~~***(5)]***~~ "Foundational public health program" is defined by ***KRS 211.186(6) [***~~***2020 Ky. Acts ch. 21, sec. 1(6)]***~~.

~~***(3)[(6)]***~~ "Local public health priorities" is defined by ***KRS 211.185(9) [***~~***2020 Ky. Acts ch. 21, sec. 1(9)]***~~.

~~***(4)[(7)]***~~ [~~(2)~~] "Local support" means local health department financial support:

(a) Including:

1. Unrestricted receipts from a local government agency or special district;
2. Receipts from the public health taxing district;
3. Nonfederal receipts from a contract with a board of education; and
4. An unrestricted donation from another source; and

(b) Excluding funds from the Unrestricted and Restricted fund balances.

~~***(5)[(8)]***~~ "Personal service contract" is defined by KRS 45A.690(1)***(h)[***~~***(g)]***~~.

~~***(6)[(9)]***~~ [~~(3)~~] "Public health department director" means:

(a) The administrative or health officer of a county or district health department;

(b) The administrative assistant of a county health department that does not have a health officer;

(c) The director of a district health department that does not have a health officer;

(d) The district director of health of an independent district department of health; or

(e) The commissioner of an urban-county department of health or of a health department serving a county with a city of the first class.

(7)[~~(10)~~] [~~(4)~~] "Restricted fund" means the portion of a local health department's total fund balance that is limited by the Department for Public Health for a specific program's expenses or other items of expense.

(8)[~~11~~] [~~(5)~~] "Unrestricted fund balance" means the portion of a local health department's total fund balance that is not limited by the Department for Public Health for a specific program's expenses or other items of expense.

Section 2. Budgeting Requirements. (1) Each local health department shall prepare a fiscal year budget in accordance with annual budgeting guidance provided by the Department for Public Health.

(2) The local health department budget narrative shall include an attestation that core and foundational public health programs will be implemented, maintained, or assured in accordance with ***KRS 211.186 [~~2020 Ky. Acts ch. 21~~]***.

(3) A description of the local public health priorities, supported by a local needs assessment in accordance with ***KRS 211.187 [~~2020 Ky. Acts ch. 21, sec. 3~~]***, to be funded by local tax or unrestricted funds shall be submitted to the Department for Public Health, Office of the Commissioner, for review and approval.

(4) Each local health department shall have a balanced budget in which receipts at least equal expenditures and shall operate within its approved budgets.

(5)[~~(3)~~] Each local health department annual budget shall be approved by both the governing local board of health and the Department for Public Health.

(6)[~~(4)~~](a) Each local health department shall be responsible for making budget changes necessitated by:

1. Changes in financial status;
2. Changes in project status; or
3. The addition or deletion of a new project.

(b) Changes shall:

1. Be subject to review and approval by the Department for Public Health; and
2. Require a corresponding change in plans if required by the Department for Public Health.

(7)[~~(5)~~] Actual capital expenditures of local health departments for furniture and equipment, data processing equipment, land, buildings, and vehicles shall not exceed the approved budgeted amount without prior approval by the appropriate governing board of health.

(8)[~~(6)~~] Actual use of a local health department's unrestricted fund balance in excess of the amount included in the approved budget shall be approved by the governing board of health and shall be used solely for the operation and maintenance of local health departments.

(9)[~~(7)~~] An actual deficit in a local health department's financial operations for the fiscal year wherein cash expenditures and payroll related liabilities exceed available cash receipts, including approved use of the unrestricted fund balance, shall not be allowable.

(10)[~~(8)~~](a) The Department for Public Health shall notify the local health department in writing if it determines that:

1. A local health department is receiving fewer receipts than are budgeted;

2. A local health department is making expenditures in excess of the approved budget; or,

3. A deficit condition is probable at the end of the fiscal year.

(b) Within fifteen (15) working days of receipt of the notification, the local health department shall inform the Department for Public Health in writing of the reasons that the determination may be in error.

(c) If the reasons and corrective actions listed by the local health department are not sufficient to prevent a deficit condition from occurring at the end of the fiscal year, the Department for Public Health shall direct the local health department to:

1. Institute a hiring freeze on employees;

2. Institute a freeze on meritorious, promotional, or other salary increments;

3. Institute a reduction in contractual and other expenditure categories; or

4. Take other action necessary to correct the deficit situation.

Section 3. Use of Receipts. (1) A local health department may, with the approval of the Department for Public Health, transfer funds from a restricted to an unrestricted account.

(2) Receipts from any source shall be used:

(a) In accordance with laws, policies, administrative regulations, and contracts governing the use of the receipts; and

(b)[~~. Receipts shall be used~~] Only for the operation and maintenance of the health department for necessary, reasonable, and proper purposes that protect and improve the health of the people of the Commonwealth.

(3) The minimum acceptable level of local support shall be determined annually by the Commissioner of the Department for Public Health.

(4) The state allotment to a local health department shall be adjusted in the following circumstances:

(a) The local health department decreases its budgeted amount of local support below the minimum acceptable level. The state allotment shall be decreased by the same percentage in the year of the decrease.

(b) The local health department receives less local financial support than the required level. The state allotment shall be decreased by the percentage that the actual local support was deficient. The decrease shall apply to the fiscal year following the shortage.

(c) The local health department accumulates an unrestricted fund balance, as of June 30 of a fiscal year, in excess of [~~thirty (30) percent of that year's expenditures for non-fee programs plus~~] forty (40) percent of that year's expenditures [~~for fee-for-service programs~~], or $100,000, whichever is greater. The local health department shall submit, to the Department for Public Health, a written plan of use for the amount of the excess. If approved, the funds shall be placed into a local restricted fund to be used solely as approved.

(5) Fees.

(a)1. A request from a local health department to change patient fees to either a sliding or nominal fee basis shall be sent to the Department for Public Health for approval.

2. A request shall include documentation of the proposed full amount of the fee, the estimated annual cost of the service, and the estimated net fee income for the service.

3. Charges for medical supplies and equipment may be requested as a percentage of the acquisition cost of the supply or equipment item or may be requested as charges for individual items.

(b) Patient fees charged to self-pay patients shall be on a sliding fee basis approved by the Department for Public Health and be based on the level of income matched with the level of poverty, utilizing the federal poverty guidelines as published annually by the U.S.[~~Federal~~] Department of Health and Human Services, according to the following scale:

1. Above 250 percent of poverty, fee shall be assessed at full charge of service;

2. From 101 to 250 percent of poverty, fee shall be based on a schedule of discounts; and

3. Below 101 percent of poverty, there shall be no fee except as specified in paragraph (c) of this subsection.

(c) A [~~nominal~~] fee up to five (5) dollars may[~~shall~~] be charged for communicable disease services specified by the Department for Public Health.

(d) The inability to pay the assessed fee shall not be a barrier to services.

(e) A charge shall not be made to school age children at a school-based clinic if requested by the local health department and authorized by the Department for Public Health.

(f) A policy of a local health department that may result in referral of services due to non-payment of fees shall be approved by the Department for Public Health.

(g)1. A local health department shall bill third-party payors for covered services provided to individuals.

2. If a third-party governmental payor is billed for services rendered to an eligible patient, the regulations of the third-party payor shall be followed for the part of the fee charged directly to the patient.

3. A patient's health insurance carrier shall be billed at 100 percent of charges. A balance not covered by the health insurance carrier shall be charged to the patient, except that the amount charged shall not exceed the amount that a patient without health insurance coverage would be charged, using standard discounts as applied to total charges for services rendered.

(h) A fee, regardless of the source of the fee or the funding of the project, shall be applied to the project that generates the fee, in accordance with income procedures of 2 C.F.R. 200.307(e). A third-party cost reimbursement payment and an interim payment shall be recorded in the same project where the costs were recorded, in proportion to the expenditures of each project that were reimbursed by the third party.

(6) A matching requirement for any source of receipts shall be the sole responsibility of each local health department.

(7) The following policies shall be applied in closing receipt accounts for the local health department fiscal year, July 1 to June 30:

(a) Receipts earned and received during a fiscal year shall be recorded as a receipt of that fiscal year; and

(b) Receipts earned in one (1) fiscal year and received after June 30 of that fiscal year shall be recorded as new fiscal year receipts.

Section 4. Expenditure Policies. Policies and procedures required by 2 C.F.R. 200 Subpart E shall be followed by local health departments for expenditures in projects, regardless of the source of

funds for the project. The following policies concerning allowable expenditures and their proper documentation shall be followed by local health departments:

(1) Salaries, wages, benefits, and personnel payments.

(a) Salaries and wages for only those positions specified in administrative regulations for local health departments, 902 KAR 8:060 through 902 KAR 8:090, and 902 KAR 8:140, shall be allowable. The positions and related expenditures shall be included in the approved budget or approved budget revisions of the local health department. Other salary, wage, or bonus payments shall not be allowable, unless specifically approved by the Department for Public Health. Uniform pay dates shall be determined annually by the Department for Public Health.

(b) Expenditures shall be authorized for payment of employer paid fringe benefits required or allowed by policies of the Department for Public Health.

1. Required benefits shall be payments of the single-coverage amount for health insurance and life insurance that are part of the state-negotiated plans.

2. Additional allowed benefits shall be determined by the public health department director and approved by the governing board of health.

3. A part-time employee or a personal services contract employee working less than 100 hours per month shall not be eligible for employer-paid fringe benefits.

4. A payment to or on behalf of an employee for another direct or fringe benefit or other reason shall not be made unless:

a. Specifically allowed by this administrative regulation;

b. Approved by the Department for Public Health; and

c. A disbursement for services of a contract employee or independent contractor shall be made in accordance with the terms of the written contract. A contract payment shall not be made without proper written documentation demonstrating that services have been rendered.

(2) Capital expenditures.

(a) Capital expenditures are allowable for necessary capital equipment, land, and buildings.

1. The equipment in this category shall cost more than $5,000 and have an expected useful life of one (1) year or more.

2. The same purchasing policies apply to capital items as apply to noncapital purchases.

3. Before purchasing land or buildings or contracting for the construction or remodeling of a building, the local health department shall notify[~~contact~~] the Department for Public Health [~~for approval~~].

(b) A local health department shall pay a vendor within thirty (30) working days of the receipt of the service or goods, or within thirty (30) working days of the receipt of the invoice or bill from the vendor, whichever is later, unless the local health department and the vendor have agreed in writing to a longer period of time.

(c) A local health department shall not donate anything of value to any individual or entity, unless approved by the Department for Public Health.

Section 5. Travel Policies. (1) The public health department director shall insure that travel expenses are economical.

(2) A person who travels on official local health department business shall state on the expense voucher the purpose of each trip and shall maintain records to support claims.

(a) A local health department may provide an employee with a credit card to cover travel expenses.

(b) Due care shall be taken to assure that use of a local health department credit card is not abused.

(c) A local health department shall not provide an employee with cash to pay travel expenses. The public health department director responsible for insuring that travel reimbursement conforms to this policy shall disallow, reduce, or strike from an expense voucher any claim contrary to this administrative regulation, and may require written justification for an amount claimed.

(3) With the exceptions cited in this policy, reimbursement shall not be claimed for expenses of a person other than an employee, or other person in the official service of the local health department. Only necessary expenses of official travel shall be reimbursed.

(4) Each day's vicinity travel shall be listed on a separate line on the expense voucher. The employee's supervisor or the public health department director shall monitor vicinity mileage claimed by an employee on travel status.

(5) A travel voucher shall be signed and dated by the employee submitting the claim and by an employee designated in accordance with the local health department's internal control procedures. The public health department director's travel voucher shall be signed by one (1) or more board of health members designated at a board of health meeting to perform the function.

(6) The official work station of an employee shall be:

(a) The street address of the local health department facility;

(b) For a local health department with more than one (1) facility, the facility in which the employee most often works;

(c) Established not for an employee's purposes, but in the best interest of the local health department; and

(d) Designated for a valid purpose.

(7) A standard travel expense voucher or another voucher approved by the Department for Public Health shall be used to claim reimbursement for travel expenses.

(a) Each travel expense voucher shall show the claimant's identifying number, name, address, and official workstation. The travel voucher may be typed, prepared by computer, or legibly prepared in ink.

(b) Receipts shall be submitted with[~~stapled to~~] the travel voucher.

(c) If leave interrupts official travel, the travel voucher shall show the dates of leave.

(8) A travel expense shall not be reimbursed unless the travel was authorized in advance by the public health department director or designee.

(9) A local health department employee traveling on local health department business shall use the most economical, standard transportation available and the most direct and usually traveled routes. Expenses added by use of other transportation or routes shall be assumed by the employee.

(10) Local health department-owned vehicles and gasoline credit cards shall be used for local health department business travel if available and feasible.

(a) Mileage payment shall not be claimed by an individual when local health department vehicles are used.

(b) Routine personal use of a local health department vehicle, including commuting use, shall not be an allowable public expenditure.

(c) An assignment of a vehicle to an employee who takes the vehicle home shall be minimal and limited to direct service personnel providing:

1. On-call direct services, or a majority of services in the field; or

2. Substantial direct services on the way to or from the employee's workstation.

(d) If a vehicle is assigned under paragraph (c) of this subsection, some personal commuting mileage may be unavoidable. A local health department shall develop a written policy to address the unavoidable personal mileage. The policy shall conform to current federal and state tax requirements for income and travel and shall be forwarded to the Department for Public Health for review and approval.

(11) Mileage claims for use of privately-owned vehicles shall be disallowed if a local health department vehicle was available and feasible.

(12) An employee on official travel status whose private or agency automobile breaks down may continue in travel status as approved by the public health department director.

(13) An employee on official travel status may be continued on travel status, as approved by the public health department director, if the employee becomes incapacitated due to illness or injury that qualifies as official sick leave. Medical expenses shall not be reimbursable travel costs.

(14) On nonworking days, an employee on official travel status shall forfeit official travel status once the employee returns to his official work station or domicile.

(15) Reimbursement shall not be paid for travel between the employee's residence and official workstation, unless requested to report to work while off duty.

(16) Commercial airline travel shall be coach or tourist class. Additional expense for first-class travel shall not be reimbursed.

(17) Mileage for each in-state trip shall be based on the Department of Transportation's official mileage map or on the Finance and Administration Cabinet's mileage chart if available. Out-of-state mileage shall be based on mileage maps. If point of origin is the claimant's residence, mileage and time shall be paid between the residence and travel destination, or between the work station and travel destination, whichever is shorter.

(18) The cost of renting a car or other special conveyance in lieu of ordinary transportation shall be allowed only with acceptable written justification to the public health department director. Privately-owned aircraft may be used only when it is to the advantage of the local health department as evidenced by a reduction in both travel costs and travel time.

(19) Lodging costs shall be the most economical available.

(a) Facilities providing special government rates or commercial rates shall be used where feasible.

(b) State-owned facilities or local health departments shall be used for meeting rooms and lodging if available, practical, and economical.

(20) A claimant who attaches the hotel's or motel's preprinted, receipted bill shall be reimbursed for the claimant's actual cost of lodging, subject to the following provisions:

(a) Reimbursement at a Kentucky state park shall be at the park's actual rate.

(b) The local health department shall not pay for lodging located within forty (40) miles of a claimant's residence or work station without approval of the public health department director.

(c) Lodging accommodations shared with another person or persons, not a local health department employee, shall be reimbursed at the rate for a single room. Lodging

accommodations shared with other local health department employees shall be reimbursed on a pro rata basis.

(21) Mileage reimbursement for official use of privately-owned vehicles shall be at the mileage reimbursement rate determined by the Department for Public Health.

(22) With receipts, actual commercial transportation costs shall be reimbursed.

(23) Reimbursement for use of privately-owned aircraft shall not exceed the cost of air coach fare or the privately-owned vehicle rate, whichever is less.

(24) A claimant using camping vehicles for lodging shall be reimbursed for actual expense plus parking or camping charges. A receipt for parking or camping charges shall be submitted.

(25) Actual parking, bridge, and toll charges shall be reimbursable. Toll receipts shall not be required for in-state travel by a two (2) axle vehicle.

(26) Reasonable expenses shall be allowed for baggage handling, for delivery to or from a common carrier or lodging, and for storage. Charges for overweight baggage shall be allowed if the excess was for official business.

(27) Registration fees required for admittance to meetings shall be allowed. An employee shall not claim meal expenses for meals included in the registration fee. A notation shall be made on the travel voucher that the registration fee included the cost of meals. Reimbursement for registration fees and other job-related training may be claimed as "other expenses" on the travel voucher and charged to the appropriate expenditure accounts. Receipts for job-related fees shall be attached to the travel voucher.

(28) Telephone and fax costs for necessary official business shall be reimbursable.

(29) If justified, other necessary miscellaneous expenses associated with official travel may be allowed by the public health department director. Receipts shall be attached to the travel voucher.

(30) Receipts shall be required for travel expenses over ten (10) dollars except for subsistence expense items.

(31) Subsistence shall include amounts determined to have been spent for meals, taxes, and tips. To be eligible for subsistence for breakfast or lunch while traveling in Kentucky, a claimant's authorized work shall require overnight accommodations at a destination more than forty (40) miles from both work station and home and shall also require absence from the work station and home during mealtime. The claimant shall attach to the[~~his~~] travel voucher, either [~~his~~] lodging receipts or other credible documentation sufficient for audit.

(32) Local health department employees assigned to attend a function of an organization not under their control may be reimbursed for actual meal costs charged or arranged for by the organization. Receipts for meals shall be attached to the travel voucher.

(33) The local health department may pay for subsistence and related expenses at staff meetings not to exceed four (4) meals per year for an employee. The subsistence expense shall not exceed the department's standard meal reimbursement amount. Travel status shall not be required for staff meeting meals.

(34) Other allowable travel expense reimbursements shall consist of the following:

(a) Expenditures for the actual and reasonable cost of meals provided for district and county board of health members for official board functions, and for meals of guests invited to participate in the official business conducted at these functions;

(b) Travel expenditures of board of health members attending official board of health functions, in accordance with travel policy provisions;

(c) Travel expenditures incurred by board members other than the chairperson if approved by the chairperson or the full board;

(d) Travel expenditures incurred by the chairperson if approved by the vice-chairperson or the full board;

(e) Expenditures for meals and transportation expenses of local health department advisory committee members attending official local health department functions; and

(f) Travel expenses of a person applying for a position that will designate the applicant as the public health department director for the department, or as the medical director subject to the limits applicable to local health department employees, but no more than one (1) round trip for each applicant.

(35) Expenditures shall be authorized for employee morale and welfare items, as defined in 2 C.F.R. 200.437, in an amount not to exceed twenty-five (25) dollars per employee per fiscal year. Receipts shall be kept for all expenditures.

(36) Expenditures shall be allowed for other items necessary for the maintenance and operation of the local health department, if the expenditure is made in accordance with statutes and administrative policies.

(a) The Department for Public Health may require a local health department to provide adequate justification for any expenditure made by the local health department.

(b) If the justification is determined to be inadequate, appropriate corrective action shall be taken by the Department for Public Health.

Section 6. Purchasing Policies. (1) Each local health department shall develop and follow formal procedures for authorizing purchases made on behalf of the local health department.

(a) These procedures shall be outlined in the local health department's written internal control procedures.

(b) Written purchase orders (service authorizations for independent contractors) and receiving reports or service verifications shall be used except for utility bills and purchase orders not in conformance with standard business practice.

(2) A local health department shall use the following minimum procedures in accordance with 2 C.F.R. 200.322 for purchasing and advertisement for bids:

(a) If an expenditure for a single type of good or service not covered by contract policies is more than $40,000 in a fiscal year, advertisements for bids shall be made in accordance with KRS 424.110-424.150. The Department for Public Health may be contacted for assistance in determining whether an expenditure is for a single type of good or service. The local health department shall:

1. Record, in writing, and maintain for department review:

a. Price quotations received; and

b. Reasons and basis for selecting and placing the order, if the lowest price was not selected; and

2. Select the lowest or best bid.

(b) If the expenditure for a single type of good or service is $3,000 but not greater than $40,000 in a fiscal year, the local health department shall:

1. Obtain three (3) or more price quotations from qualified sources of supply, if available, in the department's normal trade area; and

2. Record, in writing, and maintain for department review:

a. Price quotations received; and

b. Reason and basis for selecting and placing.

(c) If a single type of good or service purchased is less than $3,000, to the extent practicable, the local health department shall distribute purchases equitably among qualified suppliers. Purchases may be awarded without soliciting competitive quotations.

(d) The requirements for competitive bidding shall not apply to a purchase made under the provisions of a state price contract.

(e) A physician who is the health officer for more than one (1) local health department may purchase supplies and services or technical services on a cooperative purchasing basis, in accordance with the purchasing administrative regulations for local health departments.

(f) A local health department shall not enter into a lease or purchase agreement for nonprofessional services with a local health department employee or a business entity in which a local health department employee owns or controls more than five (5) percent interest, except if determined to be in the best interest of the public and approved in writing by the Department for Public Health.

Section 7. Contracting for Services. (1) A local health department may contract for a core public health program.

(2) A local health department contracting for a core public health program shall evaluate the ability of the contracting agency to provide the program in accordance with applicable state statutes and administrative regulations.

(3) The contract for a core public health program shall include:

(a) A method for ongoing, comprehensive performance evaluation of the contracted vendor;

(b) Established performance criteria and standards to evaluate the contracted vendor; and

(c) An assurance the local health department will continue core public health programs in accordance with ***KRS 211.186, if [~~2020 Ky. Acts ch. 21, sec. 2, should~~]*** the contracted vendor ***is*** no longer ***[~~be~~]*** able to operate the program, as funds allow.

Section 8. Personal Service Contracts. (1) A local health department shall not contract with a provider who is disbarred or suspended by a federal funding agency or by a Kentucky licensure board.

(2) This policy applies to personal service[~~services~~] contracts for services of a professional or technical nature not available through the local health department merit system.

(3) Services of a professional or technical nature shall be contracted for in writing in accordance with this policy except:

(a) Nonprofessional emergency repair services of skilled tradesmen shall not require written contracts. Nonemergency services of skilled tradesmen shall be procured in accordance with purchasing policies.

(b) Administrative or management services, financial management services, data processing services, or consulting services, or studies shall not be contracted for if these services can be provided to the local health department by the Department for Public Health.

(4) Allowable services.

(a) The service [~~desired~~] to be contracted for shall be an essential service that is necessary for carrying out public health services.

(b) A local health department may[~~shall not~~] use a personal service[~~services~~] contract to substitute for establishing a position in the local health department, with Department for Public Health approval.[

~~(c) A local health department shall not contract for personal services with an individual who works 1,200 hours or more in a year, except with Department for Public Health approval.~~]

(5) A provider shall not be paid more than the standard hourly rate determined by the Personnel Cabinet. In determining acceptable rates of reimbursement, consideration shall be given to:

(a) The type of service to be provided;

(b) The availability of providers;

(c) The duration of services to be performed;

(d) Rates being paid to regular employees for similar services; and

(e) Comparable rates being paid in the area and other parts of the state for similar services.

(6) A personal service contract shall not be entered into with a provider when a conflict of interest, real or apparent, exists.

(a) Conflicts of interest fall into the following categories:

1. Constitutional;
2. Statutory;
3. Common-law; and
4. Department for Public Health policies.

(b) A personal service contract shall not be entered into with a local health department employee or local board of health member, unless authorized in writing by the Department for Public Health, and except for medical or professional services under $10,000.

(c) A county board of health member who is not a member of the district board of health shall not incur a conflict of interest if the district health department contracts for the county board of health member's services.

(d) A contract exceeding $5,000 in a fiscal year shall not be entered into with a professional service corporation that has employees or governing board members as constituents, unless authorized in writing by Department for Public Health.

(7) In drafting a personal service contract, a determination shall be made concerning whether the provider of the service is an "independent contractor".

(a) If it is determined that the individual is not an independent contractor, the local health department shall withhold applicable federal, state, and local taxes and Social Security (FICA), and shall use a standard local health department personal service[~~services~~] contract.

(b) If it is determined that the provider is an independent contractor, a standard local health department independent contract shall be used.

(8) A personal service contract:

(a) Shall not exceed one (1) year in duration and shall not contain a clause that indicates the contract is automatically renewable at the end of the fiscal year;

(b) Shall expire on or before June 30 of each fiscal year unless approved by the Department for Public Health; and

(c) May be extended into the new fiscal year by filing a formal contract extension, approved by the Department for Public Health.

(9) Either party shall have the right to terminate a personal service contract at any time upon notice to the other party.

(a) A local health department may add a clause to a contract requiring up to a ninety (90) day notice prior to termination.

(b) Confirmation of termination shall be in writing and a copy of the notice of termination shall be provided to the Department for Public Health.

(10) All local health department personal service contracts and amendments are subject to review by the Department for Public Health.

(a) If the Department for Public Health questions the legality, propriety, necessity, rate of compensation, or description of services, in a personal service contract, the department shall notify the local health department of its concerns.

(b) A personal service contract for which clarification is requested by the Department for Public Health shall be put on hold until a review has been completed.

(11) A personal service contract may be modified at any time, and a proposed change shall be accomplished by formal contract amendment.

Section 9[~~8~~]. Disposition of Assets, Surplus, or Excess Property. (1) If ***a county withdraws*** ***[~~one (1) or more counties withdraw~~]*** from a district health department, the following policies shall apply to the disposition of surplus receipts, assets, and liabilities:

(a) Program restricted surplus receipts or supplies, inventories, or equipment shall be retained by the district health department except in the case of complete dissolution of the district. If the district is dissolved, program restricted surplus receipts and items shall be equitably distributed to the county or counties proportionate to their taxing district or fiscal court participation in the district;

(b) Unrestricted receipts, supplies, and inventories shall be divided among district and withdrawing county boards of health proportionate to the ratio of local taxing district support provided by each county in the year preceding the withdrawal;

(c) Deficits shall be charged to the district and withdrawing county boards of health according to the ratio of local taxing district or fiscal court support provided by each party in the year preceding the withdrawal;

(d) Equipment purchased by withdrawing county boards of health prior to the organization of the district shall be returned to the board that[~~which~~] originally purchased the equipment;

(e) Equipment purchased during the operation of the district shall be divided among the district and the withdrawing boards of health according to the ratio of local taxing district or fiscal court support provided by the withdrawing county boards of health to the total local taxing district or fiscal court support of the district in the year preceding the withdrawal:

1. The net inventoried book value of the equipment shall be used in determining the distribution.

2. The Department for Public Health shall approve the final disposition of equipment.

(f) Buildings owned by the district board of health shall remain the property of the district health department. If total dissolution of a district health department occurs, buildings owned by the district shall be sold according to the policies of the Department for Public Health and the

proceeds shall be added to the surplus receipts of the district to be divided according to the procedures listed in this subsection; and

(g) The Department for Public Health shall approve the disposition of assets and liabilities.

(2) A local health department may sell or dispose of any real or personal property including intangible property that[~~which~~] is not needed or has become unsuitable for use.

(3) The funding source shall be contacted for the exact requirements. Property purchased with restricted funds may have disposal requirements in addition to or instead of the following requirements:

(a) A written determination as to need or suitability of any property of the local health department shall be made, and shall fully describe the property, its intended use at the time of acquisition, and the reasons why it is in the public interest to dispose of the item;

(b) Surplus or excess property may be transferred, with or without compensation, to another governmental agency, or it may be sold at public auction or by sealed bids. The highest bid shall be accepted. Other methods of disposition of surplus or excess property shall not be allowable;

(c) If a local health department receives no bids for surplus or excess property, either at public auction or by sealed bid, or reasonably determines that the aggregate value of the item is less than $500, the property may be disposed of, consistent with the public interest, in any manner determined appropriate by the local health department. A written description of the property, the method of disposal, and the amount of compensation, if any, shall be made; and

(d) Any compensation resulting from the disposal of surplus or excess property shall be deposited in the local health department's bank account. If the property was purchased with restricted funds, appropriate accounting of the compensation received shall be made as required by 2 C.F.R. Part 200 Subpart E.

Section 10[~~9~~]. Bank Accounts and Investments. (1) Fidelity bonding shall be obtained on local health department employees and board of health members who handle funds of the local health department.

(a) An individual who makes deposits or signs checks or other instruments on local health department checking or investment accounts or certificates shall be bonded.

(b) Employees or board members shall be bonded in an amount sufficient to cover the total amount of funds to which they have access at any one (1) time.

(2) Local health departments may invest and reinvest money subject to their control and jurisdiction in the following investments:

(a) Obligations of the United States and of its agencies and instrumentalities. These investments may be accomplished through repurchase agreements reached with national or state banks chartered in Kentucky, and bonds or certificates of indebtedness of the state of Kentucky and of its agencies and instrumentalities;

(b) A savings and loan association insured by an agency of the government of the United States up to the amount so insured; and

(c) Interest-bearing deposits, or other authorized insurance instruments, in national or state banks chartered in Kentucky and insured by an agency of the government of the United States up to the amount so insured, and in larger amounts if the bank shall pledge as security, obligations as permitted by KRS 41.240(4), having a current quoted market value at least equal to uninsured deposits.

(3) A local health department may hold funds in its local bank account in a federally-insured bank at the minimum level necessary for efficient operations.

(4) Local health department funds shall not be transferred to a public health taxing district account or to an account not reported in the local health department financial statements.

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
Office of the Secretary

Andy Beshear
Governor

275 East Main Street, 5W-A
Frankfort, KY 40621
502-564-7042
502-564-7091
www.chfs.ky.gov

Eric C. Friedlander
Secretary

November 30, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 902 KAR 10:030. Registered environmental health specialists and sanitarians.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 10:030, the Department for Public Health proposes the enclosed suggested amendment to 902 KAR 10:030.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at 564-3970, extension 4069.

Sincerely,

Donna Little

Donna Little
Deputy Executive Director
Office of Legislative and Regulatory Affairs

SUGGESTED SUBSTITUTE

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety
(Amendment)

902 KAR 10:030. Registered environmental health specialists and sanitarians.

RELATES TO: KRS Chapter 13B, 194A.050(1), 211.090, 223.010, 223.020, 223.030, ***223.040, 223.050,*** 223.060, ***223.070,***[-]223.080, 223.990

STATUTORY AUTHORITY: KRS 223.040, 223.050, 223.055, 223.070[~~Chapter 13B, 194.050, 211.090, HB 799, Part I, G., 56., d. (1990 Acts, Chapter 514, pp. 1734-1735, 1736) "Budget Modification Report, Human Resources"; Final Budget Memorandum, Volume II, Page 288 (April 13, 1990), EO 96-862~~]

NECESSITY, FUNCTION, AND CONFORMITY: KRS 223.040, 223.050, 223.055 and 223.070[~~223.010 to 223.080, and 223.990~~] authorize the Cabinet for Health and Family Services to establish minimum standards and qualifications for registered environmental health specialists and sanitarians. This administrative regulation provides uniform standards for registered environmental health specialists and sanitarians, [~~and~~] procedures for processing applications, continuing education requirements, inactive status registration, and establishes [~~to establish~~] fees for examination and registration. [~~Executive Order 96-862, effective July 2, 1996, reorganizes the Cabinet for Human Resources and places the Department for Public Health and its programs under the Cabinet for Health Services.~~]

Section 1. Definitions. (1) "Cabinet" is defined by KRS 223.010(1).

(2) "Cabinet representative" means the secretary's designee.

(3) "Committee" means the registered environmental health specialists or sanitarian examining committee established in accordance with KRS 223.020.

(4) "Continuing education unit" or "CEU" means the completion of ten (10) hours of educational courses approved by the committee.

(5) "Secretary" is defined by KRS 223.010(3)[~~As used in this administrative regulation: "Contact hour" means a unit of measure for approved instruction by Registered Sanitarian Examining Committee. This unit is determined to equal actual classroom hours. Units of measure may be in half hour increments~~].

Section 2. Applications for Registration. (1) An applicant for registration as a registered environmental health specialist or sanitarian shall meet the qualifications listed in KRS 223.030(1).

(2) [~~Minimum Standards and Qualifications. In addition to the specific requirements provided by KRS 223.030, an applicant for registration as a sanitarian shall have graduated from an accredited college or university with a baccalaureate or higher degree, which shall include satisfactory completion of at least twenty-seven (27) quarter hours, or eighteen (18) semester hours, of academic training in the basic physical, chemical, biological, or sanitary sciences~~.

~~Section 3. Applications for Registration.~~] Applications [~~for registration as a registered sanitarian~~] shall be submitted to the committee for approval on the "Application for Registration", 05/2020, incorporated by reference or available online at https://chfs.ky.gov/agencies/dph/dphps/emb/Pages/sanitarians.aspx.

(3) An application fee of fifty (50) dollars by money order, bank draft, or check made payable to the Kentucky State Treasurer shall accompany each application.

(4) After the committee has approved an application, and all the requirements provided by law are fulfilled, the applicant can be scheduled to take the examination [~~application forms for registration as a registered sanitarian as provided by KRS Chapter 223 revised 7/90. This form is incorporated by reference and may be viewed or obtained at the Department for Public Health, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday between the hours of 8 a.m. and 4:30 p.m. Each application fee shall be remitted by a Post Office or express money order, bank draft, or check payable to the order of the Kentucky State Treasury. The committee may correspond with any references given on the applicant's application and may also contact any former employer of the applicant concerning his prior service in the field of public health sanitation~~].

Section 3[4]. Examinations. (1) The committee shall***:***

(a) Conduct examinations at least four (4) times [~~once~~] a year***; and***

(b) Determine the [~~at such~~] time and place ***for the examination[~~as it may deem expedient~~]***.

(2) A ***[~~passing~~]*** score of at least seventy (70) percent ***shall be a passing score for the examination[~~must be achieved on the exam~~]***.

(3) Applicants failing to achieve a passing score may apply to retake the exam by submitting another application and fee [~~The examination may be either oral, written, or both. A fee of thirty (30) dollars shall accompany the application for examination. All registration certificates issued under the provisions of this administrative regulation shall expire June 30 following date of issue, unless renewed by the payment of a twelve (12) dollar registration fee~~].

Section 4[~~5~~]. Issuance and Expiration of Certificates of Registration. (1) Upon successful passing of the examination as outlined in Section 3 of this administrative regulation [~~After~~

~~the committee has approved an application and all the requirements provided by law are fulfilled~~], the committee shall certify ***the passing score[~~such fact~~]*** to the secretary.

(2) The applicant shall be issued a registration card[~~, who in turn shall issue~~ a ~~small card to the approved applicant~~] certifying that he or she holds a certificate of registration.

(3) Pursuant to KRS 223.040, an individual who receives an initial certificate of registration ***shall[~~must~~]*** be under the direct supervision of a qualified registered environmental health specialist or sanitarian until the individual successfully completes an initial public health training program provided by the cabinet. ***This [~~Such~~]*** training shall be offered at least ***two (2) times [~~twice~~]*** per year at no cost to the trainee.

(4) The committee shall assign serial numbers to each certificate of registration.

(5) All registration certificates issued under the provisions of this administrative regulation shall expire on June 30 following the date of issue, unless renewed by payment of a twenty (20) dollar registration fee.

(6) The certification renewal fee shall be paid by money order, bank draft, or check made payable to the Kentucky State Treasurer, or online at the Registered Sanitarian ePayment Web site at ***https://prd.webapps.chfs.ky.gov/KYRegSan_ePay [~~https://prdweb.chfs.ky.gov/KYRegSan_ePay/~~]***.

(7) A late renewal fee of twenty (20) dollars will be assessed for all payments not received by July 1.

Section 5[~~6~~]. Renewals and CEUs. (1) All registered environmental health specialists and sanitarians shall receive a written notice of certification renewal [~~It shall be the duty of the secretary-treasurer of the committee to notify all registered sanitarians~~] at least thirty (30) days prior to the expiration date of their certificate.

(2) Before[~~that they renew their certificate of registration as provided by law. Effective July 1, 1992 before~~] the renewal of registration can be issued, the registrant shall [~~must~~] submit evidence of having completed the required CEUs.

(3) In addition to the public health training required by Section 4(3) of this administrative regulation, individuals achieving initial registered environmental health specialist or sanitarian status in any given fiscal year shall be required to submit evidence of having completed CEUs based on the quarter of the fiscal year in which certification was attained:

(a) July 1 to September 30 – ten (10) CEUs required;

(b) October 1 to December 31 – seven (7) CEUs required;

(c) January 1 to March 31 – five (5) CEUs required; or

(d) April 1 to June 30 – no CEUs required.

(4) An application for CEU approval by the committee shall include the following:

(a) An outline or summary of the course content;

(b) Identity of the instructor or sponsor of the course; and

(c) A letter or certificate of completion from the instructor or sponsor certifying the applicant satisfactorily completed the course; or

(d) Proof of attendance in the form of a copy of the course sign-in sheet or attendee roster.

(5) In-service educational conferences, courses, and seminars sponsored by professional and industrial organizations, or governmental agencies which registrants attend, or where they present, may qualify for CEUs.

(6) CEUs shall not be awarded for classes taught by the registrant or for mandatory employee trainings provided by the registrant's employer that are not related to the fields of environmental or public health, or specifically related to the duties, roles, and responsibilities of a registered environmental health specialist or sanitarian as determined by the committee.

Section 6. Extension for submitting CEUs. (1) A registrant may submit a written request to the committee for an extension to acquire CEUs until September 30. This written request ***shall[~~must~~]***:

(a) Be received by the committee on or before June 30; and

(b) Provide justification for the request.

(2) The committee may grant an extension beyond the September 30 deadline based on extenuating circumstances beyond the control of the registrant.

(3) Registrants shall be notified in writing by the cabinet representative of the committee's decision to grant or deny the September 30 extension.

(4) Failure to submit evidence of completion of the CEUs required in Section 5(3) of this administrative regulation by the September 30 extension deadline ***shall[~~will~~]*** result in suspension of the certificate of registration in accordance with Section 8 of this administrative regulation[~~ten (10) contact hours approved by the committee~~].

Section 7. Inactivation of Certificates of Registration. (1) Persons requesting to have their certificates of registration placed in inactive status shall submit a written request to the committee on or before June 30.

(2) A registered environmental health specialist or sanitarian granted inactive status by the committee shall be notified in writing.

(3) A registered environmental health specialist or sanitarian on inactive status shall be exempt from the CEU requirements specified in Section 5 of this administrative regulation but ***shall*** not ***be*** exempt from the twenty (20) dollar renewal fee required under Section 4(5) of this administrative regulation.

Section 8. Suspension and Revocation of Certificates of Registration. (1) Certificates of registration shall be suspended by the committee on July 1 for:

(a) Failure to remit payment for renewal by June 30 in accordance with Section 4 of this administrative regulation;

(b) Failure to submit evidence of completion of CEUs by June 30 in accordance with Section 5 of this administrative regulation; or

(c) Failure to request an extension for CEUs by June 30.

(2) Certificates of registration shall be suspended the next business day following the receipt of the request for an extension in accordance with Section 6 of this administrative registration.

(3) Persons whose certificates of registration have been suspended shall be sent a notice of suspension by the committee.

(4) If employed by the cabinet, a local health department, or a district health department, a copy of the notice of suspension shall be provided to the employer.

(5) A registered environmental health specialist or sanitarian with a suspended certificate of registration shall receive a written notice to appear before the committee at the next regularly scheduled committee meeting to provide justification for:

(a) Failing to remit payment by June 30; or

(b) Failing to submit evidence of completed CEUs by June 30 or by the extension granted by the committee in accordance with Section 6 of this administrative regulation.

(6) Failure to appear before the committee at the next regularly scheduled meeting shall be grounds for the committee to recommend revocation of a certificate of registration to the secretary.

(7) A registered environmental health specialist or sanitarian suspended for failure to remit payment in accordance with Section 4, or CEUs in accordance with Section 5, by June 30, may, at any time before the next regularly scheduled committee meeting, submit payment or evidence of completed CEUs and be returned to active status without having to appear before the committee.

(8) In any action involving the revocation of a certificate of registration, the committee shall refer the matter to the secretary.

(a) Prior to revocation, the committee shall send a notice of revocation to the last known address available to the committee.***[; and]***

(b) The notice of revocation shall include the option for the certificate holder to submit a request for an administrative hearing within ten (10) days of the notice to show cause as to why their certificate should not be revoked.

(9)[~~The committee is authorized to set the time and place of a hearing.~~] All administrative hearings shall be conducted in accordance with KRS Chapter 13B[~~902 KAR 1:400~~]

(10) Persons who have their certificate of registration revoked solely for failure to remit renewal payment or submit required CEUs may reapply for registration by submitting an application and fee in accordance with Section 3 of this administrative regulation and by successfully completing the examination.

(11) Upon revocation of a registered environmental health specialist or sanitarian certification by the secretary for causes established in KRS 223.070, the person shall:

(a) ***Not[~~No longer~~]*** be eligible to serve as a registered environmental health specialist or sanitarian in the Commonwealth; and

(b) Cease and desist practice.

(12) If employed by the cabinet, a local health department, or a district health department, a copy of the notice of revocation shall be provided to the employer.

Section 9[~~8~~]. Expenditure of Funds. Expenditures for examinations, clerical expenses, training and reference materials, including approved home study courses, and for affiliation with any national sanitarian registration organization, may be made out of the trust and agency fund created by KRS 223.050.

Section 10. Material Incorporated by Reference. (1) "Application for Registration", 05/2020, is incorporated by reference.

(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, 8:00 a.m. to 4:30 p.m.

CABINET FOR HEALTH AND FAMILY SERVICES
Office of the Secretary

Andy Beshear
Governor

275 East Main Street, 5W-A
Frankfort, KY 40621
502-564-7042
502-564-7091
www.chfs.ky.gov

Eric C. Friedlander
Secretary

November 30, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 902 KAR 50:040. Hauler requirements.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 50:040, the Department for Public Health proposes the enclosed suggested amendment to 902 KAR 50:040.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at 564-3970, extension 4069.

Sincerely,

Donna Little

Donna Little
Deputy Executive Director
Office of Legislative and Regulatory Affairs

Final 11-20-2020, Revised 5:17 PM

SUGGESTED AMENDMENT

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety

902 KAR 50:040. Hauler requirements.

Page 1
RELATES TO
Line 6
After "KRS Chapter 13B,", insert "Chapter 217,".

Page 1
STATUTORY AUTHORITY
Line 7
After "KRS", insert "194A.050".
Delete "194.050".

Page 1
NECESSITY, FUNCTION, AND CONFORMITY
Line 8
After "KRS", insert "194A.050".
Delete "194.050".

Page 1
Section 1(1)
Line 20
After "(1)", insert "A".
Delete "No".
After "shall", insert "not".

Page 2
Section 1(3)
Line 3
After "(3)", insert "An owner of a".
Delete "Owners of".
After "bulk tank route", insert "truck".
Delete "trucks".
After "the cabinet of", insert "each new hauler".
Delete "new haulers".

Page 2
Section 1(3)(a)
Line 4
After "(a)", insert "Each new hauler shall".
Delete the following:
New haulers shall be required to

After "submit an", delete the opening quotation marks.

Line 5

After "Raw Milk", delete the closing quotation marks.

Page 2
Section 1(3)(b)
Line 6

After "cabinet", delete the comma.

Page 2
Section 1(4)
Line 10

After "(4)", insert "A permit".
Delete "Permits".
After "with respect to", insert "the person or location".
Delete "persons or locations".

Page 2
Section 1(5)
Line 11

After "(5)", insert "A permit".
Delete "Permits".

Page 2
Section 1(6)
Line 12

After "(6)", insert "Each hauler".
Delete "All haulers".

Page 2
Section 1(7)
Line 14

After "(7)", insert "Each hauler".
Delete "All haulers".

Page 2
Section 2(3)
Line 20

After "(3)", insert "A milk hauler".
Delete "Milk haulers".

Page 2
Section 2(5)
Line 22

After "Chapter 217", delete the comma.

Page 3
Section 2(12)
Line 15

After "ticket and the", insert "producer's".
Delete "producers".

Page 4
Section 2(17)(a)
Lines 10-11
After "against the", insert "hauler's".
Delete "haulers".

Page 4
Section 2(17)(b)
Line 12
After "(b) The", insert "hauler's".
Delete "haulers".
Line 13
After "corrections", insert "shall be".

Page 4
Section 2(18)
Line 21
After "and the tank", insert "shall be".

Page 5
Section 3(1)
Line 2
After "cabinet", insert a semi-colon.
Delete the period.

Page 5
Section 3(2)
Line 5
After "contamination", insert a semi-colon.
Delete the period.

Page 5
Section 3(3)
Line 9
After "receiving station", insert a comma.
After "transfer station", insert "; and".
Delete the period.

Page 5
Section 4(2)
Line 22
After "more", insert a comma.

Page 5
Section 4(3)
Line 23
After "(3)", insert "A sample".
Delete "Samples".
After "in the", delete "following".
After "manner", insert "established in this subsection.".
Delete the colon.

Page 6
Section 4(4)
Line 17
After "the milk producer", insert a comma.
Line 18
After "and the", insert "name of the".

Page 7
Section 5(2)
Lines 5 and 6
After "case of", insert "an emergency".
Delete "emergencies".

Page 8
Section 6(6)
Line 11
After "(6)", insert "A receiving location".
Delete "Receiving locations".

Page 8
Section 6(7)
Line 13
After "and the tags", insert "shall be".

Page 8
Section 6(8)
Line 15
After "(8)", insert "A truck".
Delete "Trucks".
After "that", insert "picks up and delivers".
Delete "pick up and deliver".

Page 8
Section 6(9)
Line 18
After "requirements", insert "shall".

Page 8
Section 6(10)
Line 20
After "If", insert "a".
After "transport", insert "truck is".
Delete "trucks are".

Page 8
Section 6(11)
Line 22
After "(11)", insert "A".
Lowercase "Bulk".
After "milk", insert "truck".
Delete "trucks".

Page 9
Section 6(16)
Lines 17 and 18
After "in the vehicle.", insert "A".
Lowercase "Milk".
Line 18
After "processing", insert "plant".
Delete "plants".
After "producer", insert "if the milk".
Delete "which".

Page 9
Section 7
Line 20
After "Receiving Station", insert a comma.

Page 10
Section 7(2)
Line 2
After "the samples", insert "shall be".

Page 10
Section 7(5)
Line 9
After "(5)", insert "A".
Lowercase "Producer".
After "raw milk", insert "sample".
Delete "samples".
Line 10
After "after", insert "the sample has".
Delete "they have".

Page 10
Section 7(7)
Line 13
After "(7)", insert "A".
Lowercase "Milk".
After the now-lowercased "milk", insert "producer or".
Delete "producers and".
After "bulk milk", insert "hauler".
Delete "haulers".

Page 11
Section 8(3)
Line 4
After "submit an", delete the opening quotation marks.
Line 5
After "of Permit", delete the closing quotation marks.

Page 11
Section 8(5)
Line 8

After "regulation", insert a comma.

Page 11
Section 8(6)
Line 12

After "unless the" delete the opening quotation marks.

Lines 12-13

After "Request for", insert "a".

Line 13

After "Hearing", insert the following:

, incorporated by reference in 902 KAR 50:033, is

Delete the closing quotation marks.

After "filed", delete "in".

Page 11
Section 9(2)
Line 18

After "law, at", insert "the".

CABINET FOR HEALTH AND FAMILY SERVICES
Office of the Secretary

Andy Beshear
Governor

275 East Main Street, 5W-A
Frankfort, KY 40621
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502-564-7091
www.chfs.ky.gov

Eric C. Friedlander
Secretary

November 30, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 902 KAR 50:040. Hauler requirements.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 50:040, the Department for Public Health proposes the enclosed agency amendment to 902 KAR 50:040.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at 564-3970, extension 4069.

Sincerely,

Donna Little

Donna Little
Deputy Executive Director
Office of Legislative and Regulatory Affairs

Final 11-20-2020

AGENCY AMENDMENT

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Public Health Protection and Safety

902 KAR 50:040. Hauler requirements.

Page 7
Section 5(3)
Line 7

After "at least every", insert "seventy-two (72)".
Delete "forty-eight (48)".

CABINET FOR HEALTH AND FAMILY SERVICES
Office of the Secretary

Andy Beshear
Governor

275 East Main Street, 5W-A
Frankfort, KY 40621
502-564-7042
502-564-7091
www.chfs.ky.gov

Eric C. Friedlander
Secretary

December 1, 2020

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 908 KAR 1:400. Licensing and standards for substance use and misuse prevention.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 908 KAR 1:400, the Department for Behavioral Health, Developmental and Intellectual Disabilities proposes the enclosed suggested substitute to 908 KAR 1:400.

If you have any questions regarding this matter, please contact Justin Dearinger, Department for Behavioral Health, Developmental and Intellectual Disabilities, at (502) 782-7212.

Sincerely,

Donna Little

Donna Little
Deputy Executive Director
Office of Legislative and Regulatory Affairs

SUGGESTED SUBSTITUTE

CABINET OF HEALTH AND FAMILY SERVICES

Department for Behavioral Health, Developmental and Intellectual Disabilities

Division of Behavioral Health

(Amended After Comments)

908 KAR 1:400. Licensing and standards [~~Procedures~~] for substance use and misuse [~~abuse~~] prevention.

RELATES TO: KRS ***Chapter 13B,*** 61.870 to 61.884, 194A.005 [~~194A.050~~], 194A.070, 209.030, ***222.003,*** 222.005(2), 222.221, ***222.990, 223.231,*** 620.030

STATUTORY AUTHORITY: 194A.050, KRS 222.211, 222.231

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050 and 222.231 ***require[~~requires~~]*** the Cabinet for Health and Family Services to promulgate administrative regulations necessary to establish requirements and standards for licensing alcohol and other drug prevention (AODP) agencies [~~agencies and approving substance abuse prevention programs~~]. KRS 194A.050 requires the secretary to promulgate, administer, and enforce those 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. This administrative regulation

establishes licensing requirements for AODP [~~substance abuse prevention agencies~~].

Section 1. Definitions. (1) "Alcohol and other drug use prevention agency" or "AODP" is defined as an agency that develops, provides, and coordinates prevention services, including training and technical assistance services, that address substance use and misuse and related consequences.[~~"Agency" is defined by KRS 222.005(2).~~

~~(2)"Alcohol and other drug abuse" is defined by KRS 222.005(3).~~]

(2)[~~(3)~~] "Cabinet" is defined by KRS 194A.005.

(3) [~~(4)~~] "Certified prevention specialist" means an individual who is certified [~~approved~~] by the Kentucky Certification Board for [~~of~~] Prevention Professionals.

(4) [~~(5)~~] "Coalition" means a partnership of community stakeholders [~~volunteers~~] working to reduce alcohol, tobacco, and other drug use and misuse [~~abuse~~] problems and related consequences through community-wide prevention strategies.

(5) [~~(6)~~] "Consumer" means the recipient of prevention services.

(6) [~~(7)~~] "Department" means the Department for Behavioral Health, Developmental and Intellectual Disabilities [~~is defined by KRS 194A.030(4)~~].

(7) [~~(8) "Early Intervention Program" is a program that helps Kentucky youths under age twenty-one (21) and their families learn about risks and consequences of substance use, the benefits of good health and well-being among youths, and promotes positive decision-making to resist alcohol, tobacco, and other drugs.~~

~~(9)~~] "International Certification and Reciprocity Consortium" or "ICRC" means the

organization that establishes the standards of practice in addiction counseling, prevention, and clinical supervision through testing and credentialing of addiction professionals.

(8) [~~(10)~~] "Kentucky Certification Board for Prevention Professionals" or "KCBPP" means an ICRC member board that establishes competency-based certification for prevention specialists [~~professionals~~] that promotes and maintains integrity and quality of service for alcohol, tobacco, and other drug prevention.

(9) [~~(11)~~] "Prevention" means the act of preventing use and misuse of alcohol, tobacco, and other drugs and the related consequences. [~~problems resulting from alcohol, tobacco, and other drug use.~~]

(10) [~~(12)~~] "Prevention Director" means a certified prevention specialist [~~prevention professional~~] who manages AODP [~~Regional Prevention Center~~] staff, serves as liaison between the AODP [~~Regional Prevention Center~~] and the department, and is responsible for developing the annual plan and budget documents for the AODP [~~prevention program~~].

(11) [~~(13)~~] "Prevention Specialist [~~Professional~~]" means a paid staff, excluding clerical staff, employed by an AODP [~~a Regional Prevention Center~~] actively involved in the development and implementation of [~~a~~] substance use and misuse [~~abuse~~] prevention services [~~program~~].

(12) [~~(14)~~] "Regional Prevention Center" or "RPC" means a program funded and

licensed by the department for the purpose of developing, providing, and coordinating prevention training and technical assistance services that address substance use and misuse **and the** related consequences. [~~substance abuse prevention programs and activities in a specified geographical region of the state.~~

~~(15) "Strategic Prevention Framework" or "SPF" means a planning process identified by Substance abuse Mental Health Service Administration.~~]

Section 2. Licensing Procedures. (1) An AODP [~~agency~~] receiving remuneration for any prevention program, and any RPC, shall not operate without first obtaining an AODP [~~alcohol and other drug prevention~~] license from the cabinet, ***in accordance with the procedures of 908 KAR 1:370,*** unless the AODP [~~agency~~] is exempted under KRS 222.003(1) and (2).

(2) Any AODP operating a program without first obtaining a license shall be subject to penalties pursuant to KRS 222.990(2). [~~An agency shall be licensed to operate a Regional Prevention Center in accordance with 908 KAR 1:380, Section 2.~~]

(3) An application for licensure***, incorporated by reference in 908 KAR 1:370,*** shall be submitted in writing to the Office of Inspector General, 275 East Main Street, Frankfort, Kentucky 40621.

(4) An application for:

(a) Licensure shall be accompanied by a fee of $155; or

(b) Renewal shall be accompanied by a fee of eighty (80) dollars.

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(5) The license shall remain in effect for one (1) year from the date of issuance and may be renewed, unless a failure to comply with licensure standards causes the license to be [~~has been~~]:

(a) Revoked; or

(b) Suspended [~~; or~~

~~(c) Modified by the cabinet for a substantial failure to comply with the licensure standards~~].

(6) [~~(5)~~] The license shall be conspicuously posted in a public area at the AODP [~~agency~~] and shall indicate the year the license was issued or renewed.

(7) [~~(6)~~] An application for licensure or renewal may [~~shall~~] include an on-site inspection by cabinet representatives to determine compliance with licensure standards.

(8) [~~(7)~~] The applicant shall provide the cabinet or its representatives access during normal hours of operation to any area of the facility and any document needed to complete the inspection.

(9) [~~(8)~~] The cabinet shall notify the AODP [~~agency~~] in writing [~~within ten (10) calendar days~~] of any violation of licensure standards identified during the inspection.

(10) [~~(9)~~] The AODP [~~agency~~] shall submit to the cabinet a written plan of correction within ten (10) calendar days of receipt of the notice of violation.

(11) The correction plan shall specify the:

(a) Corrective [~~the corrective~~] action to be taken; and

(b) Date [~~the date~~] when each violation shall be corrected.

(12) [~~(10)~~] The certificate of licensure shall be the property of the cabinet and shall be returned upon closure or revocation of the license.

(13) [~~(11)~~] The cabinet shall make available to the public a list of all licensed alcohol and other drug prevention agencies and may issue revisions and corrections to this list as changes occur.

[~~(12) Any agency operating a program without first obtaining a license shall be subject to the penalties as stated in KRS 222.990(2).~~]

Section 3. Changes in AODP [~~agency~~] Status. (1) An AODP [~~agency~~] shall notify the cabinet within ten (10) working days of a change in:

(a) Name;

(b) Location;

(c) Ownership; or

(d) Discontinuance of services.

(2) If there is a change in AODP [~~agency~~] name, ownership, or location, the cabinet may issue a new license for the remainder of the current licensure period.

Section 4. Physical Plant. There shall be written housekeeping, sanitation, and maintenance procedures, which shall be followed at all times to ensure that the AODP shall be clean and in good repair.

Section 5. Organization and Administration. (1) Governing body.

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(a) An AODP shall have a governing body with overall authority and responsibility for the AODP's operation.

(b) The governing body shall have written documentation to show the AODP is a legal entity in the Commonwealth of Kentucky by means of a partnership agreement, articles of incorporation, legislative act, or executive order.

(c) The responsibilities of the governing body shall be specified in writing and shall include:

1. Adopting a mission statement that outlines the AODP's purpose;

2. Adopting a conflict of interest policy to govern participation by a governing body member in a decision that may be influenced by a member's business interest;

3. Appointing an executive director who shall be responsible for the day-to-day operation of the AODP;

4. Adopting an administrative structure and establishing a line of authority for all prevention programs operated by the AODP;

5. Documenting administrative structure and lines of authority on an organizational chart, including the name of each current governing board member;

6. Adopting written policies and procedures to direct administrative and program functions of the AODP to ensure that sufficient staff and resources are available for the successful delivery of programs;

7. Reviewing written prevention policies and procedures at least every two (2) years

and making needed revisions and incorporating relevant findings of the AODP's quality assurance system;

8. Overseeing a system of financial management and accountability;

9. Completing an annual training on alcohol and other drug prevention for members of a multiservice board that provide oversite to the prevention program; and

10. Meeting as a whole at least quarterly and keeping a written record demonstrating the ongoing discharge of its responsibilities.

Section 6 [4]. Staffing and Staff Qualifications. (1) A prevention specialist [~~professional~~] shall be certified by the Kentucky Certification Board for Prevention Professionals and ICRC as a [~~an International~~] Certified Prevention Specialist within thirty-six (36) months of initial [~~:~~

~~(a) The effective date of this administrative regulation; or~~

~~(b) Initial~~] employment.

(2) The AODP [~~agency~~] shall designate one (1) individual as the prevention director who shall:

(a) Be certified by the KCBPP as a [~~an International~~] Certified Prevention Specialist; and

(b)1. Have a bachelor's [~~bachelors~~] degree plus five (5) years of work experience in prevention or the related fields of health, social science, marketing, communication, or education; or

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2. Have a master's degree with two (2) years of work experience in prevention or [~~administration or administration in~~] the related fields of health, social science [~~sciences~~], marketing, communication, or education.

(3) [~~Staff responsible for providing prevention services within the agency shall be clearly designated.~~

~~(4)~~] The AODP [~~agency~~] shall designate an individual to serve as an ombudsman who shall be responsible for responding to:

(a) Staff or consumer complaints; and

(b) Staff or consumer grievances.

Section 7. Personnel and Employment Practices. (1) The AODP shall have written policies and procedures governing employment practices for AODP employees and subcontractors which shall include:

(a) Protection from discrimination against any employee or prospective employee based on:

1. Gender;

2. Age;

3. Race;

4. Ethnicity;

5. Religious affiliation; and

6. Disability including prior history of alcohol or other drug abuse;

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(b) Personnel policies addressing:

1. Recruitment;

2. Hiring;

3. Promotion;

4. Discipline; and

5. Termination;

(c) Procedures for conducting background checks on any individual working with minors to assure that there is no:

1. Record of conviction related to abuse or molestation of children from the:

a. Administrative Office of the Courts; or

b. Kentucky State Police; and

2. Individual employed listed on the central registry established by 922 KAR 1:470;

(d) Procedures for a central registry check that has been submitted for an individual and is pending, which shall include:

1. Provisional hiring of the individual pending the results of the registry check;

2. A requirement that the individual shall not be left unsupervised with a client under eighteen (18) years of age; and

3. A requirement that the **individual** **[~~employee~~]** shall be dismissed immediately if the results of the check show the individual is listed on the central registry;

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(e) Procedures ensuring that criminal record checks as described in paragraph (c) of this subsection shall be completed annually on a random sample of at least twenty-five (25) percent of all personnel;

(f) Maintenance of personnel records for each staff member, which shall contain the following:

1. Application for employment;

2. Job specifications;

3. Written references;

4. Results of background check;

5. Documentation of:

a. Education;

b. Work experience;

c. Training; and

d. Status of professional licensure, certification, and registration;

6. Salary information;

7. Job performance appraisals;

8. Disciplinary actions;

9. Commendations; and

10. Employee incident reports;

(g) Written job specifications for all positions identifying the:

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1. Qualifications;

2. Duties;

3. Reporting supervisor; and

4. Positions supervised;

(h) Explanation of:

1. Employee benefits;

2. Training and staff development opportunities;

3. Safety and work related injury procedures;

4. Employee grievance procedures;

5. Rules of conduct; and

6. Compensation plan;

(i) Information on equal employment opportunities and affirmative action policies;

(j) A provision for ensuring an alcohol and drug-free workplace to include actions taken when an employee is involved in the unlawful manufacture, distribution, possession, or use of alcohol or any controlled substance at the AODP;

(k) A provision for yearly job appraisal for each employee, which includes an evaluation based on objective criteria of each employee's performance in relation to their expected job duties;

(l) Ethical standards identifying acceptable employee conduct regarding consumers' rights;

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(m) Conflict of interest policies governing dual relationships with other legal entities;

(n) Provisions to assure the confidentiality of personnel records;

(o) A provision for providing an employee with access to that employee's personnel record; and

(p) Provisions for the storage and retention of personnel records.

(2) A staff member shall be given access to a copy of the AODP's policies and procedures at the time of employment and shall be notified of a revision when it is made.

Section 8 [~~5~~]. AODP Staff Responsibilities [~~Regional Prevention Centers~~]. (1) AODP [~~RPC~~] staff shall:

(a) Provide prevention services, including training and technical assistance, with a primary content that specifically addresses substance use and misuse and its related consequences;

(b) Utilize the Substance Abuse and Mental Health Services Administration (SAMHSA) approved evidence-based decision-making model for delivery of prevention services;

(c) Utilize the Center for Substance Abuse Prevention's primary prevention strategies found at https://www.samhsa.gov/grants/block-grants/sabg for delivery of prevention services; and

(d) Utilize evidence-based or evidence-informed programs and activities in delivery of services.

(2) AODP and [~~Conduct the following program management functions:~~

~~1. Planning;~~

~~2. Staffing;~~

~~3. Policy development;~~

~~4. Program development; and~~

~~5. Program evaluation;~~

~~(b)Prepare a written mission statement and program operations manuals which shall be reviewed by the prevention director at least one (1) time per year and updated as necessary;~~

~~(c) Coordinate and implement all prevention programs, initiatives, and activities funded by the department in the region, with the exception of those specifically exempted by the department;~~

~~(d) Coordinate and implement an Early Intervention Program;~~

~~(e) Assist communities to develop and implement educational and environmental strategies for adults and children to prevent the:~~

~~1. Use of illegal drugs;~~

~~2. Abuse of alcohol; and~~

~~3. Abuse of other chemicals such as tobacco, pharmaceuticals, and household products that have psychoactive properties;~~

~~(f) Collaborate with community agencies and organizations in the provision of prevention services;~~

~~(g) Tailor programs to the characteristics of specific target audiences, including age, gender, drug-use pattern, racial, ethnic, and cultural heritage;~~

~~(h) Gather and disseminate information about drug-specific prevention activities provided by other agencies, organizations, or individuals within their region;~~

~~(i) Participate in mentoring activities and statewide meetings as designated by the department;~~

~~(j) Participate in a computerized communication system with the department and other RPCs;~~

~~(k) Facilitate cooperation among agencies, groups, and individuals involved in prevention;~~

~~(l) Develop, maintain, and sustain regional and county coalitions;~~

~~(m) Create forums for coordination and networking of substance abuse prevention professionals; and~~

~~(n) Provide consultation with community organizations that wish to develop comprehensive prevention programs.~~

~~(2) A Prevention professional working in RPCs shall provide:~~

~~(a) Information on subjects relevant to substance abuse prevention;~~

~~(b) Professional information to assist community members in acquiring the knowledge necessary for their involvement in prevention efforts;~~

~~(c) Resources for use in community prevention programs;~~

~~(d) Books, pamphlets, audio visual, and training materials which shall be made available for use by the community; and~~

~~(e) Well-defined, structured training and learning experiences including both information and skill development designed to directly influence the drug use behavior of the consumer and incorporate evidence-based and professionally developed curricula. The program shall train:~~

~~1. Persons to reach others with prevention information or lead prevention activities in the groups with which they are involved; and~~

~~2. Professionals and volunteers in the community to conduct training for others.~~

~~(3) RPC staff shall submit schedules of training and other events to the department upon request.~~

~~(4) RPC staff shall:~~

~~1. Assist or serve only those prevention programs with a primary content that deals specifically with drug use; and~~

~~2. Not deliver programs with a primary content aimed at raising self-esteem, increasing general wellness, raising socio-economic status, or similar factors that may be indirectly related to drug abuse.~~

~~(5) RPCs may:~~

~~(a) Raise community awareness of the need for a comprehensive approach to prevention;~~

~~(b) Encourage and assist in community planning for prevention activities;~~

~~(c) Provide consultation and training for providers of prevention programs;~~

~~(d) Raise community awareness of the need for intervention and recovery programs as part of a comprehensive approach to prevention;~~

~~(e) Encourage and assist in community planning for intervention and recovery activities; and~~

~~(f) Provide consultation and training for providers of intervention and recovery programs.~~

~~(6) RPC~~] staff shall not provide intervention and recovery programs for persons who are in need of substance use and misuse [~~abuse~~] treatment.

Section 9. Quality Assurance. (1) Staff development.

(a) The AODP shall establish a system of on-going staff development to include training and supervision of all prevention staff that shall:

1. Be outlined in the AODP's policies and procedures manual; and

2. Support the attainment of the goals and objectives of the prevention program.

(b) The AODP shall make required training available to staff.

(c) The completion of each training shall be documented in staff personnel records and shall identify the:

1. Name of the training;

2. Clock hours earned; and

3. Dates attended.

(2) Program quality assurance. The AODP shall have written policies and procedures for assuring the quality of each program operated by the AODP that shall include the following:

(a) Designation of the individual responsible for monitoring and evaluating the quality assurance activities;

(b) Description of the range of activities and services provided in each program;

(c) A statement of intended program outcomes and indicators of effectiveness; and

(d) Establishment of a mechanism and a schedule for the collection, organization, and analysis of data to:

1. Be used for process evaluation;

2. Be used for outcome evaluation; and

3. Determine the quality of the service.

Section 10. Consumer Rights. An AODP shall have written policies and procedures for ensuring the rights of the consumer that shall include:

(1) An assurance that there shall be no unlawful discrimination in determining eligibility for admission to a prevention program;

(2) A statement of consumer rights posted in the AODP with the name, address, and telephone number of the AODP's ombudsman;

(3) Assurance of the confidentiality of consumer's substance use and misuse; and

(4) Posting of the grievance procedure in the AODP, which shall include at a minimum:

(a) The period for reviewing and responding to a consumer complaint;

(b) A requirement for documentation of a grievance in the:

1. Consumer record; and

2. Central AODP incident file; and

(c) A requirement that a grievance alleging abuse or neglect be referred in accordance with:

1. KRS 209.030 regarding the abuse or neglect of an adult; and

2. KRS 620.030 regarding the abuse or neglect of a minor.

Section 11. Complaints. (1) A suspected violation of a licensure standard shall be reported to the cabinet.

(2) The complainant and information related to a suspected violation shall be kept confidential and shall not be disclosed publicly during an investigation. Once the investigation is complete, disclosure of the information shall be subject to the provisions of KRS 61.870 to 61.884.

(3) The cabinet shall conduct an investigation and inspections based upon a complaint.

Section 12. Denial, Revocation, and Reapplication. (1) The cabinet shall deny or revoke a license if:

(a) It finds that there has been a failure with the provisions of this administrative regulation **and an acceptable corrective action plan is not completed**;

(b) Access is denied to the cabinet or its representatives during normal hours of operation to any area of the facility and any document needed to complete an inspection;

(c) The cabinet finds that the licensee misrepresented or submitted false information to the cabinet;

(d) The cabinet has probable cause to believe that continued operation would constitute an immediate danger to the health, welfare, or safety of clients;

(e) **The AODE fails to comply with the annual renewal process;**

(f) An individual having a significant financial interest in the AODP has, within the seven (7) year period prior to the application date, had significant financial interest in a facility or service that was licensed or certified by the cabinet, and the license or certificate to operate was denied, suspended, revoked, or voluntarily relinquished as the result of an investigation or adverse action that placed patients, residents, or clients at risk of death or serious harm;

(g) An individual having significant financial interest in the AODP has been:

1. Previously discontinued or disqualified from participation in any governmental assistance program due to fraud or abuse of the program; or

2. The subject of disciplinary action taken against the individual by a professional licensing board for misconduct related to endangering a patient or client;

(h) The licensee commits fraud in obtaining a license or in connection with a service provided; or

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(i) [~~(f)~~] The licensee fails to comply with a cabinet approved corrective action plan.

Section 13. Penalties. (1) Denial or revocation of a license.

(a) Plan of correction.

1. An AODP shall submit to the cabinet, within ten (10) calendar days of a notice of a violation, a written plan for the correction of the regulatory violation.

2. The plan of correction shall be signed by the AODP's administrator, the licensee, or a person designated by the licensee and shall specify:

a. The date by which the violation shall be corrected;

b. The specific measures utilized to correct the violation; and

c. The specific measures utilized to ensure the violation will not recur.

3. The cabinet shall review the plan of correction and notify the AODP in writing of the decision to:

a. Accept the plan;

b. Not accept the plan; or

c. Deny, suspend, or revoke the license for a substantial regulatory violation in accordance with KRS 222.231(6).

4. If the cabinet finds the statement of correction unacceptable, the cabinet shall notify the AODP:

a. Of the specific reasons the plan is unacceptable; and

b. That an amended plan of correction is required within ten (10) calendar days of

receipt of the notice by the AODP.

5. The cabinet shall review the amended plan of correction and notify the AODP in writing of the decision to:

a. Accept the plan;

b. Deny, suspend, or revoke the license for a substantial regulatory violation; or

c. Require the AODE to submit an acceptable plan of correction.

6. An AODP that fails to submit an acceptable amended plan of correction may be notified that the license will be denied, suspended, or revoked.

[~~If an AODP fails to submit an acceptable plan of correction within ten (10) calendar days from the date of a notice of violation, the license shall be denied or revoked thirty (30) calendar days after the date of the notice of denial or revocation unless:~~

~~1. The AODP requests a hearing in accordance with Section 14 of this administrative regulation; or~~

~~2. The AODP notifies the cabinet in writing that the application for licensure is withdrawn.~~]

(b) Denial of an application for licensure. ***If[~~When~~]*** an application for licensure is denied, the legal entity named in the application may reapply for a license in accordance with Section 2 of this administrative regulation after a period of:

1. One (1) year from the date of denial; or

2. Thirty (30) days from the date an application for licensure was withdrawn by the

AODP.

(2) Reapplication. The legal entity named in the application may reapply for a license in accordance with Section 2 of this administrative regulation after a period of one (1) year from the date of revocation.

Section 14. Appeals. (1) If the cabinet takes action to deny or revoke an AODP license in accordance with KRS 222.231(6), the cabinet shall notify the AODP in writing stating the reason for the adverse action and the AODP's right to appeal to the cabinet.

(2) The cabinet shall conduct the hearing in accordance with KRS Chapter 13B.

(3) An AODP that continues to operate after the closing date established by the secretary, or designee, shall be subject to action by the cabinet as provided by law.

[~~Section 6. Department Responsibilities. The department shall:~~

~~(1) Conduct on-site visits to:~~

~~(a) Review program progress and compliance; and~~

~~(b) Conduct random record checks for accuracy and validity;~~

~~(2) Review and approve budgets and quarterly reports to ensure accuracy and efficiency in spending;~~

~~(3) Review training plans for RPC staff; and~~

~~(4) Ensure adherence to the Strategic Prevention Framework to include:~~

~~(a) Assessment;~~

~~(b) Building capacity;~~

~~(c) Planning;~~

~~(d) Implementation;~~

~~(e) Evaluation;~~

~~(f) Sustainability; and~~

~~(g) Cultural competence.~~]