Andy Beshear
Governor

Commonwealth of Kentucky
Finance and Administration Cabinet
DEPARTMENT OF REVENUE
OFFICE OF TAX POLICY AND REGULATION
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Holly M. Johnson
Secretary

Thomas B. Miller
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June 2, 2021

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: 103 KAR 26:131, Landscaping services.

Dear Co-Chairs West and Hale:

After discussions with the Administrative Regulation Review Subcommittee staff of the issues raised by 103 KAR 26:131, the Department of Revenue proposes the attached substitute to 103 KAR 26:131.

Kind regards,

Lisa S. Swiger

Lisa S. Swiger, Tax Policy Research Consultant II
Office of Tax Policy and Regulation
Department of Revenue
501 High Street, St 1
Frankfort, Kentucky 40601

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FINANCE AND ADMINISTRATION CABINET
Department of Revenue
(As Amended at ARRS)

103 KAR 26:131. Landscaping services.

RELATES TO: KRS 139.010, 139.200, 139.260, 139.270, 139.470, 139.480
STATUTORY AUTHORITY: KRS 131.130
NECESSITY, FUNCTION, AND CONFORMITY: KRS 131.130(1) authorizes the Department of Revenue to promulgate administrative regulations for the administration and enforcement of Kentucky tax laws. This administrative regulation interprets the sales and use tax law as it applies to landscaping services.

Section 1. Definitions. (1) "Construction contract" is defined by 103 KAR 26:070, Sec. 1***(1).[;]***
(2) "Contractor" is defined ***by*** ***[~~in~~]*** 103 KAR 26:070 Sec. 1(2)(a).
(3) "Department" means the Department of Revenue.
(4) "De minimis threshold exemption" is defined ***by*** ***[~~in~~]*** KRS 139.470(23).
(5) "Farm machinery" is defined ***by*** ***[~~in~~]*** KRS 139.480(11).
(6) "Landscaping services" ***means*** ***[~~includes~~]*** those services listed in KRS 139.200(2)(g)***.[;]***
(7) "Person" is defined ***by*** ***[~~in~~]*** KRS 139.010(26).
(8) "Practice of landscape architecture" is defined ***by*** ***[~~in~~]*** KRS 323A.010(3).
(9) "Professional services" is defined ***by*** ***[~~in~~]*** KRS 323A.010(4).
(10) "Resale certificate" means Resale Certificate Form 51A105, Streamlined Sales and Use Tax Agreement – Certificate of Exemption, Form 51A260, or Multistate Tax Commission's Uniform Sales and Use Tax Exemption/Resale Certificate – Multi-jurisdiction.
(11) "Retailer" is defined ***by*** ***[~~in~~]*** KRS 139.010(35).
(12) "Seller" is defined ***by*** ***[~~in~~]*** KRS 139.010(39).
(13) "Subcontractor" is defined ***by*** ***[~~in~~]*** 103 KAR 26:070 Sec. 1(2)(a).

Section 2. Landscaping Services. (1) The furnishing of landscaping services is subject to sales tax pursuant to KRS 139.200(2)(g). Sales tax shall apply to the sales price received from the furnishing of landscaping services.
(2) Persons engaged in the business of providing landscaping services are retailers of the landscaping services furnished. Landscaping service providers shall register for, collect, and remit sales tax.
(3) The list provided in this subsection shall serve as examples of the furnishing of landscaping services:
(a) Aerating;
(b) Applying chemicals to lakes or ponds to control the growth of algae or plant life;
(c) Bush hogging;
(d) Dethatching;
(e) Diagnosing lawn conditions for the purpose of providing landscaping services;
(f) Fertilizing;
(g) Hydro seeding;

(h) Installation of decorative bricks, blocks, and timbers such as those installed for a flower bed;
(i) Installation of lawn edging, decorative rock, and weed control fabric;
(j) Installation of free-standing planter boxes;
(k) Landscape design and installation services;
(l) Lawn care and maintenance services;
(m) Lawn fungus treatments;
(n) Leaf removal;
(o) Mowing and trimming;
(p) Mulching;
(q) Planting, pruning, bracing, removal, surgery, and trimming of plants, trees, and shrubs;
(r) Raking, including power raking;
(s) Seeding or reseeding;
(t) Services for the removal of gophers, moles, voles, and other lawn pests;
(u) Snow plowing or removal services;
(v) Sod laying;
(w) Soil moving, grading, removal, or installation as part of a landscaping service (such as removing a top layer of soil to install sod);
(x) Spraying or other applications of chemicals and fertilizer within the landscape. Examples include:
1. Granular and liquid lawn fertilizers;
2. Lime applications;
3. Seed and fertilizer combination applications;
4. Herbicides; or
5. Insecticides, including those to eliminate grubs, ants, fleas, and ticks.
(y) Stump removal;
(z) Tilling and soil preparation;
(aa) Turf installation; or
(bb) Watering, including the installation of soak hoses.

Section 3. Non-landscaping Services. The list provided in this section shall serve as examples of activities not considered the furnishing of landscaping services:
(1) Vegetative management of highway rights-of-way including mowing, line trimming, and tree trimming;
(2) Vegetative management of utility rights-of-way including mowing, line trimming, and tree trimming;
(3) Perpetual care of gravesites at a cemetery;
(4) Government-mandated land reclamation at a mining site;
(5) Mosquito spraying services;
(6) Professional services authorized as part of the licensed practice of professional landscape architecture provided under separate contract from landscape design and installation services;
(7) Mowing, spraying, tree trimming, and fence clearing, provided to a person regularly engaged in the business of farming and provided on land that is:
(a) Being cultivated for the production of crops as a business;
(b) Being directly used in the occupation of raising and feeding livestock or poultry for sale;

(c) Being directly used in the occupation of producing milk for sale;
(d) Being directly used in the occupation of egg production;
(e) Being directly used in the occupation of breeding or producing:
1. Aquatic organisms;
2. Buffalos;
3. Cervids;
4. Llamas or alpacas; or
5. Ratites; and
(8) Mowing, spraying, tree trimming, and fence clearing, provided to a person engaged in the raising of equine as a business; provided however, that the landscaping services are performed on the portion of land directly used in the raising of equine.

Section 4. Property Purchased for Resale by Persons Furnishing Landscaping Services. (1) Persons furnishing landscaping services may issue a fully completed resale certificate for the purchase of property to be resold to a customer when furnishing the landscaping services where the property remains with the customer after the furnishing of landscaping services. The purchaser of the property to be resold to a customer when furnishing the landscaping services shall collect sales tax from the customer on the sales price of the property.
(2) The list provided in this subsection shall serve as examples of property purchased for resale that demonstrate the types of property that generally are received by, or remain with, the customer after landscaping services are performed:
(a) Bulbs;
(b) Bushes;
(c) Chemicals;
(d) Dirt;
(e) Fertilizer;
(f) Insecticides;
(g) Landscaping materials;
(h) Lawn care chemicals;
(i) Mulch;
(j) Rock;
(k) Shrubs;
(l) Sod;
(m) Trees; or
(n) Weed barriers.

Section 5. Property Used or Consumed by Persons Furnishing Landscaping Services. (1) Persons furnishing landscaping services shall not issue a resale certificate for property used or consumed in the performance of the landscaping services. Property sold to landscaping service providers and used or consumed by the landscaping service providers when furnishing landscaping services shall be subject to sales tax at the time of purchase by the landscaping service provider.
(2) The list provided in this subsection shall serve as examples of property consumed in the performance of landscaping services:
(a) Chemical applicators;

(b) Equipment rentals;
(c) Gasoline;
(d) Gloves;
(e) Lawnmowers;
(f) Oil;
(g) String trimmers, string trimmer lines and spools;
(h) Tools; or
(i) Wheelbarrows.

Section 6. Resale of Landscaping Services. (1) A person furnishing landscaping services may issue a fully completed resale certificate to another person furnishing landscaping services for the purchase of the landscaping services that will be resold to the end consumer. The purchaser of the landscaping services to be resold shall collect sales tax from the end consumer on the sales price for the furnished landscaping services.

(2) Example. Landscaping services provider A may issue a fully completed resale certificate to landscaping services provider B for the purchase of lawn mowing services to fulfill his obligations to the end consumer. Landscaping services provider A shall collect the sales tax from the end consumer on the sales price of the landscaping services.

(3) A contractor or subcontractor shall not issue a resale certificate for the purchase of landscaping services.

Section 7. De Minimis Threshold Exemption. (1) Transactions are exempt from tax for the furnishing of landscaping services or the furnishing of landscaping services combined with other services listed in KRS 139.200(h) through (q) ***if*** ***[~~when~~]*** a service provider's receipts have never exceeded the de minimis threshold exemption in a calendar year. Gross receipts from the furnishing of landscaping services that exceed the de minimis threshold exemption amount in a calendar year shall be subject to sales tax. All subsequent receipts in the calendar year and all gross receipts for each calendar year thereafter ***shall be*** ***[~~are~~]*** subject to sales tax.

(2) The de minimis threshold exemption described in subsection 1 of this section ***shall*** ***[~~does~~]*** not apply if the landscaping services provider is also engaged in the business of selling tangible personal property or digital property, or furnishing other services listed under KRS 139.200(2)(a) to (f). For example, if a landscaping services provider also sells grass seed, weed and feed, lawn equipment, or other similar products at retail, then all of the sales (both landscaping services and sales of tangible personal property) shall be subject to sales tax.

Section 8. Non-taxable Services and Exemptions for Purchases Applicable to Landscaping Services Providers Engaged in Dual Businesses. (1) This section applies to persons engaged in furnishing landscaping services that are also engaged in a dual business.

(2) Contractors and subcontractors ***shall be*** ***[~~are~~]*** subject to ***[~~Regulation~~]*** 103 KAR 26:070.

(3) ***If*** ***[~~When~~]*** a person furnishing landscaping services also operates as a contractor or subcontractor, the following list shall serve as examples of services not considered to be landscaping services when performed by a contractor or subcontractor to fulfill the terms on a construction contract.

(a) Installation, repair, or removal of the following:

1. Berm walls;

2. Driveways, sidewalks, parking areas, and patios, including those constructed of asphalt, brick, concrete, crushed stone, or gravel;

3. Decks;

4. Fences;

5. Fountains or other water works installed as plumbing fixtures;

6. Gazebos;

7. In-ground sprinkler and irrigation systems;

8. Masonry, stone setting, terrazzo, tile marble, or mosaic work;

9. Ponds, excluding decorative or ornamental ponds; or

10. Retaining walls, including those constructed of block, stone, or brick;

(b) Land clearing, excavation, erosion control, and finish grading for the construction of a permanent structure.

(4) Purchases of tangible personal property such as building materials, fixtures, and supplies that are to be incorporated or fabricated into any structure or any improvement to real estate ***shall be*** ***[~~are~~]*** subject to sales and use tax at the time of the sale to the contractor or subcontractor furnishing landscaping services in conjunction with his business as a contractor or subcontractor.

(5) ***If*** ***[~~When~~]*** a person furnishing landscaping services is also acting as a retailer of tangible personal property, and sells tangible personal property to a person who is claiming an exemption, the retailer shall not be relieved of the burden of collecting the tax until the purchaser provides the retailer with a fully completed certificate of exemption or a direct pay authorization.

Section 9. Forms. The forms ***referenced in [~~incorporated by reference into~~]*** this administrative regulation may be inspected, copied, or obtained, subject to applicable copyright law, at:

(1) The Kentucky Department of Revenue, 501 High Street, Frankfort, Kentucky 40601;

(2) A Kentucky Taxpayer Service Center, Monday through Friday, 8:00 a.m. to 4:30 p.m.; or

(3) The Department or Revenue Web site at http://revenue.ky.gov.

CONTACT PERSON: Lisa Swiger, Tax Policy Research Consultant II, Department of Revenue, 501 High Street, Station 1, Frankfort, Kentucky 40601, phone (502) 564-9526, fax (502) 564-3875, email Lisa.Swiger@ky.gov.

ANDY BESHEAR
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EXECUTIVE DIRECTOR
LARRY A. HADLEY, R.PH.

June 2, 2021

Legislative Research Commission
Ms. Emily Caudill, Regulations Compiler
702 Capitol Avenue
Capitol Annex 029
Frankfort, Kentucky 40601

Dear Ms. Caudill:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:040, 201 KAR 2:171, 201 KAR 2:205 and 201 KAR 2:390, the Kentucky Board of Pharmacy proposes the attached staff suggested amendment to 201 KAR 2:040, 201 KAR 2:171, 201 KAR 2:205 and 201 KAR 2:390.

Sincerely,

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

Final 5-27-2021

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:040. Registration of pharmacist interns.

RELATES TO: KRS 315.010***(18)[~~(16)~~]***, 315.020(3), (4), 315.050(4), (5), 315.191(1)(h)
STATUTORY AUTHORITY: KRS 315.050(4), (5), 315.191(1)(a), (h)
NECESSITY, FUNCTION, AND CONFORMITY: ***[~~The Kentucky Board of Pharmacy is required by~~]*** KRS 315.050(4) ***requires the Kentucky Board of Pharmacy*** to establish standards for pharmacy intern certification. KRS 315.191(1)(h) authorizes the board to establish an internship program for training, qualifications, and registration of applicants for registration of pharmacist interns. This administrative regulation establishes the standards for training, qualifications, and registration of pharmacist interns.

Section 1. Definitions. (1) "Academic experience program" means a course or series of courses taken by a pharmacist intern at a school or college of pharmacy approved by the board that involves actual practice of pharmacy experiences.

(2) "Preceptor" means the pharmacist who is responsible to the board for the practice of pharmacy experiences of a pharmacist intern.

Section 2. An applicant for registration as a pharmacist intern shall:

(1) File an Application for Registration as a Pharmacist Intern, Form I, with the board; and

(2) [~~Attach a recent head and shoulders passport photograph, that is not a proof copy or plastic identification; and~~

~~(3)~~] Submit proof of acceptance by a college or school of pharmacy approved by the board.

Section 3. An applicant for examination for licensure as a pharmacist shall:

(1) Complete 1,500 hours of internship;

(2) Be awarded credit for internship for hours worked in a pharmacy or in related research during the time the pharmacist intern is enrolled in an approved school or college of pharmacy;

(3) Not be awarded credit for hours worked in a pharmacy or in related research during the period the pharmacist intern is completing the academic experience program;

(4) Be limited to internship credit:

(a) Of forty-eight (48) hours per week during non-academic sessions if the pharmacist intern is in good standing with a college or school of pharmacy and the board; and

(b) Of twenty (20) hours per week during academic sessions in a college or school of pharmacy. The maximum credit allowed for this enrolled time shall be 500 hours;

(5) Be given credit for the following forms of internship:

(a) Completion of an academic experience program;

(b) Work performed in a pharmacy under the supervision of a preceptor;

(c) Work or research related to the practice of pharmacy that was performed under the supervision of a preceptor for a government body, college or university, pharmacy business, or other entity if the pharmacist intern has received prior approval by the board. The maximum credit allowed for this time shall be 400 hours, and the pharmacist intern shall ***[~~also~~]*** file an essay of at least 500 words describing the work or research experience and the relation of the work or research to the practice of pharmacy, which shall be approved by the board president; or

(d) An internship performed outside of Kentucky if the:

1. Requirements for internship in that state are at least equivalent to the requirements established in this administrative regulation; and

2. Board of licensure in that state has certified that the preceptor, pharmacy, government body, college or university, pharmaceutical business, or other entity is in good standing; and

(6) Not be awarded credit for an internship completed prior to registration with the board.

Section 4. A pharmacist intern shall:

(1) Be issued a Registration Identification Card;

(2) Carry the Registration Identification Card when on duty;

(3) Show it upon request to a member of the board or its authorized agent; and

(4) Notify the board within thirty (30) days of any charge of:

(a) A felony;

(b) A violation of drug laws; or

(c) A violation of alcohol laws.

Section 5. The registration of a pharmacist intern shall be revoked if the pharmacist intern is not:

(1) ***(a)*** Currently enrolled in a college or school of pharmacy approved by the board; ***and***

(b) Under the exceptions as established in Section 6 of this administrative regulation;

(2) A current applicant for licensure as a pharmacist in Kentucky; or

(3) Awaiting the results of an examination.

Section 6. The registration of a pharmacist intern shall not be revoked ***if[~~when~~]*** the intern is not currently enrolled in a college or school of pharmacy approved by the board if the board finds that:

(1) The intern is on a semester break; or

(2) Personal or family health concerns or other reasons beyond the control of the pharmacist intern necessitate a temporary absence from enrollment and the absence is approved by the board.

Section 7. A person who is not registered as a pharmacist intern shall not:

(1) Hold himself or herself out as a pharmacist intern; or

(2) Perform the duties of a pharmacist intern.

Section 8. (1) A preceptor shall be a pharmacist who:

(a) Has a license in good standing;

(b) Has been licensed by the board for at least one (1) year; and

(c) Has requested in writing to be designated as a preceptor.

(2) A preceptor shall be actively engaged in the practice of pharmacy in the location where the pharmacist intern performs his or her internship.

(3) The preceptor shall supervise only one (1) pharmacist intern at a time for the purpose of the intern obtaining credit for the practice of pharmacy experience, unless the pharmacist is supervising interns as a faculty member at a school or college pharmacy approved by the board during an academic experience program.

Section 9. Credit for Non-Academic Experience Programs. (1) Within ten (10) days of beginning an internship credit for non-academic experience program, a pharmacist intern shall submit a Pharmacist Preceptor's Affidavit, Form II.

(2) On or before graduation from a college or school of pharmacy, a pharmacist intern shall submit an Internship Report, Form III.

Section 10. Credit for Academic Experience Programs. (1) For a Doctor of Pharmacy degree, credit shall be awarded for each hour of successful completion of an academic experience program at a college or school of pharmacy approved by the board.

(2) An academic experience program shall be reported on an Academic Experience Affidavit, Form IV, which shall be filed with the board upon completion of the academic experience program or prior to certification for examination.

Section 11. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Application for Registration as a Pharmacist Intern", Form I, 03/2021 [~~11/2012~~];

(b) "Pharmacist Preceptor's Affidavit", Form II, 03/2021; [~~11/2012~~]

(c) "Internship Report", Form III, 03/2021 [~~11/2012~~]; and

(d) "Academic Experience Affidavit", Form IV, 03/2021 [~~11/2012~~].

(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 Monday through Friday, 8 a.m. to 4:30 p.m. ***This material is also available on the board's Web site at https://pharmacy.ky.gov/professionals/Pages/Pharmacist-Interns.aspx.***

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.

ANDY BESHEAR
GOVERNOR

KENTUCKY BOARD OF PHARMACY
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June 2, 2021

Legislative Research Commission
Ms. Emily Caudill, Regulations Compiler
702 Capitol Avenue
Capitol Annex 029
Frankfort, Kentucky 40601

Dear Ms. Caudill:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:040, 201 KAR 2:171, 201 KAR 2:205 and 201 KAR 2:390, the Kentucky Board of Pharmacy proposes the attached staff suggested amendment to 201 KAR 2:040, 201 KAR 2:171, 201 KAR 2:205 and 201 KAR 2:390.

Sincerely,

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

Final 5-27-2021

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:171. Computerized recordkeeping.

RELATES TO: KRS 217.215, 217.216, 315.191
STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1), (a), (f)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.215(2) ***authorizes[~~provides for~~]*** the board to establish administrative regulations relating to the storage and retrieval of ***prescription[~~prescriptions~~]*** records ***in licensed pharmacies***, including ***administrative regulations regarding*** computerized recordkeeping. This administrative regulation provides standards for ***licensed pharmacies[~~those~~]*** using computerized recordkeeping.

Section 1. The following information shall be entered into the system:
(1) All information pertinent to a prescription shall be entered into the system, including ***items such as[~~, but not limited to,~~]*** each of the following:
(a) The prescription number;
(b) The patient's name and address;
(c) The prescriber's name and address;
(d) The prescriber's Federal Drug Enforcement Administration number, if appropriate;
(e) Refill authorization;
(f) Any prescriber's instructions or patient's preference permitted by ***KRS Chapters 217, 218A, and 315, or 201 KAR Chapter 2[~~law or administrative regulation~~]***;
(g) The name, strength, dosage form, and quantity of the drug dispensed originally and upon each refill; and
(h) The date of dispensing of the prescription and the identifying designation of the dispensing pharmacist for the original filling and each refill.
(2) The entries shall be made into the system ***when[~~at the time~~]*** the prescription is first filled and ***upon[~~at the time of~~]*** each refill, except that the format of the record may be organized so that the data already entered may appear for the prescription or refill without reentering that data. Records that are received or sent electronically may be kept electronically. The dispensing pharmacist shall ***ensure[~~be responsible for~~]*** the completeness and accuracy of the entries.
(3) ***(a)*** The original prescription and a record of each refill, if received written or oral, shall be preserved as a hard copy for a period of three (3) years and thereafter be preserved as a hard copy or electronically for no less than an additional two (2) years.
(b) The original prescription and a record of each refill, if received by facsimile, shall be preserved as a hard copy, the original electronic image, or electronically for a period of three (3) years and thereafter be preserved as a hard copy, the original electronic image, or electronically for no less than an additional two ***(2)*** years.
(c) The original and electronic prescription shall be subject to inspection by authorized

agents. An original ***and electronic*** prescription shall not be obstructed in any manner.

(4) The original prescription and a record of each refill, if received as an e-prescription, shall be preserved electronically for a period of no less than five (5) years. The electronic prescription shall be subject to inspection by authorized agents. An original ***and electronic*** prescription shall not be obstructed in any manner.

(5) The required information shall be entered into the system for all prescriptions filled at the pharmacy.

(6) The system shall provide adequate safeguards against improper manipulation or alteration of the data.

(7)The system shall have the capability of producing a hard-copy printout of all original and refilled prescription data as required in ***this*** section ~~***[1 of this administrative regulation]***~~. A hard-copy printout of the required data shall be made available to an authorized agent within forty-eight ***(48)*** hours of the receipt of a written request.

(8) The system shall maintain a record of each day's prescription data as follows:

(a) This record shall be verified, dated, and signed by the ***pharmacist or pharmacists***~~***[pharmacist(s)]***~~ who filled those prescription orders either:

1. Electronically;
2. Manually; or
3. In a log.

(b) This record shall be maintained for no less than five (5) years; and

(c) This record shall be readily retrievable and shall be subject to inspection by authorized agents.

(9) An auxiliary recordkeeping system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason. The auxiliary system shall ***ensure***~~***[insure]***~~ that all refills are authorized by the original prescription order and that the maximum number of refills is not exceeded. If the automated data processing system is restored to operation, the information regarding prescriptions filled and refilled during the inoperative period shall be entered into the automated data processing system within seventy-two (72) hours.

(10) Controlled substance data shall be identifiable apart from other items appearing in the record.

(11) The pharmacist shall ~~***[be responsible to]***~~ assure continuity in the maintenance of records throughout any transition in computerized record systems utilized.

Section 2. A computer malfunction or data processing ***service***~~***[services]***~~ provider's negligence shall not be a defense against charges of improper recordkeeping.

Section 3. This administrative regulation is not applicable to the recordkeeping for drugs prescribed for and administered to patients confined as inpatients in an acute care facility.

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.

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June 2, 2021

Legislative Research Commission
Ms. Emily Caudill, Regulations Compiler
702 Capitol Avenue
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Frankfort, Kentucky 40601

Dear Ms. Caudill:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:040, 201 KAR 2:171, 201 KAR 2:205 and 201 KAR 2:390, the Kentucky Board of Pharmacy proposes the attached staff suggested amendment to 201 KAR 2:040, 201 KAR 2:171, 201 KAR 2:205 and 201 KAR 2:390.

Sincerely,

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

Final 5-28-2021

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:205. Pharmacist-in-charge.

RELATES TO: KRS 315.020, ***315.035,*** 315.0351, 315.191, 315.300, 315.335
STATUTORY AUTHORITY: KRS 315.020(1), 315.0351, 315.191(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the board to promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers. KRS 315.020(1) and 315.0351***(1)(g)[~~(7)~~]*** require applicants for pharmacy permits to place a pharmacist in charge as a prerequisite to compounding and dispensing privileges granted by the Kentucky Board of Pharmacy. This administrative regulation establishes the requirements relating to a pharmacist-in-charge.

Section 1. Definition. "Pharmacist-in-charge" means a pharmacist licensed in the Commonwealth of Kentucky[~~, or in the appropriate jurisdiction of an out-of-state pharmacy holding a Kentucky Board of Pharmacy permit~~], who accepts responsibility for the operation of a pharmacy in conformance with all laws and administrative regulations pertinent to the practice of pharmacy and the distribution of prescription drugs and who is personally in full and actual charge of the pharmacy.

Section 2. Duties and Responsibilities. (1) The pharmacist-in-charge shall be so designated in the Application for ***[a]*** Permit to Operate a Pharmacy ***in Kentucky and in the Application for Non-Resident Pharmacy Permit,*** and in each Application for ***Resident Pharmacy*** Renewal ***and Application for Non-Resident Pharmacy Permit Renewal submitted for the renewal*** of that permit thereafter.

(2) A pharmacist shall not serve as a pharmacist-in-charge:

(a) For more than one (1) pharmacy at a time, except upon written approval from the Kentucky Board of Pharmacy; and

(b) Unless he or she is physically present in that pharmacy for a minimum of ten (10) hours per week or the amount of time appropriate to provide supervision and control.

(3) The pharmacist-in-charge shall be responsible for:

(a) Quality assurance programs for pharmacy services designed to objectively and systematically monitor care, pursue opportunities for improvement, resolve identified problems as may exist, and detect and prevent drug diversion;

(b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services;

(c) Assuring that all pharmacists and interns employed by the pharmacy are currently licensed;

(d) Providing notification in writing to the Board of Pharmacy within fourteen (14) calendar days of any change in the:

1. Employment of the pharmacist-in-charge;
2. Employment of staff pharmacists; or
3. Schedule of hours for the pharmacy;

(e) Making or filing of any reports required by state or federal laws and regulations;

(f) Responding to the Kentucky Board of Pharmacy regarding identified violations or deficiencies; and

(g) Filing of any report of a theft or loss to:

1. The U. S. Department of Justice Drug Enforcement Agency as required by 21 C.F.R. 1301.76(b);

2. The Department of the Kentucky State Police as required by KRS 315.335; and

3. The board by providing a copy to the board of each report submitted.

Section 3. Incorporation by Reference. (1) The following material is incorporated by reference:

(a) "Application for Permit to Operate a Pharmacy in Kentucky" Form 1, 5/2020[~~07/2012~~];

(b) "Application for Non-Resident Pharmacy Permit", Form 3[~~1~~], 5/2020[~~07/2012~~];

(c) "Application for Resident Pharmacy Renewal", Form 2, 5/2020[~~07/2012~~]; and

(d) "Application for Non-Resident Pharmacy Permit Renewal", Form 4[~~2~~], 5/2020[~~07/2012~~].

(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, Monday through Friday, 8 a.m. to 4:30 p.m. ***This material is also available on the board's Web site at https://pharmacy.ky.gov/Businesses/Pages/Pharmacy.aspx.***

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.

ANDY BESHEAR
GOVERNOR

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pharmacy.ky.gov

June 2, 2021

Legislative Research Commission
Ms. Emily Caudill, Regulations Compiler
702 Capitol Avenue
Capitol Annex 029
Frankfort, Kentucky 40601

Dear Ms. Caudill:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:040, 201 KAR 2:171, 201 KAR 2:205 and 201 KAR 2:390, the Kentucky Board of Pharmacy proposes the attached staff suggested amendment to 201 KAR 2:040, 201 KAR 2:171, 201 KAR 2:205 and 201 KAR 2:390.

Sincerely,

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

Final 5-28-2021

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy

201 KAR 2:390. Requirements for third-party logistics providers[~~provider~~].

RELATES TO: KRS ***315.0351, 315.121,***[~~315.002, 315.005,~~] 315.191(1)(a), 315.400[~~(18)~~], 315.4102, 315.4104, 315.4106, 315.4108, 315.4110***, 21 U.S.C. 360eee-360eee-4***

STATUTORY AUTHORITY: KRS ***315.191(1)(a),*** 315.4102, 315.4104, 315.4106, 315.4108, 315.4110

NECESSITY, FUNCTION AND CONFORMITY: KRS 315.191(1)(a), 315.4102, 315.4104, 315.4106, 315.4108, and 315.4110 authorizes the board to promulgate administrative regulations to regulate third-party logistics providers. [~~KRS 315.4102 requires a third-party logistics provider to be licensed and that the board establish the renewal fee by administrative regulation. KRS 315.4104 requires a board-approved application, licensure fee, and accompanying information. KRS 315.4106 establishes eligibility factors for licensure and renewal. KRS 315.4108 identifies persons disqualified as owners and designated representatives of third-party logistics providers. KRS 315.4110 establishes criteria for lawfully conducting business as a third-party logistics provider in the Commonwealth of Kentucky.~~] This administrative regulation establishes requirements for the regulation of third-party logistics providers [~~to become licensed and operate~~].

Section 1. Definitions.

(1) ***"Board" means the Board of Pharmacy.***

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

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

(4)[~~(3)~~] "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.

(5) "Illegitimate product" is defined by KRS 315.400(11).

(6)[~~(4)~~] "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)[~~(5)~~] "Suspect product" means a component, prescription drug, or drug-related device for which there is a reason to believe that ***the[~~such~~]*** component, prescription drug, or drug-related device:

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

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

(8) "Third-party logistics provider" is defined by KRS 315.400(18). [~~Application Requirements for Licensure Application and Renewal. (1) An applicant for initial licensure or renewal as a third-party logistics provider shall submit:~~

~~(a) A non-refundable initial licensure or renewal fee of $200 by check or money order made payable to the Kentucky State Treasurer;~~

~~(b) A complete, sworn, and notarized Application to Operate as a Third-Party Logistics Facility;~~

~~(c) Unless previously provided, documentation of licensure as a third-party logistics provider through proof of registration with either:~~

~~1. The secretary of the U.S. Department of Health and Human Services, Food and Drug Administration; or~~

~~2. The state in which the provider ships;~~

~~(d) Unless previously provided, copy of current inspection report conducted by the United States Food and Drug Administration, if applicable. If a current inspection report is not available from the United States Food and Drug Administration, the applicant shall submit an inspection report by:~~

~~1. The National Association of Boards of Pharmacy (NABP); or~~

~~2. The board's authorized agent;~~

~~(e) A confirmation statement of the previous owner if ownership changed;~~

~~(f) Legal proof of any name change, if applicable;~~

~~(g) An explanation if an applicant, officer, partner, or director has ever been convicted of a felony or had a professional license or permit disciplined under federal, state, or local law;~~

~~(h) Ownership information for each partner, director, or officer, including:~~

~~1. Name and title;~~

~~2. Email addresses;~~

~~3. Federal employer identification number;~~

~~4. Address;~~

~~5. Phone number;~~

~~6. Social security number; and~~

~~7. Date of birth;~~

~~(i) State of incorporation or organization if the owner is a corporation; and~~

~~(j) Upon request, a list of all manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services.~~

~~(2) An applicant applying for any ownership or address change shall submit a non-refundable ownership change fee of $100 and a change of address fee of $100.~~

~~(3) Each License shall expire on June 30 following date of issuance, unless earlier suspended or revoked. There shall be a delinquent renewal fee of $200 for failure to renew by June 30 of each year.~~]

Section 2. [~~General~~]Requirements. [~~A third-party logistics provider shall:~~](1) A third-party logistics provider providing services in the Commonwealth, including distributing into the Commonwealth, shall apply for a license from the board ***[~~of Pharmacy~~]*** in accordance with KRS 315.4102 and this administrative regulation.

(2) A separate license shall be required for each third-party logistics provider's facility that provides services in the Commonwealth, including distributing into the Commonwealth, regardless of whether joint ownership or control exists.

(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.

(4) A license shall not be issued or renewed unless the applicant 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 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, prescription drugs, or drug-related devices;

(b) Separation and quarantine of deteriorated, damaged, outdated, misbranded, adulterated, or recalled components, prescription drugs, or drug-related devices until they are destroyed or returned; and

(c) If applicable, provide proof of registration with the U.S. Food and Drug Administration (FDA) and U.S. Drug Enforcement Administration (DEA) and shall comply with all federal laws, state and local laws, and regulations.

(5) A third-party logistics provider shall comply with all requirements as outlined in the Drug Supply Chain Security Act (DSCSA), 21 U.S.C 360eee-360eee-4, and other applicable federal laws.

(6) A third-party logistics provider shall establish a system to quarantine or destroy suspect or illegitimate product if directed to do so by the manufacturer, repackager, wholesale distributor, dispenser, or authorized government agency.

(7) A third-party logistics provider shall have readily retrievable within forty-eight (48) hours[~~immediately provide~~], upon written request of the board ***[~~of Pharmacy~~]*** or its agents, and maintain for board ***[~~of Pharmacy~~]*** inspection, a list of all manufacturers, wholesale distributors, repackagers, and dispensers for whom the third-party logistics provider provides services;

(8)[~~(2)~~] A third-party logistics provider shall have readily retrievable within forty-eight (48) hours [~~immediately provide~~], upon written request of the board ***[~~of Pharmacy~~]*** or its agents, and maintain for board ***[~~of Pharmacy~~]*** inspection, a list of each partner, limited liability company member, [~~and~~] corporate officer or director, and facility manager, including a description of the duties and qualifications of each; and

(9)[~~(3) Make available for board inspection, records of providing third-party logistics services involving prescription drugs, if such records are maintained; and~~] A third-party logistics provider shall have readily retrievable within forty-eight (48) hours, upon written request of the board ***[~~of Pharmacy~~]*** or its agents, and maintain for board ***[~~of Pharmacy~~]*** inspection, records with capability to trace the receipt and outbound distribution or disposition of components, prescription drugs, or drug-related devices and records of inventory.[

~~(4) Follow closure procedures established in 201 KAR 2:106, Section 2.~~]

Section 3. Qualifications for Licensure. (1) The board ***[~~of Pharmacy~~]*** shall consider, at a minimum, the following factors in determining the eligibility for initial licensure and renewal of third-party logistics providers:

(a) Minimum considerations in KRS 315.4106(1);

(b) Any convictions of the applicant or its officers under any federal, state, or local laws relating to drugs, ***including[~~to include~~]*** drug samples and controlled substances;

(c) The applicant's and its officers' past experience with distribution of prescription drugs and drug-related devices, including drug samples and controlled substances; and

(d) Compliance with the requirements under any previously granted license or permit, if any.

(2) The board ***may [~~of Pharmacy shall have the right to~~]*** deny a license to an applicant if it ***finds[~~determines~~]*** that the granting of that license would not be in the public interest based on health and safety considerations.

(3) 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, state, and local laws and regulations relating to prescription drugs and ***drug***-related devices; and

(b) That the applicant is equipped as to land, buildings, and security to properly conduct the business described in the application.

(4) A license issued pursuant to this administrative regulation [~~may be disciplined, suspended, or revoked for failure~~] failing to comply with the provisions of KRS 315.400, 315.4102, 315.4104, 315.4106, 315.4108, 315.4110, or this administrative regulation may result in discipline, suspension, or revocation under KRS 315.121.

Section 4. Application, Fees, Renewals.

(1) An applicant for initial licensure or renewal as a third-party logistics provider shall submit:

(a) A non-refundable initial licensure or renewal fee of $200 by check or money order made payable to the Kentucky State Treasurer;

(b) A complete, sworn, and notarized ***[~~"~~]***Application to Operate as a Third-Party Logistics ***Provider or Application for Third-Party Logistics Provider License Renewal[~~"~~]***;

(c) Unless previously provided, documentation of licensure as a third-party logistics provider through proof of registration with either:

1. The FDA; or

2. The state in which the third-party logistics provider is located;

(d) Unless previously provided, copy of most current inspection report conducted by the FDA. If the most current inspection report is not available from the FDA, the applicant shall submit an inspection report by:

1. The National Association of Boards of Pharmacy (NABP); or

2. The resident state licensing or permitting authority's authorized agent;

(e) A confirmation statement from the previous owner if ownership changed;

(f) Legal proof of any name change, if applicable;

(g) An explanation if an applicant, officer, partner, or director has ever been convicted of a felony or had a professional license or permit disciplined under federal, state, or local law;

(h) Ownership information for each partner, director, or officer, including:

1. Name and title;

2. Email addresses;

3. Federal employer identification number;

4. Address;

5. Phone number;

6. Social security number; and

7. Date of birth;

(i) State of incorporation or organization if the owner is a corporation; and

(j) Upon request, a list of all manufacturers, repackagers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services.

(2) An applicant applying for any ownership or address change shall submit a non-refundable fee of $100.

(3) Each license shall expire on June 30 following date of issuance, unless earlier suspended or revoked. There shall be a delinquent renewal fee of $200 for failure to renew by June 30 of each year.

Section 5. Standards. (1) Facilities.

(a) All facilities in which components, prescription drugs, or drug-related devices are held shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations;

(b) All facilities shall meet all applicable federal, state, and local laws and regulations;

(c) A third-party logistics provider shall quarantine components, prescription drugs, or drug-related devices that are outdated, damaged, deteriorated, misbranded, recalled, or adulterated;

(d) A facility shall not be located in a residence; and

(e) A facility shall be located apart and separate from any pharmacy permitted by the board ***[~~of Pharmacy~~]***.

(2) Security.

(a) A third-party logistics provider shall be equipped with an alarm system to detect entry after hours.

(b) A third-party logistics provider shall assure that access from outside ***the provider's[~~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, prescription drugs, or drug-related devices are held to authorized personnel. These policies shall provide protection against tampering with computers or electronic records.

(d) A third-party logistics provider shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in providing these services.

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

(a) Inventories and other records regarding the receipt and distribution or disposition of components, prescription drugs, or drug-related devices shall be maintained and readily retrievable within forty-eight (48) hours for inspection or photocopying by the board ***[~~of Pharmacy~~]*** and authorized officials of any federal, state or local law enforcement agencies for a period of six (6) years. These records shall include:

1. The business name and address of the third-party logistics provider's client and the address of the location from which the component, prescription drugs, or drug-related devices were received;

2. The business name and address to whom the components, prescription drugs, or drug-related devices were distributed or disposed of;

3. The identity and quantity of the components, prescription drugs, or drug-related devices received and distributed or disposed of; and

4. The dates of receipt and distribution or disposition of the components, prescription drugs, or drug-related devices.

(b) Records described in this section that are kept at the inspection site or that ***may[~~can~~]*** be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by the board ***[~~of Pharmacy~~]*** or an authorized official of any federal, state or local law enforcement agency.

(c) Third-party logistics providers shall maintain an ongoing list of verified persons or businesses to whom they ship prescription drugs and ***drug-***related devices.

(d) Third-party logistics providers may distribute components, prescription drugs, or drug-related devices only to the following, except as ***established[~~provided~~]*** in KRS 315.0351(2) and ***[~~KRS~~]*** 315.404:

1. A currently permitted manufacturer;
2. A currently licensed wholesaler;
3. A currently licensed third party logistics provider;
4. A currently permitted pharmacy;
5. A currently licensed outsourcing facility;
6. A currently licensed practitioner;
7. A currently permitted repackager;
8. A currently licensed hospital, but only for use by or in that hospital;
9. A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes; or

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

(4) Written policies and procedures.

(a) A third-party logistics provider shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, and distribution or disposition of components, prescription drugs, or drug-related devices.

(b) There shall be written policies and procedures for identifying, recording, and reporting significant losses or thefts to the board ***[~~of Pharmacy~~]***, and, if applicable, the FDA and the DEA.

(c) There shall be written policies and procedures for protecting against, and handling 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) There shall be written policies and procedures for managing and correcting all errors or inaccuracies in inventories.

(e) There shall be written policies and procedures as to the handling of any outdated, returned, or damaged prescription drugs and ***drug***-related devices. Any outdated, returned, or damaged components, prescription drugs, or drug-related devices shall be segregated.

(f) There shall be written policies and procedures by which the third-party logistics provider exercises control over the shipping and receiving of all components, prescription drugs, or drug-related devices within the operation.

(g) There shall be written policies and procedures for quarantining suspect product and illegitimate product if directed to do so by the respective manufacturer, repackager, wholesale distributor, dispenser, or authorized government agency.

(5) Handling recalls. A third-party logistics provider shall establish, maintain, and adhere to a written policy and procedure in accordance with business agreements as to the handling of recalls and withdrawals of components, prescription drugs, or drug-related devices.

Section 6. Violations. (1) A third-party logistics provider shall not distribute components, prescription drugs, or drug-related devices directly to a consumer or a patient, except as ***established[~~provided~~]*** in KRS 315.0351(2).

(2) A third-party logistics provider shall not operate in a manner that endangers the public health.

(3) Violations of any of these provisions shall be grounds for action under KRS 315.121.

Section 7. Incorporation by Reference.

(1) ***The following material is incorporated by reference:***

(a) "Application to Operate as a Third-Party Logistics [~~Facility~~]Provider", May 2020***; and***

(b) [~~July 2017~~]***[~~, is incorporated by reference.~~***

~~(2)~~] "Application for Third-Party Logistics Provider License Renewal", May 2020***[~~, is incorporated by reference~~]***.

(2)[~~(3)~~] ***This material[~~These forms~~]*** may be ***[~~obtained,~~]*** inspected, ***[~~or~~]*** 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, ***Monday through Friday,*** 8:00 a.m. to 4:30 p.m. ***This material is also available on the board's Web Site at https://pharmacy.ky.gov/Businesses/Pages/Third-Party-Logistics-Provider-License-Information.aspx [~~Monday through Friday~~]***.

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.

KENTUCKY BOARD OF ALCOHOL & DRUG COUNSELORS

Andy Beshear
Governor

PO Box 1360
Frankfort, KY 40602
Phone (502) 782-8814 - Fax (502) 564-4818
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June 4, 2021

(Via email to RegsCompiler@LRC.KY.GOV)

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 35:010E. Definitions for 201 KAR Chapter 35.
201 KAR 35:020E. Fees.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 35:010E and 201 KAR 35:020E, the Board of Alcohol and Drug Counselors proposes the attached amendments to 201 KAR 35:010E and 201 KAR 35:020E.

Sincerely,

Kevin R. Winstead, Acting Commissioner
Department of Professional Licensing
500 Mero Street, 237CW, Frankfort, KY 40601
502-782-0562 (office) | KevinR.Winstead@ky.gov

Final 6-4-2021

SUGGESTED AMENDMENT *EMERGENCY ONLY*

GENERAL GOVERNMENT CABINET
Board of Alcohol and Drug Counselors
(Emergency Amended After Comments)

201 KAR 35:010E. Definitions for 201 KAR Chapter 35.

Page 1
NECESSITY, FUNCTION, AND CONFORMITY
Line 16
After "specialists", delete the following:
, and the designation of certified alcohol and drug counselor degreed

Page 2
Section 1(8) and Section 1(9)
Lines 10-12
After "(8)", delete the following:
"Certified alcohol and drug counselor degreed" means a certified alcohol and drug counselor possessing a baccalaureate degree.
(9)

Page 2
Section 1(9) and Section 1(10)
Lines 12-13
After "KRS 309.080(5).", insert "(9)".
Delete "(10)".

Page 2
Section 1(10) and Section 1(11)
Lines 13-14
After "board.", insert "(10)".
Delete "(11)".

Page 2
Section 1(11) (*Renumbered as subsection (10) by the compiler)*
Line 15
After "established in subsection", insert "(15)".
Delete "(14)".

Pages 2 through 5
Section 1(12) through Section 1(32)
Lines 18 and 20, Lines 3, 6, 13, and 19, Lines 4, 6, 8, 11, 15, 18, 21, and 22, Lines 1, 3, 4, 6, 8, 9, and 11

NOTE TO COMPILER: Beginning with Section 1(12), renumber Section 1(12) through Section 1(32), as Section 1(11) through Section 1(31) of this administrative regulation to conform to the deletion of the definition of "certified alcohol and drug counselor degreed".

KENTUCKY BOARD OF ALCOHOL & DRUG COUNSELORS

Andy Beshear
Governor

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Frankfort, KY 40602
Phone (502) 782-8814 - Fax (502) 564-4818
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June 4, 2021

(Via email to RegsCompiler@LRC.KY.GOV)

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 35:010E. Definitions for 201 KAR Chapter 35.
201 KAR 35:020E. Fees.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 35:010E and 201 KAR 35:020E, the Board of Alcohol and Drug Counselors proposes the attached amendments to 201 KAR 35:010E and 201 KAR 35:020E.

Sincerely,

Kevin R. Winstead, Acting Commissioner
Department of Professional Licensing
500 Mero Street, 237CW, Frankfort, KY 40601
502-782-0562 (office) | KevinR.Winstead@ky.gov

Final 6-4-2021

SUGGESTED AMENDMENT *EMERGENCY ONLY*

GENERAL GOVERNMENT CABINET
Board of Alcohol and Drug Counselors
(Emergency Amended After Comments)

201 KAR 35:020E. Fees.

Page 1
Section 1(1)
Lines 20-21

After "licensed alcohol and drug counselor,", delete the following:
certified alcohol and drug counselor degreed,

Page 10
Section 9(1)(a)
Line 6

After "Application", and the closing quotation marks and comma, insert "June".
Delete "May".

MATERIAL INCORPORATED BY REFERENCE

At the time that it files this staff suggested amendment the agency will need to file one (1) clean copy of KBADC Form 1, Application that includes the following changes:

- **Updates the Edition date to June 2021**
- **Deletes references to "certified alcohol and drug counselor degreed" on the form**

Andy Beshear
Governor

Ray Perry
Deputy Secretary

Public Protection Cabinet
Kentucky Horse Racing Commission
4063 Iron Works Parkway, Building B
Lexington, KY 40511
Telephone: (859) 246-2040
Fax: (859) 246-2039
KHRC.ky.gov

Kerry B. Harvey
Secretary

Marc Guilfoil
Executive Director

Jonathan Rabinowitz
Chairman

June 4, 2021

VIA ELECTRONIC MAIL
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: 810 KAR 5:080. Harness racing and county fairs (to be renamed to Kentucky Proud Series).

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 810 KAR 5:080, the Kentucky Horse Racing Commission proposes the attached suggested substitute to 810 KAR 5:080.

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

Jennifer Wolsing

Jennifer Wolsing
General Counsel

TEAM KENTUCKY

Final Version 6/4/2021 8:45 AM

STAFF-SUGGESTED SUBSTITUTE

PUBLIC PROTECTION CABINET
Kentucky Horse Racing Commission

810 KAR 5:080. Kentucky Proud Series[~~Harness racing at county fairs~~].

RELATES TO: KRS 230.215, 230.260, 230.280, 230.290, 230.310, 230.398
STATUTORY AUTHORITY: KRS 230.215, 230.260, 230.398
NECESSITY, FUNCTION, AND CONFORMITY: KRS 230.215(2) and 230.260(8) authorize the Kentucky Horse Racing Commission ***[(the "commission")]***to promulgate administrative regulations prescribing the conditions under which horse racing shall be conducted in Kentucky. KRS 230.398 authorizes the commission to promulgate administrative regulations governing the conduct of county fair races, branded as the ***["]***Kentucky Proud Series.***["]***[.] This administrative regulation establishes conditions, [~~races,~~] purses, and payments in races conducted as part of the Kentucky Proud Series,[~~at county fairs~~] in which funds for purses are provided by the commission, and regulates eligibility for participation in the Kentucky Proud Series[~~harness racing at county fairs~~].

Section 1. Eligibility. A horse ***shall be[is]*** eligible to participate in a two (2) or three (3) year old Kentucky Proud Series stakes race[~~at a county fair~~] if the [:
~~(1) The~~]horse is a two (2) year old or a three (3) year old that is "Kentucky-bred" as defined ***by[in]*** 810 KAR 7:040[;
~~(2) All owners of the participating horse are current members of the Kentucky Colt Racing Association, Inc.;~~
~~(3) All owners of the participating horse hold a current license with the commission; and~~
~~(4) The trainer and driver of the participating horse hold current licenses with the commission~~].

Section 2. Track Requirements.
(1) A fair shall have a safe and adequate track, and the entire track, including start and finish lines, shall be visible to judges and spectators.
(2) The track shall be inspected and approved by a representative of the commission.
(3) A track shall have a hub rail or pylons approved by the commission.
(4)(a) A fair shall have safe and adequate stalls for participating horses.
(b) If permanent stalls are not available, tents or other tie-in type stalls may be used.
(c) Except as ***established[~~provided~~]*** by paragraph (d) of this subsection, a county fair shall not charge stall rent for horses racing at the fair.
(d) A county fair may charge stall rent if the fair is held on state-owned property.

Section 3. [~~Fair Fees.~~
~~(1) The Kentucky Colt Racing Association fees shall be as follows:~~

~~(a) A nomination fee of fifty (50) dollars per horse due on or before February 15 of each racing year;~~

~~(b) A sustaining fee of $200 per horse due on or before April 15 of each racing year;~~

~~(c) A starting fee of fifty (50) dollars per horse, per fair, due at the time of entry for the fair; and~~

~~(d) A twenty-five (25) dollar fee per horse for starting in an overnight race, due at the time of entry for the fair.~~

~~(2) A $200 payment shall be due at the time of entry for a horse eligible for the fair finals.~~

~~Section 4.~~]Officials.

(1) The host track[~~Kentucky Colt Racing Association~~] shall submit to the commission, at least sixty (60) days prior to the opening of a race meeting, a written list of racing officials and applicable employees.

(2) 810 KAR 2:050 shall govern the judges and racing officials at Kentucky Proud Series stakes races.[~~At a county fair, there shall be at least one (1) presiding judge approved by the commission in the judges' stand. In addition, at a meeting in which races are charted, the association member shall provide both a licensed charter and licensed clerk of the course.~~

~~(3) A fair shall use licensed United States Trotting Association judges to preside over the racing.~~

~~(4) The judges shall review the ownership of any horse that is entered in order to ensure the horse's eligibility to race.~~

~~(5) The judges may determine the validity for racing purposes of any lease, transfer, or agreement pertaining to ownership of a horse and may call for adequate evidence of ownership at any time.~~

~~(6) The judges may declare a horse ineligible to race if the ownership or control of the horse is in question.~~]

(3)[~~(7)~~] Officials shall be paid by the entity hosting the races, with the exception of judges. Judges shall be paid by the commission. The Commission shall determine the number of judges, notwithstanding any provision of 810 KAR 2:050 to the contrary [~~Kentucky Colt Racing Association.~~

~~Section 5. Starter. A fair shall use a licensed starter with adequate equipment.~~

~~Section 6. Use of Entry Fees.~~

~~(1) The entry fees established in Section 3(1)(c) and (d) of this administrative regulation shall be retained by each fair as compensation for conducting its harness racing program and in reimbursement of the expenses incurred.~~

~~(2) A fair shall, upon request, make a full accounting of the entry fees to the commission.~~

~~Section 7. Application for a License and Approval for Purse Distributions.~~

~~(1) The Kentucky Colt Association on behalf of a fair shall apply to the commission for a license to conduct a harness racing event. A request for pari-mutuel wagering shall be included at the time of application.~~

~~(2) Distribution of revenue for the Kentucky County Fairs shall be reviewed annually, not later than December 15 of each calendar year, by the advisory panel established in 810 KAR 7:040~~].

Section 4[8]. Requirements. ***Each race[All races]*** shall be held in accordance with KRS Chapter 230 and 810 KAR Chapters 2, 3, 5, 6, 7, and 8[~~Changes in Racing Program. A fair shall have the right to change the order of its program and to postpone or cancel an event due to bad weather or unavoidable cause. If a race is canceled because of lack of entries, entry fees shall be refunded.~~

~~Section 9. Early Closers.~~

~~(1) An early closing event, and all divisions of that event, shall race a single heat at a distance of one (1) mile and shall be contested for a purse approved by the commission on an annual basis.~~

~~(2) An early closing race shall be contested regardless of the number of entries. However, a fair may cancel an overnight race with less than five (5) entries~~].

Section 5[~~10~~]. Kentucky Sire Stakes Panel.***[~~(1)~~]*** No later than December 15 of each calendar year, the Kentucky Sire Stakes advisory panel established in 810 KAR 7:040 may annually address, and the commission may annually approve, ***based on promoting the best interests of racing,*** at least the following conditions, which ***shall, once approved,[~~may~~]*** be placed in the condition book for the following year:[~~Number of Starters and Purse Distributions. There shall be no more than two (2) trailers in any race at a county fair.~~

~~(1) On a one (1) mile track, there shall be ten (10) horses on the gate and the race shall split on eleven (11) horses.~~

~~(2) On a half mile track or five-eighths mile track, there shall be five (5) horses on the gate with two (2) trailers, and the race shall split on eight (8) horses.~~]

(1)[~~(a)~~][~~(3)~~] The purse for each race;

(2)[~~(b)~~] Race dates;

(3)[~~(c)~~] Fees, such as nomination, sustaining, starting, and finals fees;

(4)[~~(d)~~] Distribution of revenue for the Kentucky Proud Series;

(5)[~~(f)~~] Early closers; and

(6)[~~(g)~~] Other conditions necessary to participate in the Kentucky Proud Series.[~~ shall be divided as follows:~~

~~(a) Five (5) starters - fifty (50) percent, twenty-five (25) percent, twelve (12) percent, eight (8) percent, and five (5) percent;~~

~~(b) Four (4) starters - fifty (50) percent, twenty-five (25) percent, twelve (12) percent, eight (8) percent, and the remaining five (5) percent reverts back to the fund;~~

~~(c) Three (3) starters - fifty (50) percent, twenty-five (25) percent, twelve (12) percent, and the remaining thirteen (13) percent reverts back to the fund;~~

~~(d) Two (2) starters - fifty (50) percent, twenty-five (25) percent, and the remaining twenty-five (25) percent reverts back to the fund; and~~

~~(e) One (1) starter - fifty (50) percent, and the remaining fifty (50) percent reverts back to the fund.~~

~~Section 11. Points Distribution.~~

~~(1) Points shall be awarded in an early closing race, and any division of an early closing race, as follows:~~

~~(a) First place finisher - fifty (50) points;~~

~~(b) Second place finisher - twenty-five (25) points;~~

~~(c) Third place finisher - twelve (12) points;~~

~~(d) Fourth place finisher - eight (8) points;~~

~~(e) Fifth place finisher - five (5) points; and~~

~~(f) Each starter that finishes out of the money - one (1) point.~~

~~(2) If two (2) horses dead-heat for any position, they shall each receive one-half (1/2) of the points awarded for that position and one-half (1/2) of the points awarded for the next lower position. The same procedure shall be used for the allocation of points if there is a dead-heat of three (3) or more horses.~~

~~(3) A horse that is declared in and then is the subject of a judge's scratch shall be awarded one (1) point based upon the decision of the presiding judge. This decision shall be final.~~

~~(4) If there is a tie among two (2) or more horses with the same number of points, the tie shall be resolved in favor of the horse with the higher earnings in the early closing fair events in which the horses have competed.~~

~~(5) If any division of a race is rained out before the completion of all other divisions of that race, the points for distribution set forth in this section shall not apply, and instead one (1) point shall be awarded to each horse entered in each division of that race that was rained out.~~

~~Section 12. Entry Limitation. A horse shall not be allowed to compete in more than one (1) race at any fair.~~]

Section 6[~~13~~]. Drug Testing.

(1) The winning horse at a fair race and any other horse or horses as selected by the judges may be ***required to take[~~subjected to~~]*** a drug test as ***established[~~set forth~~]*** in 810 KAR 8:010 and 810 KAR 8:060.

(2) A fair shall provide two (2) enclosed stalls and bedding to be used by the commission veterinarian for drug testing.

(3) The stalls required by subsection (2) of this section shall be located as close to the race track as possible.

(4) The stalls shall be positioned to allow the track announcer to be heard.

(5) The expense of the testing laboratory or other testing processes, whether furnished by contract or otherwise, together with all supplies and equipment used in connection therewith, shall be paid by the entity operating harness races under this administrative regulation.[

~~Section 14. Coggins Test. A current negative Coggins test shall be required for each horse racing at a fair.~~

~~Section 15. Drivers. A driver shall wear full colors, white pants, a safety vest as required by 810 KAR 5:070 Section 17, and a safety helmet that meets the standards set forth in 810 KAR 5:070 Section 16, if on the track less than one (1) hour before the start of a fair racing program.~~

~~Section 16. Trophies. A fair shall provide a trophy or blanket to the winner of a race. If a race is contested in heats or divisions, the trophy shall be presented to the winner of the fastest heat or division.~~

~~Section 17. Early Deadlines. The deadline for entries at a fair shall be set by the Kentucky Colt Racing Association at its annual October meeting preceding the racing year.~~

~~Section 18. Programs. A county fair track holding races for purses shall provide a printed program available to the public containing the following information:~~

~~(1) For non pari-mutuel tracks:~~

~~(a) Horse's name and sex;~~

~~(b) Color and age of horse;~~

~~(c) Sire and dam of horse;~~

~~(d) Owner's name;~~

~~(e) Driver's name and colors;~~

~~(f) Trainer's name; and~~

~~(g) Summary of starts in purse races, earnings, and the best win time for the current and preceding year, which may be earned in either a purse or nonpurse race; and~~

~~(2) For pari-mutuel tracks:~~

~~(a) All of the program information required by subsection (1) of this section;~~

~~(b) At least the last six (6) performance and accurate chart lines. An accurate chart line shall include:~~

~~1. Date of race;~~

~~2. Location of race;~~

~~3. Size of track if other than a one-half (1/2) mile track;~~

~~4. Symbol for free-legged pacers;~~

~~5. Track condition;~~

~~6. Type of race;~~

~~7. Distance;~~

~~8. The fractional times of the leading horse including race times;~~

~~9. Post position;~~

~~10. Position of the one-quarter (1/4) marker, the one-half (1/2) marker, and the three-quarters (3/4) marker;~~

~~11. Stretch with lengths behind leader;~~

~~12. Finish with lengths behind leader;~~

~~13. Individual time of the horse;~~

~~14. Closing dollar odds;~~

~~15. Name of the driver;~~

~~16. Names of the horses that placed first, second, and third by the judges; and~~

~~17. Standard symbols for breaks and park-outs, if applicable;~~

~~(c) Indicate drivers racing with a provisional license; and~~

~~(d) Indicate pacers that are racing without hobbles.~~

~~Section 19. Payments. Nomination and sustaining payments shall be made to the Kentucky Colt Racing Association. Entry fees shall be paid to the fair for which the entry is taken.~~]

Section 7[~~20~~]. Violations. A person or association that violates a provision of this administrative regulation shall be subject to the penalties ***established[~~set forth~~]*** in 810 KAR 8:030, Section ***10[~~1~~]***[~~10~~].

CONTACT PERSON: Jennifer Wolsing, General Counsel, Kentucky Horse Racing Commission, 4063 Iron Works Parkway, Building B, Lexington, Kentucky 40511, phone (859) 246-2040, fax (859) 246-2039, email jennifer.wolsing@ky.gov.

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Chairman

June 3, 2021

VIA ELECTRONIC MAIL
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: 810 KAR 8:010. Medication; testing procedures; prohibited practices.
810 KAR 8:025. Drug, medication, and substance withdrawal guidelines.
810 KAR 8:030. Disciplinary measures and penalties.
810 KAR 8:040. Out-of-competition testing.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 810 KAR 8:010, 810 KAR 8:025, 810 KAR 8:030, and 810 KAR 8040, the Kentucky Horse Racing Commission proposes the attached suggested substitutes to 810 KAR 8:010, 810 KAR 8:025, 810 KAR 8:030, and 810 KAR 8:040.

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

Jennifer Wolsing
General Counsel

TEAM KENTUCKY

Version: 6/2/21

SUGGESTED SUBSTITUTE

PUBLIC PROTECTION CABINET
Kentucky Horse Racing Commission

810 KAR 8:010. Medication; testing procedures; prohibited practices.

RELATES TO: KRS 230.215, 230.225, 230.240, 230.260, 230.265, 230.290, 230.320, 230.370
STATUTORY AUTHORITY: KRS 230.215(2), 230.225, 230.240(2), 230.260(8), 230.320, 230.370
NECESSITY, FUNCTION, AND CONFORMITY: KRS 230.215(2), 230.260(8), and 230.320 authorize the Kentucky Horse Racing Commission to promulgate administrative regulations prescribing conditions under which all legitimate horse racing and wagering thereon is conducted in Kentucky. KRS 230.240(2) requires the commission to promulgate administrative regulations restricting or prohibiting the administration of drugs or stimulants or other improper acts to horses prior to the horse participating in a race. This administrative regulation establishes requirements and controls in the administration of drugs, medications, and substances to horses, governs certain prohibited practices, and establishes trainer responsibilities relating to the health and fitness of horses.

Section 1. Definitions.
(1) "AAS" or "anabolic steroid" means an anabolic androgenic steroid.
(2) "Administer" means to apply to or cause the introduction of a substance into the body of a horse.
(3) "Commission laboratory" means a laboratory chosen by the commission to test biologic specimens from horses taken under the supervision of the commission veterinarian.
(4) "Location under the jurisdiction of the commission" means a licensed race track or a training center as described in KRS 230.260(5).
(5) "Positive finding" means the commission laboratory has conducted testing and determined that a drug, medication, or substance, the use of which is restricted or prohibited by this administrative regulation, 810 KAR 8:020, 810 KAR 8:025, or 810 KAR 8:040, was present in the sample.
(a) For the drugs, medications, or substances listed in this administrative regulation, [~~or~~] 810 KAR 8:020, or 810 KAR 8:025, for which an established concentration level is provided, it shall be necessary to have a finding in excess of the established concentration level as provided for the finding to be considered a positive finding.
(b) Positive finding also includes:
1. Substances present in the horse in excess of concentrations at which the substances could occur naturally; and
2. Substances foreign to a horse that cause interference with testing procedures.
(6) "Primary sample" means the primary sample portion of the biologic specimen taken under the supervision of the commission veterinarian to be tested by the commission laboratory.
(7) "Split sample" means the split sample portion of the biologic specimen taken under the supervision of the commission veterinarian to be tested by the split sample laboratory.
(8) "Split sample laboratory" means the laboratory approved by the commission to test the split sample portion of the biologic specimen from horses taken under the supervision of the commission veterinarian.
(9) "Test barn" means a fenced enclosure sufficient in size and facilities to accommodate the stabling of horses temporarily detained for obtaining biologic specimens for testing.

Section 2. Use of Medication.

(1) Therapeutic measures and medication necessary to improve or protect the health of a horse shall be administered to a horse in training under the direction of a licensed veterinarian.

(2) Except as expressly permitted in 810 KAR Chapter 8, while participating in a race (betting or non-betting), qualifying race, or time trial, it shall be a violation for a horse to carry in its body any drug, medication, substance, or metabolic derivative, that:

(a) Is foreign to the horse; or

(b) Might mask the presence of a prohibited drug, or obstruct testing procedures.

(3) It shall be a violation for therapeutic medications to be present in excess of established threshold concentrations established in this administrative regulation, [~~or in~~] 810 KAR 8:020, or in 810 KAR 8:025. The thresholds for permitted NSAIDs are established in Section 8 of this administrative regulation.

(4) Except as provided by paragraphs (a), (b), and (c) of this subsection, it shall be a violation for a substance to be present in a horse in excess of a concentration at which the substance could occur naturally. It shall be the responsibility of the commission to prove that the substance was in excess of normal concentration levels.

(a) Gamma amino butyric acid shall not be present in a concentration greater than 110 nanograms per milliliter in serum or plasma.

(b) Cobalt shall not be present in a concentration greater than twenty-five (25) parts per billion in serum or plasma.

(c) Free prednisolone shall not be present in a concentration greater than ten (10) nanograms per milliliter in urine.

(5) It shall be prima facie evidence that a horse was administered and carried, while running in a race (betting or non-betting), qualifying race, or time trial, a drug, medication, substance, or metabolic derivative thereof prohibited by this section if:

(a) A biologic specimen from the horse was taken under the supervision of the commission veterinarian promptly after a horse ran in a race (betting or non-betting), qualifying race, or time trial; and

(b) The commission laboratory presents to the commission a report of a positive finding.

(6) The commission shall utilize the Kentucky Horse Racing Commission Uniform Drug, Medication, and Substance Classification Schedule as provided in 810 KAR 8:020, for classification of drugs, medications, and substances violating this administrative regulation. Penalties for violations of this administrative regulation shall be implemented in accordance with 810 KAR 8:030.

Section 3. Treatment Restrictions.

(1) Except as provided in Section 4 of this administrative regulation, only a veterinarian licensed to practice veterinary medicine in Kentucky and licensed by the commission shall administer by injection a prescription or controlled drug, medication, or other substance to a horse at a location under the jurisdiction of the commission.

(2) The only injectable substance allowed within twenty-four (24) hours prior to post time of the race in which the horse is entered shall be furosemide, as established in Section 6 of this administrative regulation.

(3) Except as provided by subsection (5) of this section, only a veterinarian licensed to practice veterinary medicine in Kentucky and licensed by the commission may possess a hypodermic needle, syringe, or injectable of any kind at a location under the jurisdiction of the commission.

(4) A veterinarian licensed to practice veterinary medicine in Kentucky and licensed by the commission shall use only single-use disposable needles and syringes, and shall dispose of them in a container approved by the commission veterinarian.

(5) If a person regulated by the commission has a medical condition that makes it necessary

to possess a needle and syringe at a location under the jurisdiction of the commission, the person shall request prior permission from the stewards or judges and furnish a letter from a licensed physician explaining why it is necessary for the person to possess a needle and syringe. The stewards or judges may grant approval for a person to possess and use a needle and syringe at a location under the jurisdiction of the commission, but may also establish necessary restrictions and limitations.

(6) A commission employee may accompany a veterinarian at a location under the jurisdiction of the commission and take possession of a syringe, needle, or other device used to administer a substance to a horse.

(7) Electronic therapeutic treatments, other than nebulization, shall not be administered to a horse within twenty-four (24) hours prior to post time of a race in which the horse is entered.

Section 4. Certain Permitted Substances. Liniments, antiseptics, antibiotics, ointments, leg paints, washes, and other products commonly used in the daily care of horses may be administered by a person, other than a licensed veterinarian if:

(1) The treatment does not include any drug, medication, or substance otherwise prohibited by this administrative regulation;

(2) The treatment is not injected; and

(3) The person is acting under the direction of a licensed trainer or veterinarian licensed to practice veterinary medicine in Kentucky and licensed by the commission.

Section 5. Anti-ulcer Medications.

The following anti-ulcer medications may be administered orally, at the dosage stated in this section, up to twenty-four (24) hours prior to post time of the race in which the horse is entered:

(1) Cimetidine (Tagamet): eight (8) to twenty (20) milligrams per kilogram;

(2) Omeprazole (Gastrogard): two and two-tenths (2.2) grams;

(3) Ranitidine (Zantac): eight (8) milligrams per kilogram; and

(4) Sucralfate: two (2) to four (4) grams.

Section 6. Furosemide Use on Race Day.

(1) Furosemide may be administered, in accordance with this section, to a horse that is entered to compete in a race, qualifying race, or time trial, except as provided in subsection (6) of this section.

(2) Furosemide shall only be administered prior to a race, qualifying race, or time trial by:

(a) The commission veterinarian; or

(b) A licensed veterinarian approved by the commission to perform the administration if the commission veterinarian is unavailable. If the furosemide is administered by an approved licensed veterinarian, the administering veterinarian shall provide a written report to the commission veterinarian no later than two (2) hours prior to post time of the race in which the horse receiving the furosemide is competing.

(3) Except as provided in subsection (6) of this section, furosemide may be used if administered:

(a) At a location under the jurisdiction of the commission where the horse is scheduled to race;

(b) By a single intravenous injection, not less than four (4) hours prior to post time for the race, qualifying race, or time trial in which the horse is entered; and

(c) In a dosage not less than 150 milligrams and not more than 500 milligrams.

(4) The specific gravity of a post-race urine sample shall not be below one and one one-hundredths (1.010). If the specific gravity of the post-race urine sample is determined to be below one and one one-hundredths (1.010), a quantification of furosemide in serum or plasma shall be performed by the commission laboratory. If a horse fails to produce a urine specimen, the commission laboratory shall perform a quantification of furosemide in the serum or plasma

sample. Concentrations above 100 nanograms of furosemide per milliliter of serum or plasma shall constitute a violation of this section.

(5) The initial cost of administering the furosemide shall be twenty (20) dollars per administration. The commission shall monitor the costs associated with administering furosemide and consult with industry representatives to determine if the cost should be lowered based on prevailing veterinarian services and supplies. The commission shall maintain records documenting the basis for its determination, and if the cost is determined to be less than twenty (20) dollars per administration, then the commission shall lower the cost accordingly. The cost shall be prominently posted in the racing office.

(6)(a) A two (2) year old or stakes horse shall not be administered any drug, medication or other substance, including furosemide, within twenty-four (24) hours of the post time of the race in which the horse is entered. Participation by the horse shall not affect the status of the participating horse on the official authorized bleeder medication list.

(b) The implementation and enforcement of the prohibition in paragraph (a) of this subsection shall begin on:

1. January 1, 2020 for all two (2) year olds; and

2. January 1, 2021 for all horses entered to run in a stakes race; including the races comprising the Breeders' Cup World Championships and the races designated as graded stakes by the American Graded Stakes Committee of the Thoroughbred Owners and Breeders Association.

(c) A concentration of furosemide greater than one and zero-tenths (1.0) nanograms per milliliter in serum in a post-race sample shall constitute a violation of this administrative regulation.

Section 7. Furosemide Eligibility.

(1)(a) Except as provided in Section 6(6) of this administrative regulation, a horse shall be eligible to race with furosemide if the licensed trainer or a licensed veterinarian determines that it would be in the horse's best interests to race with furosemide. Notice that a horse eligible to receive furosemide will race with or without furosemide shall be made at the time of entry to ensure public notification, including publication in the official racing program.

(b) It shall constitute a violation of this administrative regulation if notice is made pursuant to this section that a horse will race with furosemide, and the post-race urine, serum, or plasma does not show a detectable concentration of furosemide in the post-race urine, serum, or plasma.

(2) After a horse has been determined to no longer be required to receive furosemide, the horse shall not be eligible to receive furosemide unless the licensed trainer or a licensed veterinarian determines that it would be in the horse's best interest to race with furosemide and the licensed trainer or a licensed veterinarian complies with the requirements of this section.

Section 8. Permitted Non-steroidal Anti-inflammatory Drugs (NSAIDs).

(1) NSAIDs shall not be administered within forty-eight (48) hours prior to post time for the race in which the horse is entered. The detection in a post-race sample of blood of a detectable concentration of an NSAID, except as allowed by subsection (2) of this section, shall constitute a violation of this administrative regulation. The detection in a post-race sample of blood of more than one (1) of phenylbutazone, flunixin, and ketoprofen in excess of the concentrations permitted by subsection (2) of this section shall constitute a violation of this administrative regulation.

(2)(a) A finding of phenylbutazone below a concentration of three-tenths (0.3) microgram per milliliter of serum or plasma shall not constitute a violation of this section.

(b) A finding of flunixin below a concentration of five (5) nanograms per milliliter of serum or plasma shall not constitute a violation of this section.

(c) A finding of ketoprofen below a concentration of two (2) nanograms per milliliter of serum or plasma shall not constitute a violation of this section.

Section 9. Anabolic Steroids.

(1) An exogenous AAS shall not be present in a horse that is racing. The detection of an exogenous AAS or metabolic derivative in a post-race sample shall constitute a violation of this administrative regulation.

(2) The detection in a post-race sample of an endogenous AAS or metabolic derivative where the concentration of the AAS or metabolic derivative exceeds naturally occurring physiological levels shall constitute a violation of this administrative regulation. The following shall be deemed to be naturally occurring physiological levels:

(a) Boldenone:

1. In male horses other than geldings, free and conjugated boldenone fifteen (15) nanograms per milliliter in urine or free boldenone twenty-five (25) picograms per millliliter in serum or plasma; and

2. In geldings and female horses, free and conjugated boldenone one (1) nanogram per milliliter in urine or free boldenone twenty-five (25) picograms per milliliter in serum or plasma.

(b) Nandrolone:

1. In geldings, free and conjugated nandrolone one (1) nanogram per milliliter in urine or free nandrolone twenty-five (25) picograms per milliliter in serum or plasma;

2. In fillies and mares, free and conjugated nandrolone one (1) nanogram per milliliter in urine or free nandrolone twenty-five (25) picograms per milliliter in serum or plasma; and

3. In male horses other than geldings, forty-five (45) nanograms per milliliter of metabolite, 5α-estrane-313, 17α-diol in urine or a ratio in urine of 5α-estrane-313, 17α-diol to 5α-estrene-313, 17α-diol of >1:1.

(c) Testosterone:

1. In geldings, free and conjugated testosterone twenty (20) nanograms per milliliter in urine or free testosterone one hundred (100) picograms per milliliter in serum or plasma; and

2. In fillies and mares (unless in foal), free and conjugated testosterone fifty-five (55) nanograms per milliliter in urine or free testosterone one hundred (100) picograms per milliliter in serum or plasma.

(3) The gender of the horse from which a post-race biologic specimen is collected shall be identified to the commission veterinarian and the testing laboratory.

Section 10. Clenbuterol.

(1) Clenbuterol use ***shall be[~~is~~]*** prohibited in racing and training unless the ***[~~following~~]*** conditions ***established by this subsection*** are met.***[:]***

(a) The prescription for clenbuterol ***shall be[~~is~~]*** made for a specific horse based upon a specific diagnosis.

(b) The veterinarian ***shall[~~must~~]*** provide a copy of the treatment sheet to the Equine Medical Director or his or her designee for review within twenty-four (24) hours of any administration of clenbuterol.

(c) A horse administered clenbuterol shall be placed on the veterinarian's list for a minimum of twenty-one (21) days after the date of last administration. The horse ***shall[~~must~~]*** meet all conditions for removal from the list, including blood and urine sampling taken after the twenty-one (21) day period. Both samples ***shall[~~must~~]*** have no detectable clenbuterol.

(2)[~~(d)~~] A horse shall not be eligible to race until it has completed all the requirements in ***subsection (1)(c) of this section[~~paragraph (c) of this subsection~~].***

(3)[~~(2)~~] If clenbuterol is detected in a horse's post-race or out of competition sample and appropriate notification as ***established in subsection (1)(b) of this section[~~outlined above~~]*** was not completed, the horse shall immediately be placed on the veterinarian's list pending the outcome of an investigation. The horse shall be required to meet all conditions for removal from the veterinarian's list ***as established[~~outlined~~]*** in ***subsection (1)(c) of this section [~~paragraph (c) of this subsection~~].***

Section 11. Test Barn.

(1) A licensed association shall provide and maintain a test barn on association grounds.

(2) The test barn shall be a fenced enclosure sufficient:

(a) In size and facilities to accommodate the stabling of horses temporarily detained for the taking of biologic specimens; and

(b) In structural design to prevent entry by unauthorized persons.

(3) The test barn shall be under the supervision and control of the Chief Racing Veterinarian or his or her designee, and no access to individuals other than commission personnel shall be permitted unless with the permission of the Chief Racing Veterinarian or his or her designee. If association personnel require immediate access to the test barn due to fire or other emergency, the association shall report the access to commission officials as soon as possible after the emergency.

Section 12[~~11~~]. Sample Collection, Testing and Reporting.

(1) Sample collection shall be done in accordance with the procedures provided in this administrative regulation, 810 KAR 8:060, and under the instructions provided by the commission veterinarian.

(2) The commission veterinarian, in consultation with the commission laboratory shall determine a minimum sample requirement which shall be uniform for each horse and which shall be separated into primary and split samples.

(3) An owner or trainer may request that a split sample be tested by a split sample laboratory approved by the commission.

(4) The cost of testing under subsection (3) of this section, including shipping, shall be borne by the owner or trainer requesting the test.

(5)(a) Stable equipment other than that necessary for washing and cooling out a horse shall not be permitted in the test barn.

(b) Buckets and water shall be furnished by the commission veterinarian.

(c) If a body brace is to be used on a horse, it shall:

1. Be supplied by the trainer; and

2. Applied only with the permission and in the presence of the commission veterinarian or his designee.

(d) A licensed veterinarian may attend to a horse in the test barn only with the permission of and in the presence of the commission veterinarian or his designee.

(6) Within five (5) business days of receipt of notification by the commission laboratory of a positive finding, the stewards and judges shall notify the owner and trainer orally or in writing of the positive finding.

(7) The stewards or judges shall conduct a hearing as soon as possible after the conclusion of an investigation of a positive finding. A person charged with a violation may request a continuance, which the stewards or the judges may grant for good cause shown.

Section 13[~~12~~]. Storage and Shipment of Split Samples.

(1) Split samples shall be secured and made available for further testing in accordance with the procedures established in this subsection.*[:]*

(a) Split samples shall be secured in the test barn in the same manner as the primary samples for shipment to the commission laboratory, as established in Section 12[~~11~~] of this administrative regulation, until the primary samples are packed and secured for shipment to the commission laboratory. Split samples shall then be transferred to a freezer or refrigerator at a secure location approved and chosen by the commission.

(b) A freezer or refrigerator for storage of split samples shall be equipped with a lock. The lock shall be secured to prevent access to the freezer or refrigerator at all times except as specifically provided by paragraph (c) of this subsection.

(c) A freezer or refrigerator for storage of split samples shall be opened only for depositing or removing split samples, for inventory, or for checking the condition of samples.

(d) A log shall be maintained by the commission veterinarian that shall be used each time a split sample freezer or refrigerator is opened to specify each person in attendance, the purpose for opening the freezer or refrigerator, identification of split samples deposited or removed, the date and time the freezer or refrigerator was opened, the time the freezer or refrigerator was closed, and verification that the lock was secured prior to and after opening of the freezer or refrigerator. A commission veterinarian or his designee shall be present when the freezer or refrigerator is opened.

(e) Evidence of a malfunction of a split sample freezer or refrigerator shall be documented in the log.

(f) The commission shall be considered the owner of a split sample.

(2)(a) A trainer or owner of a horse receiving notice of a positive finding may request that a split sample corresponding to the portion of the sample tested by the commission laboratory be sent to the split sample laboratory. The party requesting the split sample shall select a laboratory solicited and approved by the commission to perform the analysis.

(b) The request shall be made in writing and delivered to the stewards or judges within three (3) business days after the trainer or owner of the horse receives oral or written notice of the positive finding by the commission laboratory.

(c) A split sample so requested shall be shipped as expeditiously as possible.

(3)(a) The owner or trainer requesting testing of a split sample shall be responsible for the cost of the testing, including the cost of shipping.

(b) Failure of the owner, trainer, or a designee to appear at the time and place designated by the commission veterinarian in connection with securing, maintaining, or shipping the split sample shall constitute a waiver of any right to be present during split sample testing procedures.

(c) Prior to shipment of the split sample, the commission shall confirm:

1. That the split sample laboratory has agreed to provide the testing requested;
2. That the split sample laboratory has agreed to send results to the commission; and
3. That arrangements for payment satisfactory to the split sample laboratory have been made.

Section 14[~~13~~]. Split Sample Chain of Custody.

(1) Prior to opening the split sample freezer or refrigerator, the commission shall provide a split sample chain of custody verification form. The form to be used shall be the Split Sample Chain of Custody Form. The form shall be fully completed during the retrieval, packaging, and shipment of the split sample and shall contain the following information:

(a) The date and time the sample is removed from the split sample freezer or refrigerator;

(b) The sample number; and

(c) The address where the split sample is to be sent.

(2) A split sample shall be removed from the split sample freezer or refrigerator by a commission employee after notice to the owner, trainer, or designee thereof and a commission-designated representative shall pack the split sample for shipment in accordance with the packaging procedures directed by the commission. The Split Sample Chain of Custody Form shall be signed by both the owner's representative, if present, and the commission representative to confirm the proper packaging of the split sample for shipment. The exterior of the package shall be secured and sealed to prevent tampering with the package.

(3) The owner, trainer, or designee, if present, may inspect the package containing the split sample immediately prior to transfer to the delivery carrier to verify that the package is intact and has not been tampered with.

(4) The Split Sample Chain of Custody Form shall be completed and signed by the representative of the commission and the owner, trainer, or designee, if present.

(5) The commission representative shall retain the original Split Sample Chain of Custody Form

and provide a copy to the owner, trainer, or designee, if requested.

Section 15[~~14~~]. Medical Labeling.

(1) A drug or medication that, by federal or state law, requires a prescription shall not be used or kept on association grounds unless validly prescribed by a duly licensed veterinarian.

(2) A drug or medication shall bear a prescription label that is securely attached and clearly ascribed to show the following:

(a) The name of the product;

(b) The name, address, and telephone number of the veterinarian prescribing or dispensing the product;

(c) The name of the horse for which the product is intended or prescribed;

(d) The dosage, duration of treatment, and expiration date of the prescribed or dispensed product; and

(e) The name of the trainer to whom the product was dispensed.

Section 16[~~15~~]. Trainer Responsibility.

(1) In the absence of substantial evidence to the contrary, a trainer shall be responsible for the condition of a horse in his or her care.

(2) In the absence of substantial evidence to the contrary, a trainer shall be responsible for the presence of a prohibited drug, medication, substance, or metabolic derivative, including permitted medication in excess of the maximum allowable concentration, in a horse in his or her care.

(3) A trainer shall prevent the administration of a drug, medication, substance, or metabolic derivative that may constitute a violation of this administrative regulation.

(4) A trainer whose horse has been claimed shall remain responsible for a violation of this administrative regulation regarding that horse's participation in the race in which the horse is claimed.

(5) A trainer shall be responsible for:

(a) Maintaining the assigned stable area in a clean, neat, and sanitary condition at all times;

(b) Using the services of those veterinarians licensed by the commission to attend to horses that are on association grounds;

(c) The proper identity, custody, care, health, condition, and safety of horses in his or her care;

(d) Promptly reporting the alteration of the sex of a horse to the horse identifier and the racing secretary;

(e) Promptly reporting to the racing secretary and the commission veterinarian if a posterior digital neurectomy (heel nerving) is performed on a horse in his or her care and ensuring this fact is designated on its certificate of registration;

(f) Promptly reporting to the racing secretary the name of a mare in his or her care that has been bred and is entered to race;

(g) Promptly notifying the commission veterinarian of a reportable disease or communicable illness in a horse in his or her care;

(h) Promptly reporting the serious injury or death of a horse in his or her care at a location under the jurisdiction of the commission to the stewards or judges and the commission veterinarian and ensuring compliance with Section 23[~~22~~] of this administrative regulation and 810 KAR 4:010, Section 14, governing postmortem examinations;

(i) Complying with the medication and recordkeeping requirements in subsection (6) of this section;

(j) Promptly notifying the stewards or judges and the commission veterinarian if the trainer has knowledge or reason to believe that there has been an administration to a horse of a drug, medication, or other substance prohibited by this administrative regulation or has knowledge or reason to believe that a prohibited practice has occurred as established in Section 21[~~20~~] of this administrative regulation;

(k) Ensuring the fitness of every horse in his or her care to perform creditably at the distance entered;

(l) Ensuring that every horse he or she has entered to race is present at its assigned stall for a pre-race soundness inspection as prescribed by 810 KAR 2:010, Section 4(1)(l);

(m) Ensuring proper bandages, equipment, and shoes;

(n) Ensuring the horse's presence in the paddock at the time prescribed by racing officials before the race in which the horse is entered;

(o) Personally attending in the paddock and supervising the saddling or preparation of a horse in his or her care, unless an assistant trainer fulfills these duties or the trainer is excused by the judges or stewards pursuant to 810 KAR 4:100, Section 3(2)(f); and

(p) Attending the collection of a biologic specimen taken from a horse in his or her care or delegating a licensed employee or the owner to do so.

(6)(a) A trainer shall maintain a clear and accurate record of any treatment administered to a horse in his or her care.

(b) A trainer shall ensure the transfer of copies of all medical records to the subsequent owner and trainer of a horse.

(c) Failure to comply with this subsection may result in the imposition of penalties pursuant to 810 KAR 8:030.

(d) The stewards and judges may at any time require presentation of a horse's medical records.

Section 17[~~16~~]. Licensed Veterinarians.

(1) A veterinarian licensed by the commission and practicing at a location under the jurisdiction of the commission shall be considered under the supervision of the commission veterinarian and the stewards or judges.

(2) A veterinarian shall report to the stewards, judges or the commission veterinarian a violation of this administrative regulation by a licensee.

Section 18[~~17~~]. Veterinary Reports.

(1) A veterinarian who treats a horse at a location under the jurisdiction of the commission shall submit a Veterinary Report of Horses Treated to be Submitted Daily form to the commission veterinarian containing the following information:

(a) The name of the horse treated;

(b) The type and dosage of drug or medication administered or prescribed;

(c) The name of the trainer of the horse;

(d) The date and time of treatment; and

(e) Other pertinent treatment information requested by the commission veterinarian.

(2) The Veterinary Report of Horses Treated to be Submitted Daily form shall be signed by the treating practicing veterinarian.

(3) The Veterinary Report of Horses Treated to be Submitted Daily form shall be on file not later than the time prescribed on the next race day by the commission veterinarian.

(4) The Veterinary Report of Horses Treated to be Submitted Daily form shall be confidential, and its content shall not be disclosed except in the course of an investigation of a possible violation of this administrative regulation or in a proceeding before the stewards, judges or the commission, or to the trainer or owner of record at the time of treatment.

(5) A timely and accurate filing of a Veterinary Report of Horses Treated to be Submitted Daily form by the veterinarian or his designee that is consistent with the analytical results of a positive test reported by the commission laboratory may be used as a mitigating factor in determining the appropriate penalties pursuant to 810 KAR 8:030.

(6) A veterinarian having knowledge or reason to believe that a horse entered in a race has received a drug, medication, or substance prohibited under this administrative regulation or has knowledge or reason to believe that a prohibited practice has occurred as established in Section

21[~~20~~] of this administrative regulation shall report this fact immediately to the commission veterinarian or to the stewards or judges.

(7) A practicing veterinarian shall maintain records of all horses treated and of all medications sold or dispensed. The records shall include:

(a) The name of the horse;

(b) The trainer of the horse;

(c) The date, time, amount, and type of medication administered;

(d) The drug or compound administered;

(e) The method of administration; and

(f) The diagnosis.

(8) The records shall be retained for at least sixty (60) days after the horse has raced and shall be available for inspection by the commission.

Section 19[~~18~~]. Veterinarian's List.

(1) The commission veterinarian shall maintain a list of horses determined to be unfit to compete in a race due to illness, physical distress, unsoundness, infirmity, or other medical condition.

(2) A horse may be removed from the veterinarian's list when, in the opinion of the commission veterinarian, the horse is capable of competing in a race.

(3) The commission shall maintain a bleeder list of all horses that have demonstrated external evidence of exercise-induced pulmonary hemorrhage during or after a race or workout as observed by the commission veterinarian.

(4) Every horse that is a confirmed bleeder, regardless of age, shall be placed on the bleeder list and be ineligible to participate in a race (betting or non-betting), qualifying race, time trial, or for the following time periods:

(a) First incident - fourteen (14) days;

(b) Second incident within a 365-day period - thirty (30) days;

(c) Third incident within a 365-day period - 180 days; and

(d) Fourth incident within a 365-day period - barred from racing for life.

(5) For the purpose of counting the number of days a horse is ineligible to run, the day after the horse bled externally shall be the first day of the recovery period.

(6) The voluntary administration of furosemide without an external bleeding incident shall not subject a horse to the initial period of ineligibility as established in this section.

Section 20[~~19~~]. Distribution of Purses, Barn Searches, and Retention of Samples.

(1)[~~(7)~~] For all races, purse money in thoroughbred and other flat racing shall be paid or distributed pursuant to the process provided in 810 KAR 2:070, Section 27(3), and in standardbred racing, no later than twenty-four (24) hours after notice from the commission that a final laboratory report has been issued.

(2)[~~(8)~~] The distribution of purse money prior to the issuance of a final laboratory report shall not be considered a finding that no prohibited drug, medication, substance, or metabolic derivative has been administered to a horse.

(3)[~~(9)~~] After the commission laboratory issues a positive finding the executive director of the commission or the stewards or judges may authorize and execute an investigation into the circumstances surrounding the incident that is the subject of the positive finding.

(4)[~~(10)~~] If the purse money has been distributed, the stewards or judges shall order the money returned immediately to the association upon notification from the commission laboratory that a prohibited drug, medication, substance, or metabolic derivative was administered to a horse eligible for purse money.

(5)[~~(11)~~] At the conclusion of testing by the commission laboratory and split sample laboratory, the remaining portion of the samples at the commission laboratory and split samples remaining

at the test barn may be retained at a proper temperature at a secure facility approved and chosen by the commission. If a report indicating a positive finding has been issued, the commission shall use its best reasonable efforts to retain any remaining portion of the sample until legal proceedings have concluded. The commission may freeze samples.

Section 21[~~20~~]. Other Prohibited Practices Constituting a Violation of this Administrative Regulation.

(1) A drug, medication, substance, or device shall not be possessed or used by a licensee, or his designee or agent, within a nonpublic area at a location under the jurisdiction of the commission:

(a) The use of which may endanger the health and welfare of the horse; or

(b) The use of which may endanger the safety of the rider or driver.

(2) Without the prior permission of the commission or its designee, a drug, medication, or substance that has never been approved by the United States Food and Drug Administration (USFDA) for use in humans or animals shall not be possessed or used at a location under the jurisdiction of the commission. The commission shall determine whether to grant prior permission after consultation with the Equine Drug Research Council.

(3) The following blood-doping agents shall not be possessed or used at a location under the jurisdiction of the commission:

(a) Erythropoietin;

(b) Darbepoietin;

(c) Oxyglobin;

(d) Hemopure; or

(e) Any substance that abnormally enhances the oxygenation of body tissue.

(4) A treatment, procedure, or therapy shall not be practiced, administered, or applied that may:

(a) Endanger the health or welfare of a horse; or

(b) Endanger the safety of a rider or driver.

(5) Extracorporeal Shock Wave Therapy or Radial Pulse Wave Therapy shall not be used unless the conditions established in this subsection are met.

(a) A treated horse shall not race for a minimum of ten (10) days following treatment.

(b) A veterinarian licensed to practice by the commission shall administer the treatment.

(c) The commission veterinarian shall be notified prior to the delivery of the machine on association grounds.

(d) Prior to administering the treatment, a report shall be submitted by the veterinarian administering the treatment to the commission veterinarian on the Veterinary Report of Horses Treated with Extracorporeal Shock Wave Therapy or Radial Pulse Wave Therapy.

(6) Other than furosemide, an alkalizing substance that could alter the serum or plasma pH or concentration of bicarbonates or carbon dioxide in a horse shall not be used within twenty-four (24) hours prior to post time of the race in which the horse is entered.

(7) Without the prior permission of the commission veterinarian or his designee, based on standard veterinary practice for recognized conditions, a nasogastric tube which is longer than six (6) inches shall not be used for the administration of any substance within twenty-four (24) hours prior to post time of the race in which the horse is entered.

(8) A serum or plasma total carbon dioxide (TCO2) level shall not exceed thirty-seven (37.0) millimoles per liter; except, a violation shall not exist if the TCO2 level is found to be normal for the horse following the quarantine procedure established in Section 22[~~21~~] of this administrative regulation.

(9) A blood gas machine shall not be possessed or used by a person other than an authorized representative of the commission at a location under the jurisdiction of the commission.

(10) A shock wave therapy machine or radial pulse wave therapy machine shall not be

possessed or used by anyone other than a veterinarian licensed by the commission at a location under the jurisdiction of the commission.

Section 22[~~21~~]. TCO2 Testing and Procedures.

(1)(a) The stewards, judges, or commission veterinarian may order the pre-race or post-race collection of blood specimens from a horse to determine the total carbon dioxide concentration in the serum or plasma of the horse. The winning horse and other horses, as selected by the stewards or judges, may be tested in each race to determine if there has been a violation of this administrative regulation.

(b) Pre-race sampling shall be done at a reasonable time, place, and manner directed by the chief state steward in consultation with the commission veterinarian.

(c) A specimen consisting of at least two (2) blood tubes shall be taken from a horse to determine the TCO2 concentration in the serum or plasma of the horse. If the commission laboratory determines that the TCO2 level exceeds thirty-seven (37.0) millimoles per liter plus the laboratory's measurement of uncertainty, the executive director of the commission shall be informed of the positive finding.

(d) Split sample testing for TCO2 may be requested by an owner or trainer in advance of the collection of the specimen by the commission veterinarian; however, the collection and testing of a split sample for TCO2 testing shall be done at a reasonable time, place, and manner directed by the commission veterinarian.

(e) The cost of split sample testing, including the cost of shipping, shall be borne by the owner or the trainer.

(2)(a) If the level of TCO2 is determined to exceed thirty-seven (37.0) millimoles per liter plus the laboratory's measurement of uncertainty and the licensed owner or trainer of the horse certifies in writing to the stewards or judges within twenty-four (24) hours after the notification of the test result that the level is normal for that horse, the owner or trainer may request that the horse be held in quarantine. If quarantine is requested, the licensed association shall make guarded quarantine available for that horse for a period of time to be determined by the steward or judges, but in no event for more than seventy-two (72) hours.

(b) The expense for maintaining the quarantine shall be borne by the owner or trainer.

(c) During quarantine, the horse shall be retested periodically by the commission veterinarian.

(d) The horse shall not be permitted to race during a quarantine period, but it may be exercised and trained at times prescribed by the licensed association and in a manner that allows monitoring of the horse by a commission representative.

(e) During quarantine, the horse shall be fed only hay, oats, and water.

(f) If the commission veterinarian is satisfied that the horse's level of TCO2, as registered in the original test, is physiologically normal for that horse, the stewards or judges:

1. Shall permit the horse to race; and

2. May require repetition of the quarantine procedure established in paragraphs (a) through (f) of this subsection to reestablish that the horse's TCO2 level is physiologically normal.

Section 23[~~22~~]. Postmortem Examination.

(1) A horse that dies or is euthanized on the grounds of a licensed association or training center under the jurisdiction of the commission shall undergo a postmortem examination at the discretion of the commission and at a facility designated by the commission, through its designee, as provided in 810 KAR 4:010, Section 14.

(2) The commission shall bear the cost of an autopsy that is required by the commission.

(3) The presence of a prohibited drug, medication, substance, or metabolic derivative thereof in a specimen collected during the postmortem examination of a horse may constitute a violation of this administrative regulation.

Section 24[~~23~~]. Corticosteroids.

(1) A corticosteroid shall not be administered intra-articularly within fourteen (14) days before post time for the race in which the horse is entered.

(2) The presence of a detectable concentration of more than one (1) corticosteroid in a post-race sample of blood, urine, or any combination of blood and urine shall constitute a violation of this section.

Section 25[~~24~~]. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Veterinary Report of Horses Treated to be Submitted Daily", KHRC 8-010-1, 11/2018;

(b) "Split Sample Chain of Custody Form", KHRC 8-010-2, 11/2018; and

(c) "Veterinary Report of Horses Treated with Extracorporeal Shock Wave Therapy or Radial Pulse Wave Therapy", KHRC 8-010-3, 11/2018.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Horse Racing Commission, 4063 Iron Works Parkway, Building B, Lexington, Kentucky 40511, Monday through Friday, 8:00 a.m. to 4:30 p.m. This material is also available on the commission's Web site at ***https://khrc.ky.gov/new_docs.aspx?cat=32*** ***[~~http://khrc.ky.gov~~]***.

CONTACT PERSON: Jennifer Wolsing, General Counsel, Kentucky Horse Racing Commission, 4063 Iron Works Parkway, Building B, Lexington, Kentucky 40511, phone (859) 246-2040, fax (859) 246-2039, email jennifer.wolsing@ky.gov.

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May 28, 2021

Emily Caudill, Regulations Compiler
Legislative Research Commission
029, Capitol Annex
702 Capitol Aven.
Frankfort, KY 40601

Re: 810 KAR 8:025 Agency Amendment

Via Electronic Mail

Dear Ms. Caudill:

The Kentucky Horse Racing Commission hereby withdraws its previously proposed agency amendment to 810 KAR 8:025, which was submitted by letter dated May 25, 2021. In its place, the Commission proposes the attached revised agency amendment. This amendment does not change the substance of how the Commission proposes to treat clenbuterol. Instead, this amendment clarifies 8:025 and brings it into compliance with 810 KAR 8:010 Section 10. 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 8:025. Drug, medication, and substance withdrawal guidelines.

Page 9
Section 1(4)
Line 1
Clenbuterol, Administration Specifications box

After "0.8 mcg/kg orally", insert the following:

Pursuant to 810 KAR 8:010, Section 10, clenbuterol shall be prohibited unless the prescription is made for a specific horse based on a specific diagnosis. The veterinarian shall provide a copy of the treatment sheet to the Equine Medical Director or designee for review within twenty-four (24) hours of administration. A horse administered clenbuterol shall be placed on the veterinarian's list for at least twenty-one (21) days after the last administration. The horse shall meet all conditions for removal from the list, including negative blood and urine sampling.

Andy Beshear
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Deputy Secretary

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Marc Guilfoil
Executive Director

Jonathan Rabinowitz
Chairman

June 3, 2021

VIA ELECTRONIC MAIL
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: 810 KAR 8:010. Medication; testing procedures; prohibited practices.
810 KAR 8:025. Drug, medication, and substance withdrawal guidelines.
810 KAR 8:030. Disciplinary measures and penalties.
810 KAR 8:040. Out-of-competition testing.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 810 KAR 8:010, 810 KAR 8:025, 810 KAR 8:030, and 810 KAR 8040, the Kentucky Horse Racing Commission proposes the attached suggested substitutes to 810 KAR 8:010, 810 KAR 8:025, 810 KAR 8:030, and 810 KAR 8:040.

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

Jennifer Wolsing

Jennifer Wolsing
General Counsel

Version: 6/3/21

SUGGESTED SUBSTITUTE

PUBLIC PROTECTION CABINET
Kentucky Horse Racing Commission

810 KAR 8:025. Drug, medication, and substance withdrawal guidelines.

RELATES TO: KRS 230.215, 230.225, 230.240, 230.260, 230.265, 230.290, 230.320, 230.370

STATUTORY AUTHORITY: KRS 230.215(2), 230.225, 230.240(2), 230.260, 230.320, 230.370

NECESSITY, FUNCTION, AND CONFORMITY: KRS 230.215(2) authorizes the Kentucky Horse Racing Commission ***[(the "commission")]*** to promulgate administrative regulations prescribing conditions under which all legitimate horse racing and wagering thereon is conducted in Kentucky. KRS 230.240(2) requires the commission to promulgate administrative regulations restricting or prohibiting the administration of drugs or stimulants or other improper acts to horses prior to the horse participating in a race. This administrative regulation establishes the withdrawal guidelines for permitted drugs, medications, and substances that may be administered to race horses competing in Kentucky.

Section 1. The Kentucky Horse Racing Commission Withdrawal Guidelines Thoroughbred; Standardbred; Quarter Horse, Appaloosa, and Arabian.

(1) This administrative regulation shall provide certain mandatory treatment requirements, guidance, and advice on medication withdrawal intervals.

(2)(a) These withdrawal guidelines ***shall[do]*** not apply to two (2) year-old or stakes horses pursuant to 810 KAR 8:010, Section 6.

(b) Unless otherwise specified in these withdrawal guidelines, ***KAR*** Title 810 ***[of the Kentucky Administrative Regulations]***, or ***KRS*** Chapter 230 ***[of the Kentucky Revised Statutes]***, the following withdrawal guidelines are voluntary and advisory. The guidelines are recommendations based on current scientific knowledge that may change over time.

(c) A licensee may present evidence of full compliance with these guidelines to the commission and the stewards as a mitigating factor to be used in determining violations and penalties.

(d) These withdrawal interval guidelines assume that administration of medications will be performed at doses that are not greater than the manufacturer's maximum recommended dosage, or the dosage recommended in this document. Medications administered at dosages above manufacturer's recommendations, in compounded formulations, or in combination with other medications or administration inside the withdrawal interval may result in test sample concentrations above threshold concentrations that could lead to positive test results and the imposition of penalties.

(e) The time of administration of an orally administered substance, for the purposes of withdrawal interval, shall be considered to be the time of complete ingestion of the medication by the horse via eating or drinking.

(f) For products containing multiple medications, the withdrawal time to be used should be no less than the longest identified for any of the individual constituent substances--even if that substance is not present in the highest concentration in the product.

(g) Brand names of medications, where applicable, are listed in parentheses following the generic name of a drug.

(3)(a) Withdrawal Guidelines. Furosemide shall be administered pursuant to 810 KAR 8:010.

(b) The following substances may be administered or applied up to the scheduled paddock time of the race in which the horse is to compete:

1. Topical applications, such as liniments, leg paints, salves, and ointments, which may contain antibiotics or DMSO, but do not contain steroids, anesthetics, or any other prohibited substances.

2. The following substances may be administered up to twenty-four (24) hours prior to the scheduled post time of the race in which the horse is to compete as long as their use follows ***subsection (2) of this*** section ~~***[1(a) of this administrative regulation]***~~:

a. Antibiotics, except those containing prohibited drugs, such as Procaine;

b. Antiprotozoals, such as ponazuril (Marquis), toltrazuril (Baycox), sulfamethoxazole/pyrimethamine (Daraprim);

c. Antifungal agents, such as Griseofulvin and Ketoconazole;

d. Certain inhalation agents that do not exhibit bronchodilator properties, such as cromolyn sodium (Intal), and acetylcysteine (Mucomyst);

e. Cimetadine (Tagamet), orally at 20 mg/kg twice daily for 7 doses;

f. Electrolytes, Vitamins, and Minerals, via IV, IM or oral administration;

g. Any oral supplements or nutrients not containing drugs;

h. Hyaluronic Acid (Legend), via IV administration;

i. Misoprostol;

j. Non-Androgenic Reproductive Hormones, such as HCG, Regumate and GnRH, in fillies and mares only;

k. Omeprazole (Gastrogard), orally at 2.2 g once daily for 4 days;

l. Polysulfated glycosaminoglycan (Adequan), via IM administration;

m. Proprionibacterium acnes suspension (Eqstim), or comparable immunostimulants, excluding levamisole;

n. Ranitidine (Zantac), orally at 8 mg/kg twice daily for 7 doses; and

o. Sucralfate.

3. Non-steroidal anti-inflammatory drugs (NSAIDS):

a. Elected NSAID: Only one of the following three NSAIDS may be administered up to the manufacturer's maximum labeled dosage until forty-eight (48) hours prior to the scheduled post time of the race in which the horse is to compete, as long as their use follows Section 1(2) of this ***administrative*** regulation and the requirements of 810 KAR 8:010.

(i) Phenylbutazone (Butazolidin) 4.4 mg/kg, via IV administration only;

(ii) Flunixin Meglumine (Banamine) 1.1 mg/kg, via IV administration only; and

(iii) Ketoprofen (Ketofen) 2.2 mg/kg, via IV administration only.

b. In accordance with the European Horserace Scientific Liaison Committee, the following withdrawal intervals shall be observed for all NSAIDS, except for those ***established***~~***[set forth]***~~ in ***subparagraph 3.a. of this paragraph***~~***[Section 1(b)(3)(a) of this regulation]***~~, for administration prior to the scheduled post time of the race in which the horse is to compete, as long as their use follows Section 1(2) of this ***administrative*** regulation:

(i) Flunixin Meglumine (Banamine) 1.1 mg/kg, via IV administration: 6-day withdrawal interval;

(ii) Phenylbutazone (Butazolidin) 4.4 mg/kg, via IV administration: 7-day withdrawal interval;

(iii) Ketoprofen (Ketofen) 2.2 mg/kg, via IV administration: 4-day withdrawal interval;

(iv) Diclofenac Sodium Topical (Surpass Cream), via a single, 5-inch application: 7- day withdrawal interval; and

(v) Firocoxib (Equioxx) 0.1 mg/kg, via a single oral or IV dose, repeated daily administration: 15-day withdrawal interval from date of last administration.

c. The following substances have a forty-eight (48) hour withdrawal guidance prior to the scheduled post time of the race in which the horse is to compete as long as their use follows Section 1(2) of this ***administrative*** regulation:

(i) Acepromazine (Promace), via IV administration at 0.05 mg/kg;

(ii) Butorphanol (Torbugesic), via IV administration at 0.1 mg/kg;

(iii) Cetirizine (Zyrtec), orally at 0.4 mg/kg twice daily for 5 doses; although it is recommended that ivermectin should not be administered within forty-eight (48) hours of a race if horse has been administered cetirizine;

(iv) Dantrolene (Dantrium), via oral administration at 500 mg total dose;

(v) Detomidine (Dormosedan), via IV administration at 5 mg single dose;

(vi) DMSO via IV, oral, or topical administration up to 60 ml;

(vii) Glycopyrrolate (Robinol), via IV administration at 1 mg total dose;

(viii) Guaifenesin, orally at 2 g twice daily for 5 doses;

(ix) Methocarbamol (Robaxin-V), via single IV at 15 mg/kg;

(x) Procaine penicillin, via IM administration at 17 mg/kg; and

(xi) Xylazine (Rompun), via IV administration at 200 mg single dose.

d. The following substances shall not be administered within forty-eight (48) hours of a race:

(i) Beta-2 agonists by inhalation, such as terbutaline, salmeterol, and fenoterol;

(ii) Ergot alkaloids, such as Ergonovine and Methergine;

(iii) Ipratopium;

(iv) Isoxsuprine; and

(v) Pentoxyphylline (Trental).

e. The following substances may be administered up to seventy-two (72) hours prior to the scheduled post time of the race in which the horse is to compete as long as their use follows Section 1(2) of this ***administrative*** regulation:

(i) Albuterol (Proventil) via inhalation at 720 mcg;

(ii) Dexamethasone (Azium), via oral, IV, IM administration at 0.05 mg/kg. However, if another corticosteroid was administered systemically or intra-articularly, this withdrawal guidance ***shall[~~does~~]*** not apply and a minimum five (5) day withdrawal is recommended;

(iii) Lidocaine, via subcutaneous administration at 200 mg total dose;

(iv) Mepivacaine (Carbocaine), via subcutaneous administration at 0.07 mg/kg; ***and***

(v) Romifidine (Sedivet), via IV administration at 50 mg.

f. The following substances may be administered up to ninety-six (96) hours prior to the scheduled post time of the race in which the horse is to compete as long as their use follows Section 1(2) of this ***administrative*** regulation:

(i) Hydroxyzine (Atarax); and

(ii) Phenytoin (Dilantin).

g. Reserpine (Serpasil) may be administered up to seven (7) days prior to the scheduled post time of the race in which the horse is to compete as long as its use follows Section 1(2) of this ***administrative*** regulation.

h. The use of an extra-corporeal shock wave therapy or radial pulse wave therapy machine may be performed until ten (10) days prior to the scheduled post time of the race in which the horse is to compete, as long as its use complies with 810 KAR 8:010.

i. The following substance may be administered up to twenty-one (21) days prior to the scheduled post time of the race in which the horse is to compete, as long as its use follows Section

1(2) of this ***administrative*** regulation, and its use complies with 810 KAR 8:010, Section 10: Clenbuterol (Ventipulmin), orally up to 0.8 mcg/kg twice daily.

j. Any horse that has been treated with therapeutic medications found in Section 1 of this ***administrative*** regulation may, at the trainer's request and expense, and on permission of a commission veterinarian, have samples of blood ***or[~~and/or~~]*** urine collected by the commission veterinarian for analysis by the commission***[~~authorized~~]*** laboratory prior to entry to race in the state of Kentucky.

(i) As a condition of this elective testing, the trainer ***shall[~~will~~]*** be required to disclose the date and time, dose, and route of administration of the substance for which clearance testing is requested.

(ii) A report from the commission laboratory of a negative finding in this pre-race, elective testing ***shall[~~does~~]*** not provide a safe harbor for the owner, trainer, veterinarian, or horse. A report from the commission laboratory of a positive finding in a post-race sample shall be treated as a violation of ***KAR Title 810[~~KHRC regulations~~]*** even if there was a negative finding by the commission laboratory in the clearance testing sample.

k. The following ***shall*** have a fourteen (14) day stand down period for intra-articular injection. Any IA corticosteroid injection within fourteen (14) days ***shall be[~~is~~]*** a violation:

(i) Betamethasone, via IA administration at 9 mg total dose in a single articular space. Withdrawal time should be increased for use of betamethasone products with a ratio of greater than 1:1 betamethasone acetate to betamethasone sodium phosphate. Intramuscular administration is associated with substantially longer withdrawal times.

(ii) Isoflupredone (Predef 2x), via IA administration at 20 mg in a single joint space or 10 mg subcutaneous.

(iii) Methyprednisolone (Depo-Medrol), via IA administration at a total dose of less than 100 mg in a single articular space. Intramuscular administration is associated with substantially longer withdrawal times and is not recommended, in accordance with the Racing Medication and Testing Consortium. Clearance testing is recommended in blood and urine prior to entry.

(iv) Triamcinolone acetonide (Vetalog), via IA administration at 9 mg total dose in a single articular space. Intramuscular administration is associated with substantially longer withdrawal times.

l. It is recommended that any horses receiving Fluphenazine (Prolixin) receive pre-race clearance testing.

(4) Withdrawal Guidelines Chart:

Substance	Brand Name	Recommended Minimum Withdrawal	Administration Specifications
Acepromazine	PromAce	48 hours	0.05 mg/kg via IV administration
Acetylcysteine	Mucomyst	24 hours	Inhalation
Albuterol	Proventil	72 hours	720 mcg via inhalation
Beclomethasone	Beclovent	24 hours	Inhalation only
Butorphanol	Torbugesic	48 hours	0.1 mg/kg via IV administration
Cetirizine	Zyrtec	48 hours	0.4 mg/ml orally twice daily for 5 doses
Cimetadine	Tagamet	24 hours	20 mg/kg orally twice daily for 7 doses

Clenbuterol	Ventipulmin	21 days	0.8 mcg/kg orally
Cromolyn sodium	Intal	24 hours	Inhalation
Dantrolene	Dantrium	48 hours	500 mg orally
Detomidine	Dormosedan	48 hours	5 mg via IV administration
Dexamethasone	Azium	72 hours IV PO, with no other corticosteroids administered. 5 days if other corticosteroids have been administered.	IV, PO, IM, pursuant to the European Horserace Scientific Liaison Committee.
DMSO		48 hours	Topical, IV, or oral administration up to 60 ml
Ergonovine		48 hours	No dose specified
Fenoterol		48 hours	Via inhalation, no dose specified
Furosemide 2-year-olds beginning in 2020 Stakes horses beginning in 2021	Salix	24 hours	Administration ***shall be prohibited*** ~~***[is not permitted]***~~ at less than 24 hours, and limited to a maximum 500 mg single dose via IV administration
Furosemide	Salix	4 hours	150-500 mg single IV dose administered by KHRC veterinarian. See 810 KAR 8:010, Section 6.
Guaifenesin		48 hours	2 g orally twice daily for 5 doses
Glycopyrrolate	Robinol	48 hours	1 mg
Griseofulvin	Fulvacin	24 hours	No dose specified
Hyaluronic Acid	Legend	24 hours	IV administration only; no dose specified
Hydroxyzine	Atarax	96 hours	No dose specified
Ipratropium		48 hours	Via inhalation, no dose specified
Isoxsuprine	Vasodilan	48 hours	No dose specified
Ketoconazole	Nizoral	24 hours	No dose specified
Lidocaine		72 hours	200 mg total dose SQ
Mepivacaine	Carbocaine	72 hours	0.07 mg/kg SQ
Methocarbamol	Robaxin	48 hours	15 mg/kg single IV
Methylergonovine	Methergine	48 hours	No dose specified
Misoprostol	Cytotec	24 hours	No dose specified
Omeprazole	Gastrogard	24 hours	2.2 g orally once daily for 4 days

Omeprazole	Gastrogard	24 hours	2.2 g orally once daily for 4 days
Pentoxyfylline	Trental	48 hours	No dose specified
Phenytoin	Dilantin	96 hours	No dose specified
Ponazuril/Diclazuril/Sulfadiazine-Pyrimethamine	Marquis/Protazil	24 hours	Oral
Procaine Penicillin		48 hours	17 mg/kg IM Procaine penicillin treatments ***shall[~~must~~]*** be reported to the stewards no later than twenty-four (24) hours after the last injection is administered. Horses so treated may be required to be under commission-approved, continuous surveillance for the six-hour interval prior to the post time for the race in which the horse is entered. The owner of the horse ***shall be[~~is~~]*** responsible for all costs associated with the surveillance. Prospective surveillance arrangements ***shall[~~must~~]*** be submitted to the stewards no later than close of business on the day of entry.
PSGAG	Adequan	24 hours	Via IM administration
Ranitidine	Zantac	24 hours	8 mg/kg orally twice daily for 7 doses
Reserpine	Serpasil	7 days	No dose specified
Romifidine	Sedivet	72 hours	50 mg via IV administration
Salmeterol		48 hours	Via inhalation, no dose specified
Sucralfate	Carafate	24 hours	No dose specified

Terbutaline		48 hours	No dose specified
Xylazine	Rompun	48 hours	200 mg via IV administration

(5) NSAID withdrawal guidelines chart:

Substance	Brand Name	Recommended Minimum Withdrawal	Administration Specifications
Phenylbutazone	Butazolidin	48 hours—single elected NSAID. If this is not the single elected NSAID, then 7 days, pursuant to the European Horserace Scientific Liaison Committee.	4.4 mg/kg via IV administration
Flunixin	Banamine	48 hours—single elected NSAID. If this is not the single elected NSAID, then 6 days, pursuant to the European Horserace Scientific Liaison Committee.	1.1 mg/kg via IV administration
Ketoprofen	Ketofen	48 hours—single elected NSAID, If this is not the single elected NSAID, then 4 days, pursuant to the European Horserace Scientific Liaison Committee.	2.2 mg/kg via IV administration
Diclofenac	Surpass	7 days, pursuant to the European Horserace Scientific Liaison Committee.	5 inch ribbon of Surpass every 12 hours to one site
Firocoxib	Equioxx	15 days, pursuant to the European Horserace Scientific Liaison Committee.	0.1 mg/kg once daily for 4 days

(6) Miscellaneous withdrawal guidelines chart:

Substance	Brand Name	Recommended Minimum Withdrawal	Administration Specifications
Anthemintics (except thiazide products		72 hours	
Non-androgenic reproductive hormones	Including HCG, Regumate, GnRH, in fillies and mares only	24 hours	
Proprionibacterium acnes suspension or comparable immunostimulants		24 hours	
Electrolytes, vitamins, minerals		24 hours	Via IV or IM administration
Antibiotics		24 hours	
Any injectable other than furosemide		24 hours	***810 KAR 8:010[~~KHRC regulations~~]*** specifically ***prohibits[~~prohibit~~]*** any injections at less than 24

			hours to post time for any substance.
Intra-articular injections, other than corticosteroids		72 hours	

(7) Available Threshold Levels Associated to KHRC Withdrawal Guidelines:

SUBSTANCE	THRESHOLD
Acepromazine	10 nanograms per ml in urine of hydroxyethylpromazine sulfoxide (HEPS)
Albuterol	1 nanogram per ml in urine
Boldenone Male horses other than Geldings	15 nanograms per ml in urine of boldenone, free and conjugated OR 25 picograms per ml in serum or plasma of boldenone, free
Boldenone Geldings and female horses	1 nanogram per mil in urine of boldenone, free and conjugated
Butorphanol	2 nanograms per ml in serum or plasma of butorphanol, free OR 300 nanograms per ml in urine of total butorphanol
Cetirizine	6 nanograms per ml in serum or plasma
Cimetadine	400 nanograms per ml in serum or plasma
Clenbuterol	140 picograms per ml of urine OR Limit of detection in both urine and blood
Dantrolene	0.1 nanograms per ml of serum or plasma of 5-OH dantrolene
Detomidine	2 nanogram per ml in urine of carboxydetomidine OR 1 nanogram per ml of detomidine in serum or plasma
Diclofenac	5 nanograms per ml in serum or plasma
DMSO	10 micrograms per ml in serum or plasma
Firocoxib	20 nanograms per ml in serum or plasma
Flunixin	5 nanograms per ml in serum or plasma
Furosemide	For horses eligible to race on furosemide, 100 nanograms per ml in serum or plasma AND Urine specific gravity of less than 1.010 OR 1 nanogram per ml in serum or plasma for 2-year-olds beginning in 2020 or stakes horses beginning in 2021, see 810 KAR 8:010
Glycopyrrolate	3 picograms per ml in serum or plasma
Guaifenesin	12 nanograms per ml in serum or plasma
Ketoprofen	2 nanograms per ml of serum or plasma
Lidocaine	20 picograms per ml in serum or plasma of Total 3-OH-lidocaine
Mepivacaine	10 nanograms per ml in urine of OH-mepivicaine OR Limit of detection in serum or plasma

Methocarbamol	1 nanogram per ml in serum or plasma
Methylprednisolone	100 picograms per ml in serum or plasma
Nandrolone Male horses other than geldings	45 nanograms per ml in urine of 5α-estrane-3β, 17α-diol OR In urine a ratio of 5α estrane-3β, 17 α-diol to 5α estrene-3β, 17 α-diol of > 1:1
Nandrolone Geldings and female horses	1 nanogram per ml in urine of nandrolone, free and conjugated OR 50 picograms per ml of procaine in blood, serum, or plasma of nandrolone, free
Omeprazole	10 nanograms per ml omeprazole sulfide in serum or plasma
Phenylbutazone	0.3 micrograms per ml in serum or plasma
Prednisolone	10 nanograms per ml free Prednisolone in urine
Procaine Penicillin Horses reported to have been treated with procaine penicillin	25 nanograms per ml of procaine in serum or plasma Procaine penicillin treatments ***shall[~~must~~]*** be reported to the stewards no later than 24 hours after the last injection is administered. Horses so treated may be required to be under KHRC approved, continuous surveillance for the six hour interval prior to the post time for the race in which the horse is entered. The owner of the horse ***shall be[~~is~~]*** responsible for all costs associated with the surveillance. Prospective surveillance arrangements ***shall[~~must~~]*** be submitted to the stewards no later than close of business on the day of entry.
Procaine Penicillin Horses not reported to have been treated with procaine penicillin	Limit of detection for procaine in serum or plasma 2 nanograms per ml of serum or plasma. Procaine penicillin treatments ***shall[~~must~~]*** be reported to the stewards no later than 24 hours after the last injection is administered. Horses so treated may be required to be under KHRC approved, continuous surveillance for the six hour interval prior to the post time for the race in which the horse is entered. The owner of the horse ***shall be[~~is~~]*** responsible for all costs associated with the surveillance. Prospective surveillance arrangements ***shall[~~must~~]*** be submitted to the stewards no later than close of business on the day of entry.
Ranitidine	40 nanograms per ml in serum or plasma
Testosterone Geldings	20 nanograms per ml in urine of testosterone, free and conjugated OR 25 picograms per ml in serum or plasma of testosterone, free
Testosterone Female horses (unless in foal)	55 nanograms per ml in urine of testosterone, free and conjugated OR 100 picograms per ml in serum or plasma of testosterone, free
Xylazine	200 picograms per ml in serum or plasma

(8) All other NSAIDs not listed on the withdrawal guidelines ***shall*** have a threshold set at limit of detection in serum or plasma.

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June 3, 2021

VIA ELECTRONIC MAIL
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: 810 KAR 8:010. Medication; testing procedures; prohibited practices.
810 KAR 8:025. Drug, medication, and substance withdrawal guidelines.
810 KAR 8:030. Disciplinary measures and penalties.
810 KAR 8:040. Out-of-competition testing.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 810 KAR 8:010, 810 KAR 8:025, 810 KAR 8:030, and 810 KAR 8040, the Kentucky Horse Racing Commission proposes the attached suggested substitutes to 810 KAR 8:010, 810 KAR 8:025, 810 KAR 8:030, and 810 KAR 8:040.

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

Jennifer Wolsing

Jennifer Wolsing
General Counsel

TEAM KENTUCKY

Version: 6/3/2021

SUGGESTED SUBSTITUTE

PUBLIC PROTECTION CABINET
Kentucky Horse Racing Commission

810 KAR 8:030. Disciplinary measures and penalties.

RELATES TO: KRS 230.215, 230.260, 230.265, 230.290, 230.300, 230.310, 230.320, 230.361
STATUTORY AUTHORITY: KRS 230.215(2), 230.240(2), 230.260(8), 230.265, 230.320
NECESSITY, FUNCTION, AND CONFORMITY: KRS 230.215(2) and 230.260(8) authorize the Kentucky Horse Racing Commission to promulgate administrative regulations under which racing shall be conducted in Kentucky. KRS 230.240(2) requires the commission to promulgate administrative regulations restricting or prohibiting the use and administration of drugs or stimulants or other improper acts to horses prior to the horse participating in a race. This administrative regulation establishes the penalty structure for rule violations and also establishes disciplinary powers and duties of the stewards, judges, and the commission.

Section 1. Definitions.
(1) "Associated person" means the spouse of an inactive person, or a companion, family member, employer, employee, agent, partnership, partner, corporation, or other entity whose relationship, whether financial or otherwise, with an inactive person would give the appearance that the other person or entity would care for or train a horse or perform veterinarian services on a horse for the benefit, credit, reputation, or satisfaction of the inactive person.
(2) "Class A drug" means a drug, medication, or substance classified as a Class A drug, medication, or substance in the schedule.
(3) "Class B drug" means a drug, medication, or substance classified as a Class B drug, medication, or substance in the schedule.
(4) "Class C drug" means a drug, medication, or substance classified as a Class C drug, medication, or substance in the schedule.
(5) "Class D drug" means a drug, medication, or substance classified as a Class D drug, medication, or substance in the schedule.
(6) "Companion" means a person who cohabits with or shares living accommodations with an inactive person.
(7) "Inactive person" means a trainer or veterinarian who has his or her license denied or suspended or revoked for thirty (30) or more days pursuant to KAR Title 810 or KRS Chapter 230.
(8) "NSAID" means a nonsteroidal anti-inflammatory drug.
(9) "Schedule" means the Kentucky Horse Racing Commission Uniform Drug, Medication, and Substance Classification Schedule as provided in 810 KAR 8:020.
(10) "Withdrawal guidelines" means the Kentucky Horse Racing Commission Withdrawal Guidelines established in 810 KAR 8:025[~~810 KAR 8:020~~].

Section 2. General Provisions.
(1) An alleged violation of the provisions of KRS Chapter 230 or KAR Title 810 shall be adjudicated in accordance with this administrative regulation, 810 KAR 9:010, and KRS Chapters 230 and 13B.
(2) If a drug, medication, or substance that is not classified in the schedule is found to be present in a pre-race or post-race sample or possessed or used by a licensee at a location under the jurisdiction of the commission, the commission may establish a classification after consultation

with either or both of the Association of Racing Commissioners International and the Racing and Medication Testing Consortium or their respective successors.

(3) The stewards, judges, and the commission shall consider any mitigating or aggravating circumstances properly presented when assessing penalties pursuant to this administrative regulation. Evidence of full compliance with the withdrawal guidelines shall be considered by the stewards, judges, and the commission as a mitigating factor to be used in determining violations and penalties.

(4) A licensee whose license has been suspended or revoked in any racing jurisdiction or a horse that has been deemed ineligible to race in any racing jurisdiction shall be denied access to locations under the jurisdiction of the commission during the term of the suspension or revocation.

(5) A suspension or revocation shall be calculated in calendar days, unless otherwise specified by the stewards, judges, or the commission in a ruling or order.

(6) Notice of the assessment of a penalty, including a written warning, shall be made to the person penalized. The notice and terms of the penalty shall be posted immediately on the official Web site of the commission and sent to the United States Trotting Association, the Association of Racing Commissioners International, or their successors, as applicable, to be posted on their respective official Web sites. If an appeal is pending, that fact shall be so noted.

(7) A horse administered a substance in violation of 810 KAR 8:010 may be required to pass a commission-approved examination as determined by the stewards or judges pursuant to 810 KAR 4:010, Section 10 or 810 KAR 5:010, Section 4, or be placed on the veterinarian's list pursuant to 810 KAR 8:010, Section 19[~~18~~].

(8) To protect the racing public and ensure the integrity of racing in Kentucky, a trainer whose penalty for a Class A violation or for a Class B third offense violation has not been finally adjudicated may, if stall space is available, be required to house a horse that the trainer has entered in a race in a designated stall for the twenty-four (24) hour period prior to post time of the race in which the horse is entered. If the stewards or judges require the trainer's horse to be kept in a designated stall, there shall be twenty-four (24) hour surveillance of the horse by the association, and the cost shall be borne by the trainer.

(9) In addition to the penalties contained in Section 4 of this administrative regulation for the trainer and owner, any other person who administers, is a party to, facilitates, or is found to be responsible for any violation of 810 KAR 8:010 shall be subject to the relevant penalty as provided for the trainer or other penalty as may be appropriate based upon the violation.

(10) A veterinarian who administers, is a party to, facilitates, or is found to be responsible for any violation of KRS Chapter 230 or KAR Title 810 shall be reported to the Kentucky Board of Veterinary Examiners and the state licensing Board of Veterinary Medicine by the stewards or judges.

(11) In accordance with KRS 230.320(6), an administrative action or the imposition of penalties pursuant to this administrative regulation shall not constitute a bar or be considered jeopardy to prosecution of an act that violates the criminal statutes of Kentucky.

(12) If a person is charged with committing multiple or successive overages involving a Class C or Class D drug, medication, or substance, the stewards, judges, or the commission may charge the person with only one (1) offense if the person demonstrates that he or she was not aware that overages were being administered because the positive test results showing the overages were unavailable to the person charged. In this case, the person alleging that he or she was not aware of the overages shall bear the burden of proving that fact to the stewards, judges, or the commission.

(13) If a penalty for a medication violation requires a horse to be placed on the stewards' list or the judges' list for a period of time, the stewards or judges may waive this requirement if ownership of the horse was legitimately transferred prior to the trainer's notification by the commission of the positive result.

(14) In standardbred racing only, if the penalty is for a driving violation and does not exceed in time a period of five (5) days, the driver may complete the engagement of all horses declared in before the penalty becomes effective. The driver may drive in stake, futurity, early closing and feature races, during a suspension of five (5) days or less, but the suspension shall be extended one (1) day for each date the driver drives in a race.

(15) A horse shall not be permitted to race while owned or controlled wholly or in part by a person whose license has been suspended or revoked.

(16) An association under the jurisdiction of the commission shall not willfully allow:

(a) A person whose license has been suspended or revoked in any jurisdiction to participate in racing;

(b) A horse suspended in any jurisdiction to start in a race or a performance against time; or

(c) The use of its track or grounds by a licensee whose license has been suspended or revoked and has been denied access to the grounds by the stewards or judges in any jurisdiction.

(17) If a person is ejected or excluded from a location under the jurisdiction of the commission, the stewards, judges, and commission director of security shall be notified in writing.

(18) A licensee that has been suspended shall serve any suspension imposed:

(a) During the current race meet, if there are enough remaining days to serve out the suspension;

(b) During the next regularly scheduled race meet at the operating race track where the infraction took place if there are not enough remaining days to serve out the suspension; or

(c) At the discretion of the stewards or judges, during a race meet at another operating track in any jurisdiction where the licensee seeks to engage in the activity for which he or she is licensed if the track where the infraction took place closes before another race meet is held at that track.

(19) A penalty imposed by the governing body of any racing jurisdiction or the USTA States Trotting Association shall be recognized and reciprocally enforced by the commission unless application is made for a hearing before the stewards or judges, during which the applicant shall show cause as to why the penalty should not be enforced against him in Kentucky. The hearing shall be limited to the following issues:

(a) Whether the applicant is the same person who is subject to the penalty imposed;

(b) Whether the USTA or other racing jurisdiction in fact suspended the applicant; and

(c) Determination of the time period of the suspension as imposed by the USTA or other racing jurisdiction.

Section 3. Prior Offenses. A prior offense occurring in Kentucky or any other racing jurisdiction shall be considered by the stewards, judges, and the commission in assessing penalties. The stewards or judges shall attach to a penalty judgment a copy of the offender's prior record listing violations that were committed both inside and outside of Kentucky.

Section 4. Penalties for Class A, B, C, and D Drug Violations and NSAID and Furosemide Violations.

(1) Class A drugs. The penalties established in paragraphs (a) and (b) of this subsection shall apply to a Class A drug violation.

(a) Trainer

First offense	Second lifetime offense in any racing jurisdiction	Third lifetime offense in any racing jurisdiction
One (1) to three (3) year suspension, absent	Three (3) to five (5) year suspension, absent mitigating circumstances;	Five (5) year suspension to a lifetime ban, absent

mitigating circumstances; AND $10,000 to $25,000 fine, absent mitigating circumstances.	AND $25,000 to $50,000 fine, absent mitigating circumstances.	mitigating circumstances; AND $50,000 to $100,000 fine, absent mitigating circumstances.

(b) Owner

First offense	Second lifetime offense in any racing jurisdiction in a horse owned by the same owner	Third lifetime offense in any racing jurisdiction in a horse owned by the same owner
Disqualification and loss of purse; AND Horse shall be placed on the stewards' list or judges' list for sixty (60) days and may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges.	Disqualification and loss of purse; AND Horse shall be placed on the stewards' list or judges' list for 120 days and may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges.	Disqualification and loss of purse; AND Ninety (90) day suspension, absent mitigating circumstances; AND $50,000 fine, absent mitigating circumstances; AND Horse shall be placed on the stewards' list or judges' list for 180 days and may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges.

(2)(a) The penalties established in paragraphs (b) and (c) of this subsection shall apply to the following:

1. Class B drugs;

2. Gamma amino butyric acid in a concentration greater than 110 nanograms per milliliter; and
3. Cobalt in a concentration greater than fifty (50) parts per billion.

(b) Trainer

First offense	Second offense within a 365-day period in any racing jurisdiction	Third offense within a 365-day period in any racing jurisdiction
Thirty (30) to sixty (60) day suspension, absent mitigating circumstances; AND $500 to $1,000 fine, absent mitigating circumstances.	Sixty (60) to 180 day suspension, absent mitigating circumstances; AND $1,000 to $2,500 fine, absent mitigating circumstances.	180 to 365 day suspension, absent mitigating circumstances; AND $2,500 to $5,000 fine, absent mitigating circumstances.

(c) Owner

First offense	Second offense within a 365-day period in any racing jurisdiction in a horse owned by the same owner	Third offense within a 365-day period in any racing jurisdiction in a horse owned by the same owner
Disqualification and loss of purse; Horse may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges; AND	Disqualification and loss of purse; AND Horse may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges.	Disqualification and loss of purse; AND Horse shall be placed on the stewards' list or judges' list for forty-five (45) days and may be required to pass a commission-approved examination before being eligible to enter as determined by the

For a cobalt violation, the horse shall be placed on the stewards' list or judges' list until the horse tests below twenty-five (25) parts per billion. The owner shall be responsible for the cost of testing.		stewards or judges.

(3)(a) The penalties established in paragraphs (b) and (c) of this subsection shall apply to a Class C drug violation and an overage of permitted NSAIDs as follows:

1. Phenylbutazone in a concentration greater than three-tenths (0.3) micrograms per milliliter;
2. Flunixin in a concentration greater than five (5) nanograms per milliliter; and
3. Ketoprofen in a concentration greater than two (2) nanograms per milliliter.

(b) Trainer

First offense	Second offense within a 365-day period in any racing jurisdiction	Third offense within a 365-day period in any racing jurisdiction
Zero to ten (10) day suspension absent mitigating circumstances; AND $500 to $1,500 fine absent mitigating circumstances.	Ten (10) to thirty (30) day suspension absent mitigating circumstances; AND $1,500 to $2,500 fine absent mitigating circumstances.	Thirty (30) to sixty (60) day suspension absent mitigating circumstances; AND $2,500 to $5,000 fine absent mitigating circumstances.

(c) Owner

First offense	Second offense within a 365-day period in any racing jurisdiction	Third offense within a 365-day period in any racing jurisdiction

Disqualification and loss of purse; AND Horse may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges.	Disqualification and loss of purse; AND If same horse as first offense, horse shall be placed on the stewards' list or judges' list for forty-five (45) days and may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges.	Disqualification and loss of purse; $5,000 fine, absent mitigating circumstances; AND If same horse as first and second offenses, horse shall be placed on the stewards' list or judges' list for sixty (60) days and may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges.

(4)(a)The penalties established in paragraphs (b) and (c) of this subsection shall apply to the following:

1. Overage of furosemide in a concentration greater than one (1) nanogram per milliliter ***for horses that are not permitted by 810 KAR 8:010 to receive furosemide within twenty-four (24) hours of the post time of a race in which the horse is entered*** ~~[for horses that are not permitted by 810 KAR 8:001 to receive furosemide within twenty-four (24) hours of the post time of a race in which the horse is entered]~~;

2. Overage of furosemide in a concentration greater than 100 nanograms per milliliter for horses other than those identified in subparagraph 1. of this paragraph;

3. Furosemide not identified when notice made that the horse would run on furosemide; and

4. Cobalt in a concentration greater than twenty-five (25) parts per billion through fifty (50) parts per billion.

(b) Trainer

First offense	Second offense within a 365-day period in any racing jurisdiction	Third offense within a 365-day period in any racing jurisdiction
Written warning to a $500 fine, absent	Written warning to a $750 fine, absent mitigating circumstances.	$500 to $1,000 fine, absent mitigating circumstances.

mitigating circumstances.		

(c) Owner

First offense	Second offense within a 365-day period in any racing jurisdiction	Third offense within a 365-day period in any racing jurisdiction
Horse may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges; AND For a cobalt violation, the horse shall be placed on the stewards' list or judges' list until the horse tests below twenty-five (25) parts per billion. The owner shall be responsible for the cost of testing.	Horse may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges.	If same horse as first and second offenses, disqualification and loss of purse; AND Horse may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges.

(d) If a furosemide violation occurs due solely to the actions or inactions of the commission veterinarian, then the trainer and owner shall not be penalized.

(5) Multiple NSAIDs. The penalties established in paragraphs (a) and (b) of this subsection shall apply to an overage of two (2) permitted NSAIDs: phenylbutazone, flunixin, and ketoprofen.

(a) Trainer

	Concentrations of both permitted NSAIDs above the NSAID threshold.

First offense	Zero to sixty (60) day suspension, absent mitigating circumstances; AND $500 to $1,000 fine, absent mitigating circumstances.
Second offense within a 365-day period in any racing jurisdiction	Sixty (60) to 180 day suspension, absent mitigating circumstances; AND $1,000 to $2,500 fine, absent mitigating circumstances.
Third offense within a 365-day period in any racing jurisdiction	180 to 365 day suspension, absent mitigating circumstances; AND $2,500 to $5,000 fine, absent mitigating circumstances.

(b) Owner

	Concentrations of both permitted NSAIDs above the NSAID threshold.
First offense	Disqualification and loss of purse.
Second offense within a 365-day period in any racing jurisdiction	Disqualification and loss of purse.
Third offense within a 365-day period in any racing jurisdiction	Disqualification and loss of purse.

(6) Class D drugs.

(a) The penalties established in paragraph (b) of this subsection shall apply to a Class D drug violation.

(b) Trainer

One (1) to four (4) offenses within a 365-day period in any racing jurisdiction	Five (5) or more offenses within a 365-day period in any racing jurisdiction
Zero to five (5) day suspension, absent mitigating circumstances; AND $250 to $500 fine, absent mitigating circumstances.	Five (5) to ten (10) day suspension, absent mitigating circumstances; AND $500 to $1,000 fine, absent mitigating circumstances.

Section 5. TCO2 Penalties. The penalties established in subsections (1) and (2) of this section shall apply to a violation of 810 KAR 8:010, Section 21(6), (7), or (8) [~~20(6), (7), or (8)~~].

(1) Trainer

First offense	Second offense within a 365-day period in any racing jurisdiction	Third offense within a 365-day period in any racing jurisdiction	Subsequent offenses within a 365-day period in any racing jurisdiction
Zero to ninety (90) day suspension, absent mitigating circumstances; AND $1,000 to $1,500 fine, absent mitigating circumstances.	Ninety (90) to 180 day suspension, absent mitigating circumstances; AND $1,500 to $3,000 fine, absent mitigating circumstances.	180 to 365 day suspension, absent mitigating circumstances; AND $3,000 to $5,000 fine, absent mitigating circumstances.	One (1) year suspension to lifetime ban, absent mitigating circumstances.

(2) Owner

First offense	Second offense within a 365-day period in any racing jurisdiction	Third offense within a 365-day period in any racing jurisdiction	Subsequent offenses within a 365-day period in any racing jurisdiction
Disqualification and loss of purse.	Disqualification and loss of purse; AND If same horse as first offense, horse shall be placed on the stewards' list from fifteen (15) to sixty (60) days and may be required to pass a commission-	Disqualification and loss of purse; AND If same horse as first and second offenses, horse shall be placed on the stewards' list from sixty (60) to 180 days and may be required to pass a	Disqualification and loss of purse; AND If same horse as first, second, and third offenses, horse shall be placed on the stewards' list from 180 to 365 days and may be required to pass a

	approved examination before being eligible to enter as determined by the stewards.	commission-approved examination before being eligible to enter as determined by the stewards.	commission-approved examination before being eligible to enter as determined by the stewards.

Section 6. Shock Wave Machine and Blood Gas Machine Penalties. The penalties established in subsections (1) and (2) of this section shall apply to a violation of 810 KAR 8:010, Section 21(5), (9), or (10) [~~Section 20(5), (9), or (10)~~].

(1) Trainer

First offense	Second lifetime offense in any racing jurisdiction	Third lifetime offense in any racing jurisdiction
Thirty (30) to sixty (60) day suspension absent mitigating circumstances; AND $1,000 to $5,000 fine absent mitigating circumstances.	Sixty (60) to 180 day suspension absent mitigating circumstances; AND $5,000 to $10,000 fine absent mitigating circumstances.	180 to 365 day suspension absent mitigating circumstances; AND $10,000 to $20,000 fine absent mitigating circumstances.

(2) Owner

First offense	Second lifetime offense in any racing jurisdiction	Third lifetime offense in any racing jurisdiction
Disqualification and loss of purse.	Disqualification and loss of purse; AND If same horse as first offense, horse shall be placed on the stewards' list or judges' list from	Disqualification and loss of purse; AND If same horse as first and second offenses, horse shall be placed on the stewards' list or judges' list from sixty (60) to 180

	fifteen (15) to sixty (60) days and may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges.	days and may be required to pass a commission-approved examination before being eligible to enter as determined by the stewards or judges.

Section 7. Persons with a Suspended or Revoked License.

(1) A person shall not train a horse or practice veterinary medicine for the benefit, credit, reputation, or satisfaction of an inactive person. The partners in a veterinary practice may provide services to horses if the inactive person does not receive a pecuniary benefit from those services.

(2) An associated person of an inactive person shall not:

(a) Assume the inactive person's responsibilities at a location under the jurisdiction of the commission;

(b) Complete an entry form for a race to be held in Kentucky on behalf of or for the inactive person or an owner or customer for whom the inactive person has worked; or

(c) Pay or advance an entry fee for a race to be held in Kentucky on behalf of or for the inactive person or an owner or customer for whom the inactive person has worked.

(3) An associated person who assumes the responsibility for the care, custody, or control of an unsuspended horse owned (fully or partially), leased, or trained by an inactive person shall not:

(a) Be paid a salary directly or indirectly by or on behalf of the inactive person;

(b) Receive a bonus or any other form of compensation in cash, property, or other remuneration or consideration;

(c) Make a payment or give remuneration or other compensation or consideration to the inactive person or associated person; or

(d) Train or perform veterinary work for the inactive person or an owner or customer of the inactive person at a location under the jurisdiction of the commission.

(4) A person who is responsible for the care, training, or veterinary services provided to a horse formerly under the care, training, or veterinary services of an inactive person shall:

(a) Bill customers directly on his or her bill form for any services rendered at or in connection with any race meeting in Kentucky;

(b) Maintain a personal checking account totally separate from and independent of that of the inactive person to be used to pay expenses of and deposit income from an owner or client of the inactive person;

(c) Not use the services, directly or indirectly, of current employees of the inactive person; and

(d) Pay bills related to the care, training, and racing of the horse from a separate and independent checking account. Copies of the invoices for the expenses shall be retained for not less than six (6) months after the date of the reinstatement of the license of the inactive person or the expiration of the suspension of the inactive person's license.

Section 8. Other Disciplinary Measures.

(1) A person who violates 810 KAR 8:010, Section 21(2)[~~20(2)~~], shall be treated the same as a person who has committed a drug violation of the same class, as determined by the commission after consultation with the Equine Drug Research Council.

(2) A person who violates 810 KAR 8:010, Section 21(3)[~~20(3)~~], shall be treated the same as a person who has committed a Class A drug violation.

Section 9. Disciplinary Measures by Stewards or Judges. Upon finding a violation or an attempted violation of the provisions of KRS Chapter 230 or KAR Title 810, if not otherwise provided for in this administrative regulation, the stewards or judges may impose one (1) or more of the following penalties:

(1) If the violation or attempted violation may affect the health or safety of a horse or race participant, or may affect the outcome of a race, declare a horse or a licensee ineligible to race or disqualify a horse or a licensee in a race;

(2) Suspend or revoke a person's licensing privileges for a period of time of not more than five (5) years in proportion to the seriousness of the violation and the facts of the case;

(3) Cause a person, licensed or unlicensed, found to have interfered with, or contributed toward the interference of the orderly conduct of a race or race meeting, or person whose presence is found by the stewards or judges to be inconsistent with maintaining the honesty and integrity of the sport of horse racing to be denied access to association grounds or a portion of association grounds; and

(4) Payment of a fine in an amount not to exceed $50,000 as deemed appropriate by the commission in keeping with the seriousness of the violation and the facts of the case.

Section 10. Disciplinary Measures by the Commission.

(1) Upon finding a violation or an attempted violation of the provisions of KRS Chapter 230 or KAR Title 810, if not otherwise provided for in this administrative regulation, the commission may impose one (1) or more of the following penalties:

(a) If the violation or attempted violation may affect the health or safety of a horse or race participant or may affect the outcome of a race, declare a horse or a licensed person ineligible to race or disqualify a horse or licensed person in a race;

(b) Suspend or revoke a person's licensing privileges for a period of time of not more than five (5) years in proportion to the seriousness of the violation;

(c) Cause a person found to have interfered with or contributed toward the interference of the orderly conduct of a race or race meeting, or person whose presence is found by the commission to be inconsistent with maintaining the honesty and integrity of horse racing, to be denied access to association grounds or a portion of association grounds for a length of time the commission deems necessary;

(d) Payment of a fine of up to $50,000 as deemed appropriate by the commission in keeping with the seriousness of the violation and the facts of the case.

(2) Upon appeal of a matter determined by the stewards' or judges the commission may:

(a) Order a hearing de novo of a matter determined by the stewards' or judges; and

(b) Reverse or revise the stewards' or judges' ruling in whole or in part, except as to findings of fact by the stewards' or judges' ruling regarding matters that occurred during or incident to the running of a race and as to the extent of disqualification fixed by the stewards or judges for a foul in a race.

CONTACT PERSON: Jennifer Wolsing, General Counsel, 4063 Iron Works Parkway, Building B, Lexington, Kentucky 40511, phone (859) 246-2040, fax (859) 246-2039, email jennifer.wolsing@ky.gov.

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Chairman

June 3, 2021

VIA ELECTRONIC MAIL
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: 810 KAR 8:010. Medication; testing procedures; prohibited practices.
810 KAR 8:025. Drug, medication, and substance withdrawal guidelines.
810 KAR 8:030. Disciplinary measures and penalties.
810 KAR 8:040. Out-of-competition testing.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 810 KAR 8:010, 810 KAR 8:025, 810 KAR 8:030, and 810 KAR 8040, the Kentucky Horse Racing Commission proposes the attached suggested substitutes to 810 KAR 8:010, 810 KAR 8:025, 810 KAR 8:030, and 810 KAR 8:040.

Please do not hesitate to contact me if you have any questions or concerns.

Sincerely,

Jennifer Wolsing
General Counsel

Version: 6/3/21

SUGGESTED SUBSTITUTE

PUBLIC PROTECTION CABINET
Kentucky Horse Racing Commission

810 KAR 8:040. Out-of-competition testing.

RELATES TO: KRS 230.215, 230.225(5), 230.240, 230.260, 230.290, 230.300, 230.310, 230.320, 230.370

STATUTORY AUTHORITY: KRS 230.215(2), 230.240(2), 230.260(11)***[.]***

NECESSITY, FUNCTION, AND CONFORMITY: KRS 230.215(2) ***authorizes[~~grants~~]*** the ***Kentucky Horse Racing*** commission ***to promulgate administrative regulations prescribing [~~the authority to regulate~~]*** conditions under which horse racing shall be conducted in Kentucky. KRS 230.240(2) requires the commission to promulgate administrative regulations restricting or prohibiting the use and administration of drugs or stimulants or other improper acts to horses prior to the horse participating in a race. This administrative regulation establishes ***[~~new~~]*** sampling and testing procedures for prohibited substances, and establishes penalties for individuals found to be in violation of this administrative regulation.

Section 1. Definitions.

(1) "Endogenous" means a substance that is naturally produced by the healthy body.

(2) "Exogenous" means a substance that is not naturally produced by the healthy body.

(3) "Out of competition testing" means all testing other than:

(a) Pre-race TCO2 testing; and

(b) Post-race testing at a licensed association under the jurisdiction of the commission.

(4) "Sample" means that portion of a specimen subjected to testing by the commission laboratory.

(5) "Sampling" means the act of collecting a specimen from a horse.

(6) "Specimen" means blood, urine, or other biologic matter taken or drawn from a horse for testing.

Section 2. Prohibited Substances and Practices.

(1) All substances identified in this administrative regulation shall be prohibited unless specifically permitted. A positive finding by the commission laboratory of a substance prohibited by this administrative regulation in a specimen taken from a horse designated for testing by a commission veterinarian or his designee shall be prima facie evidence that a violation has occurred. Any reference to substances in this section does not alter the requirements for testing concentrations in race day samples established in 810 KAR 8:010 and 810 KAR 8:050.

(2) Any pharmacological substance not addressed by this administrative regulation and without current approval by the U.S. Food and Drug Administration for human or veterinary use shall be prohibited at all times without prior approval of the commission. If a veterinarian seeks approval to use a pharmacological substance not currently approved by the U.S. Food and Drug Administration, the commission or its designee may consult with the Association of Racing Commissioners International, the Racing and Medication Testing Consortium, or their successors to determine whether to authorize use of the substance.

(3) Therapeutic substances not otherwise prohibited by this administrative regulation may be used if the substances:

(a) Are currently approved for human or veterinary use by the U.S. Food and Drug Administration; and

(b) Are prescribed and administered in the context of a valid veterinarian-client-patient relationship.

(4) Compounded medications not otherwise prohibited by this administrative regulation may be used if the medications:

(a) Are permitted by federal law or the law of the state where the horse is located when the compounded medication is administered; and[~~,~~]

(b) Are prescribed and administered in the context of a valid veterinarian-client-patient relationship.

(5)(a) Except as provided in paragraph (b) of this subsection, the following Anabolic Androgenic Steroids (AAS) shall be prohibited:

1. Exogenous AAS, such as [~~including~~]: 1-androstenediol (5α-androst-1-ene-3β,17β-diol); 1-androstenedione (5α-androst-1-ene-3,17-dione); bolandiol (estr-4-ene-3β,17β-diol); bolasterone; boldenone; boldione (androsta-1,4-diene-3,17-dione); calusterone; clostebol danazol (oxazolopregna-4-en-20-yn-17α-ol); dehydrochlormethyltestosterone (4-chloro-17β-hydroxy-17α-methylandrosta-1,4-dien-3-one); desoxymethyltestosterone (17α-ethyl-5α-androst-2-en-17β-ol); drostanolone; ethylestrenol (19-norpregna-4-en-17α-ol); fluoxymesterone; formebolone; furazabol (17α-methyloxadiazolo-5α-androstan-17β-ol); gestrinone; 4-hydroxytestosterone (4,17β-dihydroxyandrost-4-en-3-one); mestanolone; mesterolone; metandienone (17β-hydroxy-17α-methylandrosta-1,4-dien-3-one); metenolone; methandriol; methasterone (17β-hydroxy-2α,17α-dimethyl-5α-androstan-3-one); methyldienolone (17β-hydroxy-17α- methylestra-4,9-dien-3-one); methyl-1-testosterone (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one); methylnortestosterone (17β-hydroxy-17α-methylestr-4-en-3-one); methyltestosterone; metribolone (methyltrienolone, 17β-hydroxy-17α-methylestra-4,9,11-trien-3-one); mibolerone; nandrolone; 19-norandrostenedione (estr-4-ene-3,17-dione); norboletone; norclostebol; norethandrolone; oxabolone; oxandrolone; oxymesterone; oxymetholone; prostanozol (17β--1'H pyrazolo-5α-androstane); quinbolone; stanozolol; stenbolone; 1-testosterone (17β-hydroxy-5α-androst-1-en-3-one); tetrahydrogestrinone (17-hydroxy-18a-homo-19-nor-17α pregna-4,9,11-trien-3-one); and trenbolone (17β-hydroxyestr-4,9,11-trien-3-one); and

2. Endogenous AAS or their synthetic esters if administered exogenously: androstenediol (androst-5-ene-3β,17β-diol); androstenedione (androst-4-ene-3,17-dione); dihydrotestosterone (17β-hydroxy-5α-androstan-3-one); prasterone (dehydroepiandrosterone, DHEA, 3β-hydroxyandrost-5-en-17-one); testosterone; and their metabolites and isomers, including but not limited to: 5α-androstane-3α,17α-diol; 5α-androstane-3α,17β-diol; 5α-androstane-3β,17α-diol; 5α-androstane-3β,17β-diol; 5β-androstane-3α, 17β-diol, androst-4-ene-3α,17α-diol; androst-4-ene-3α,17β-diol; androst-4-ene-3β,17α-diol; androst-5-ene-3α,17α-diol; androst-5-ene-3α,17β-diol; androst-5-ene-3β,17α-diol; 4-androstenediol (androst-4-ene-3β,17β-diol); 5-androstenedione (androst-5-ene-3,17-dione); androsterone (3β-hydroxy-5α-androstan-17-one); epi-dihydrotestosterone; epitestosterone; etiocholanolone; 7α-hydroxy-DHEA; 7β-hydroxy-DHEA; 7-keto-DHEA; 19-norandrosterone; 19-noretiocholanolone.

(b) Anabolic steroids may be used out of competition if:

1. The anabolic steroid is currently approved for human or veterinary use by the U.S. Food and Drug Administration;

2. The administration is:

a. Performed pursuant to a valid veterinary prescription;

b. Entered into the horse's medical record by the administering veterinarian; and

c. Reported by the administering veterinarian to the commission no later than twenty-four (24) hours after administration or dispensing of the medication;

3. The record is made available upon request for inspection by the commission or its designee; and

4. The horse is placed on the Veterinarian's List for six (6) months after the last administration of an anabolic steroid or agent.

(6)(a) Except as provided in paragraph (b) of this subsection, the following anabolic agents shall be prohibited:

1. Clenbuterol;
2. Selective androgen receptor modulators (SARMs);
3. Ractopamine;
4. Tibolone;
5. Zeranol; and
6. Zilpaterol.

(b) Clenbuterol may be administered if the treatment is:

1. Pursuant to a valid veterinary prescription; [~~and~~]
2. Reported by the administering veterinarian to the commission no later than 24 hours after administration or dispensing of the medication; and[~~.~~]
3. Otherwise compliant with 810 KAR 8:010, Section 10.

(7) The following substances shall be prohibited:

(a) Erythropoiesis-Stimulating Agents (ESAs), such as [~~including~~] darbepoetin (dEPO); erythropoietins (EPO); EPO-Fc; EPOmimetic peptides (EMP), e.g., CNTO 530 and peginesatide; and methoxypolyethylene glycol-epoetin beta (CERA);

(b) Non-erythropoietic EPO-Receptor agonists, such as [~~including~~] ARA-290, asialo EPO and carbamylated EPO; and

(c) Hypoxia-inducible factor (HIF) stabilizers, such as [~~including~~]cobalt (if detected at concentrations in excess of the threshold prescribed in 810 KAR 8:010, Section 2(4)(b)), and roxadustat (FG-4592); and HIF activators, (e.g., argon, xenon).

(8)(a) Except as provided in paragraph (b) of this subsection, Chorionic Gonadotropin (CG) and Luteinizing Hormone (LH) and their releasing factors, shall be prohibited in male horses.

(b) Chorionic Gonadatropin (CG) and Luteinizing Hormone (LH) may be used in male horses if:

1. The treatment is pursuant to a valid veterinary prescription; and
2. The administering veterinarian files a treatment plan with the commission prior to administering the medication.

(9)(a) Except as provided in paragraph (b) of this subsection, Corticotrophin releasing factors and corticotrophin releasing hormones (CCRH) shall be prohibited.

(b) Adrenocorticotrophic Hormone (ACTH) may be used if the treatment is:

1. Pursuant to a valid veterinary prescription; and
2. Reported by the administering veterinarian to the commission no later than twenty-four (24) hours after administration or dispensing of the medication by the veterinarian.

(c) Growth Hormone (GH); Growth Hormone Releasing Hormone (GHRH); CJC-1295, sermorelin and tesamorelin; Growth Hormone Secretagogues (GHS); anamorelin; ipamorelin; GH-Releasing Peptides (GHRPs); alexamorelin; GHRP-6; hexarelin; and pralmorelin (GHRP-2) shall be prohibited.

(d) Venoms and toxins from sources, such as [~~including~~] snails, snakes, frogs, and bees and their synthetic analogues, such as [~~including~~] ziconotide, shall be prohibited.

(e) Growth factors, such as [~~including~~]Fibroblast Growth Factors (FGFs), Hepatocyte Growth Factor (HGF), Insulin-like Growth Factor-1 (IGF-1) and its analogues, Mechano Growth Factors (MGFs), Platelet-Derived Growth Factor (PDGF), Vascular-Endothelial Growth Factor (VEGF) and any other growth factor affecting muscle, tendon or ligament protein synthesis/degradation, vascularization, energy utilization, regenerative capacity or fiber type switching shall be prohibited.

(10) Platelet rich plasma (PRP) and autologous conditioned plasma (IRAP) may be used if the treatment is:

(a) Pursuant to a valid veterinary prescription; and

(b) Reported to the commission's representative at the time of sampling if administered within the preceding twenty-four (24) hours.

(11) All beta-2 agonists, such as [~~including~~] all optical isomers (i.e., d- and l-) where relevant, shall be prohibited.

(12) Clenbuterol and albuterol may be used if the treatment is:

(a) Pursuant to a valid veterinary prescription; [~~and~~]

(b) Reported by the administering veterinarian to the commission no later than twenty-four (24) hours after administration or dispensing of the medication by the veterinarian; and[~~.~~]

(c) Otherwise compliant with 810 KAR 8:010, Section 10.

(13)(a) Except as established in paragraphs (b) and (c) of this subsection, hormone and metabolic modulators shall be prohibited such as [~~including~~]:

1. Aromatase inhibitors, such as [~~including~~]aminoglutethimide, anastrozole, androsta-1,4,6-triene-3,17-dione (androstatrienedione), 4-androstene-3,6,17 trione (6-oxo), exemestane, formestane, letrozole, testolactone;

2. Selective estrogen receptor modulators (SERMs), such as [~~including~~] raloxifene, tamoxifen, toremifene;

3. Other anti-estrogenic substances, such as [~~including~~] clomiphene, cyclofenil, fulvestrant;

4. Agents modifying myostatin function(s), such as [~~including~~] myostatin inhibitors;

5. Activators of the AMP-activated protein kinase (AMPK), such as [~~including~~] 5-Aminoimidazole-4-carboxamide ribonucleotide (AICAR); and Peroxisome Proliferator Activated Receptor δ (PPARδ) agonists such as [~~including~~] GW 1516;

6. Insulins;

7. Trimetazidine; and

8. Thyroxine, and thyroid modulators/hormones such as [~~including~~] T4 (tetraiodothyronine/thyroxine), T3 (triiodothyronine), or combinations thereof.

(b) Thyroxine (T4) may be used:

1. The treatment is pursuant to a valid veterinary prescription; and

2. A treatment report is filed in writing or electronically with the commission within twenty-four (24) hours of the administration or dispensing of the medication by the veterinarian.

(c) Altrenogest may be used in fillies and mares if the treatment is pursuant to a valid veterinary prescription. Altrenogest may be used is permitted in intact males if the treatment is:

1. Pursuant to a valid veterinary prescription; and

2. The administering veterinarian files a treatment plan with the commission prior to administering the medication.

(14)(a) Except as provided in paragraphs (b) and (c) of this subsection, diuretics shall be prohibited, such as [~~including~~] acetazolamide, amiloride, bumetanide, canrenone, chlorthalidone, ethacrynic acid, indapamide, metolazone, spironolactone, thiazides, such as [~~including~~] bendroflumethiazide, chlorothiazide, hydrochlorothiazide, torsemide, triamterene, vasopressin receptor antagonists or vaptans, such as [~~including~~] tolvaptan.

(b) Furosemide and trichlormethiazide may be used out of competition if the treatment is:

1. Pursuant to a valid veterinary prescription; and

2. Reported at the time of sampling if administered within the preceding twenty-four (24) hours.

(c) Other diuretics, including those established in paragraph (a) ***of this subsection[~~above~~]***, may be administered in an emergency if the treatment is:

1. Pursuant to a valid veterinary prescription; and

2. Reported to the commission within twenty-four (24) hours of administration.

(15) Masking agents, such as [~~including~~] desmopressin, plasma expanders (such as [~~including~~] glycerol; intravenous administration of albumin, dextran, and hydroxyethyl starch), and probenecid, shall be prohibited.

(16) The administration or reintroduction of any quantity of autologous, allogenic (homologous) or heterologous blood or red blood cell products of any origin into the circulatory system shall be prohibited.

(17) Artificially enhancing the uptake, transport or delivery of oxygen, with perfluorochemicals, efaproxiral (RSR13), hemoglobin products, hemoglobin-based blood substitutes, and microencapsulated hemoglobin products (excluding supplemental oxygen) shall be prohibited.

(18)(a) Except as provided in paragraph (b) of this subsection, any form of intravascular manipulation of the blood or blood components by physical or chemical means shall be prohibited.

(b) The use of a hyperbaric oxygen chamber shall not be a violation of this administrative regulation.

(19) Polymers of nucleic acids or nucleic acid analogues shall not be transferred unless prior approval is requested and received from the commission or its designee.

(20) The use of normal or genetically modified hematopoietic cells shall be prohibited.

(21) Mesenchymal stem cells may be used for treatment of musculoskeletal disorders, if the treatment is:

(a) ~~*1.*~~ Entered by the veterinarian in the horse's medical record, which record shall be made available to a designee of the commission upon request;

(b) ~~*2.*~~ Pursuant to a valid veterinary prescription; and

(c) ~~*3.*~~ Reported to the commission's representative at the time of sampling.

Section 3. Out-of-Competition Testing.

(1) Any horse eligible to race in Kentucky shall be subject to testing without advance notice for the substances specified in Section 2 of this administrative regulation. A horse shall be presumed eligible to race in Kentucky if:

(a) It is under the care, custody, or control of a trainer licensed by the commission;

(b) It is owned by an owner licensed by the commission;

(c) It is nominated to a race at an association licensed pursuant to KRS 230.300;

(d) It has raced at an association licensed pursuant to KRS 230.300 within the previous twelve (12) calendar months;

(e) It is stabled on the grounds of an association licensed pursuant to KRS 230.300 or a training facility subject to the jurisdiction of the commission; or

(f) It is nominated to participate in the Kentucky Thoroughbred Development Fund, the Kentucky Standardbred Development Fund, or the Kentucky quarter horse, paint horse, Appaloosa and Arabian Development Fund.

(2) A horse subject to testing under subsection (1) of this section may be designated for testing by the executive director, the chief state steward, chief judge, or their respective designee.

(3) An owner, trainer, or any authorized designee shall fully cooperate with the commission veterinarian, or his or her designee, by:

(a) Locating and identifying any horse designated for out-of-competition testing;

(b) Making the horse available for the collection of the specimen at a place designated by the commission veterinarian, or his or her designee; and

(c) Observing the collection of the specimen.

1. If the owner, trainer or their authorized designee, is not available to observe the collection of the specimen, the collection shall be deferred until the trainer, owner, or their authorized designee[~~,~~] becomes reasonably available, but the collection shall occur no later than six (6) hours after notice of intent to collect a specimen from a horse is issued by the commission veterinarian or his or her designee.

2. If the collection does not occur within the time provided for in this subsection, any horse that is designated for testing may be barred from racing in Kentucky and placed on the veterinarian's list, pursuant to 810 KAR 8:010, Section 18 [~~17~~], and the steward's list or judges' list, for a period

of 180 days and the owner and trainer of the horse may be subject to the penalties described in Section 8 of this administrative regulation.

(4) Responsible persons.

(a) The trainer of the horse shall be responsible for the condition of a horse sampled for an out-of-competition test while on the grounds of a licensed training facility or racetrack.

(b) If the horse is sampled while not on the grounds of a licensed training facility or racetrack, the owner shall be presumed to be the responsible person unless the owner can establish, by substantial evidence, that another licensed person had accepted the responsibility for the care, custody, and control of the horse, making that person the responsible person.

(c) If a horse sampled for an out-of-competition test was claimed, sold, or otherwise transferred during the time the substance giving rise to the positive test may have been administered, then the commission shall investigate to determine, by a preponderance of the evidence, the identity of the responsible person at the time the substance may have been administered.

(d) If the commission cannot determine a responsible person, then the commission may deem the owner responsible and may place the horse on the veterinarian's list for as long as is necessary to protect the integrity of racing.

(e) If a horse designated for testing is sampled at a location not under the jurisdiction of the commission, the trainer or his designee may declare at the time of sampling any reportable substances that have been administered to the horse but have not previously been disclosed to the commission.

Section 4. Specimen Collection.

(1) A specimen shall be collected from any horse designated by the executive director, the chief state steward, the presiding judge, or their designee, whether the horse is located in Kentucky or in another jurisdiction.

(2) If a designated horse is located in another jurisdiction, the executive director or commission veterinarian may select a veterinarian from that jurisdiction's racing commission or regulatory entity to collect the specimen.

(3) At a licensed association or training facility under the jurisdiction of the commission, the commission veterinarian, or his or her designee, may collect a specimen from a horse designated for testing at any time.

(4) At a location other than the grounds of a licensed association or a training facility under the jurisdiction of the commission, the commission veterinarian, or his or her designee, shall collect the specimen between the hours of 7 a.m. and 6 p.m., prevailing time, and shall notify orally or in writing the owner, trainer, or their designee before arriving to collect the specimen.

(5) A licensed association or training facility under the jurisdiction of the commission at which a horse designated for testing is located shall cooperate fully in the collection of the specimen.

Section 5. Minimum and split samples. The commission veterinarian, in consultation with the official laboratory, shall determine minimum and split sample requirements as established at 810 KAR 8:010, Section 12 [~~11~~].

Section 6. Sample Storage and Testing.

(1) Any out of competition sample collected pursuant to this administrative regulation shall be stored in a temperature controlled unit at a secure location chosen by the commission until the sample is submitted for testing. The samples shall be secured under conditions established by the commission veterinarian in accordance with 810 KAR 8:010, Section ***13[~~12~~]*** [~~11~~].

(2) The commission is the owner of an out of competition specimen.

(3) A trainer or owner of a horse receiving notice of a report of finding from the commission may request that a split sample corresponding to the portion of the sample tested by the commission laboratory be sent to a split sample laboratory which has documented its proficiency

in detecting the substance associated with the report of finding and has been approved by the commission.

(4) Split samples shall be subject to 810 KAR 8:010, ***Sections~~[Section]~~*** 12 ***and 13*** [~~11~~], and the chain of custody of any split sample shall be maintained in accordance with 810 KAR 8:010, Section ***14~~[13]~~*** [~~12~~].

(5) The cost of testing a split sample, including shipping, shall be borne by the owner or trainer requesting the test.

Section 7. Notice of Violation and Hearing. Within five (5) business days of receipt by the stewards or judges of notification of a violation of this administrative regulation, the stewards or judges shall notify the owner and trainer orally or in writing of the violation and shall schedule a stewards' or judges' hearing within fourteen (14) calendar days of notification by the stewards or judges to the owner and trainer. The hearing may be continued if the stewards or judges determine a continuation is necessary to accommodate the parties.

Section 8. Penalty. A trainer, owner, responsible person, or any other individual who violates this administrative regulation shall be subject to the following penalties:

(1) A positive finding of a substance prohibited by this administrative regulation shall be subject to the penalties for that substance established in 810 KAR 8:010, 810 KAR 8:020, 810 KAR 8:025, and 810 KAR 8:030.

(2) If the owner, trainer, or any authorized designee fails to cooperate or otherwise prevents a horse from being tested, the horse designated for testing shall be barred from racing in Kentucky and placed on the veterinarian's list, pursuant to 810 KAR 8:010, Section 19 [~~17~~], and the steward's list or judges' list, for 180 days, and the individual or individuals responsible for the failure to cooperate or prevention of the horse from being tested shall be subject to the penalties established in subsection (4) of this section.

(3) A horse that is barred from racing in Kentucky and placed on the Veterinarian's List and the steward's list, or judges' list pursuant to subsection (4)***(b)~~[(c)]~~*** or subsection (5) of this section shall remain barred from racing and shall remain on the veterinarian's list and the steward's list or judge's list:

(a) Upon sale or transfer of the horse to another owner or trainer until the expiration of 180 days; and

(b) Until the horse is determined by the commission to test negative for any substance prohibited by this administrative regulation and is approved for racing by the commission veterinarian and the chief state steward or presiding judge.

(4)(a) Willful failure to make a horse available for sampling, tampering with or attempting to tamper in order to alter the integrity and validity of a sample, including urine substitution or adulteration, or any other deceptive acts or interference in the sampling process, shall be penalized as follows:

1. For a first offense, a Class A penalty as established in 810 KAR 8:030; or

2. For a second offense, permanent license revocation.

(b) A horse that is not produced for out of competition testing shall be placed on the Veterinarian's List for a minimum of 180 days.

(5) Failure to report treatment as required by this administrative regulation shall be penalized as follows:

(a) For a first offense, a warning; or

(b) For a second or subsequent offense, a Class D penalty as established in 810 KAR 8:030.

(6) Upon finding a violation of this administrative regulation, the horse in which the presence of a substance described in Section 2 of this administrative regulation was detected shall be barred from racing in Kentucky and placed on the veterinarian's list pursuant to 810 KAR 8:010, Section ***19~~[18]~~*** [~~17~~], and the stewards' or judges' list, for a period of up to 180 days and shall

remain barred from racing in Kentucky until the horse is determined by the commission to test negative for any substance described in Section 2 of this administrative regulation and is approved for racing by the commission veterinarian and the chief state steward or presiding judge.

(7) Upon finding a violation of this administrative regulation, the horse in which the presence of a substance described in Section 2 of this administrative regulation was detected shall remain subject to the requirements of subsection (4) of this section:

(a) Upon sale or transfer of the horse to another owner or trainer before the expiration of 180 days; and

(b) Until the horse is determined by the commission to test negative for any substance described in Section 2 of this administrative regulation and is approved for racing by the commission veterinarian and the chief state steward or presiding judge.

CONTACT PERSON: Jennifer Wolsing, General Counsel, Kentucky Horse Racing Commission, 4063 Iron Works Parkway, Building B, Lexington, Kentucky 40511, phone (859) 246-2040, fax (859) 246-2039, email jennifer.wolsing@ky.gov.

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Health Data and Analytics
Health Benefit Exchange
275 E Main St., Frankfort, KY 40621

Eric C. Friedlander
Secretary

Edith Slone
Director

Robert E. Putt
Executive Director

June 2, 2021

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: 900 KAR 10:120
900 KAR 10:125
900 KAR 10:130

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 900 KAR 10:120, 900 KAR 10:125, and 900 KAR 10:130, the Office of Health Data and Analytics proposes the attached suggested substitutes to 900 KAR 10:120, 900 KAR 10:125, and 900 KAR 10:130.

If you have any questions regarding this matter, please contact David Verry, Office of Health Data and Analytics, david.verry@ky.gov.

Sincerely,

Sarah A. Cooper
Staff Assistant
Office of Legislative and Regulatory Affairs

Final 6-1-2021

SUGGESTED SUBSTITUTE

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Health Data and Analytics
Division of Health Benefit Exchange

900 KAR 10:120. KHBE Eligibility and Enrollment in a Qualified Health Plan, SHOP, and SHOP Formal Resolution Process.

RELATES TO: KRS ***Chapter 304,*** 304.14-110, ***[~~304.17A-125,~~]*** 304.17A-243, 304.17A-245, ***[~~Chapter 304,~~]*** 26 U.S.C. 5000A, ***[~~9831,~~]*** 6011, 6012, ***9831,*** 42 U.S.C***[~~,~~]*** 18031, 26 C.F.R. 1.36B-2, 1.36B-3, 54.9801-6, 54.9802-4, 29 C.F.R. 2590.702-2, 42 C.F.R. 435.320, 45 C.F.R. 146.123, 147.104, 147.128, Parts 155, 156.

STATUTORY AUTHORITY: KRS 194A.050(1)

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Office of Health Data and Analytics, Division of Health Benefit Exchange has responsibility to administer the Kentucky Health Benefit Exchange. KRS 194A.050(1) requires the secretary of the cabinet to promulgate administrative regulations necessary to protect, develop, and maintain the health, personal dignity, integrity, and sufficiency of the individual citizens of the Commonwealth; to operate the programs and fulfill the responsibilities vested in the cabinet; and to implement programs mandated by federal law. This administrative regulation establishes the policies and procedures relating to eligibility and enrollment in a qualified health plan in the individual market, the operation of a Small Business Health Options Program, and the formal review process related to SHOP on the Kentucky Health Benefit Exchange pursuant to and in accordance with 42 U.S.C. 18031 and 45 C.F.R. Parts 155 and 156.

Section 1. Eligibility and Enrollment.

(1) An applicant shall be eligible to enroll in a QHP through the KHBE if the applicant:

(a)1. Is a citizen or national of the United States;

2. Is a non-citizen who is lawfully present in the United States and is reasonably expected to become a citizen or national; or

3. Is a non-citizen who is lawfully present for the entire period for which enrollment is sought;

(b) Except for an incarceration pending a disposition of a charge, is not incarcerated; and

(c) Meets a residency requirement in 45 C.F.R. 155.305(a)(3).

(2) An applicant may apply for a determination of eligibility at any time during a year; however, the applicant shall only enroll during open enrollment or SEPs.

(3) An applicant determined eligible for enrollment in a QHP as set forth in subsection (1) of this section shall be eligible to enroll in a QHP during:

(a) An open enrollment period as established in Section 5(2) of this administrative regulation; or

(b) A SEP as established in Sections 5(4) and 6 of this administrative regulation.

(4) An applicant shall attest to whether or not information affecting the applicant's eligibility has changed since the most recent eligibility determination if the applicant:

(a) Was determined eligible to enroll in a QHP, but:

1. Did not select a QHP within the applicable enrollment period as set forth in Section 5 or 6 of this administrative regulation; or

2. Was not eligible for an enrollment period; and

(b) Seeks a new enrollment period prior to the date on which the applicant's eligibility is redetermined as established in Section 8 of this administrative regulation.

(5) An applicant shall submit an application for enrollment in a QHP:

(a) Via the Web site ***at www.kynect.ky.gov***;

(b) By telephone;

(c) By mail; or

(d) In person.

(6)(a) An applicant who has a Social Security number shall provide the number to the KHBE.

(b) An individual who is not seeking coverage for himself or herself shall not provide a Social Security number, except as established by Section 2(8) of this administrative regulation.

(7) In accordance with 45 C.F.R. 155.310(a)(2), an individual shall not provide information regarding citizenship, status as a national, or immigration status for an individual who is not seeking coverage for himself or herself.

(8)(a) Except as established by paragraph (b) of this subsection, an applicant who requests an eligibility determination for an insurance affordability program shall have an eligibility determination for all insurance affordability programs.

(b) An applicant who requests an eligibility determination for a QHP only shall not have an eligibility determination for an insurance affordability program.

(9) An applicant shall not provide information beyond the minimum amount necessary to determine eligibility and enrollment through the KHBE.

Section 2. Eligibility Standards for Advanced Payments of the Premium Tax Credit.

(1) A tax filer shall be eligible for APTC if:

(a) The tax filer is expected to have a household income as prescribed in 45 C.F.R. 155.305(f)(1)(i) for the benefit year for which coverage is requested; and

(b) One (1) or more applicants for whom the tax filer expects to claim a personal exemption deduction on the tax filer's tax return for the benefit year:

1. Meets the requirements for eligibility for enrollment in a QHP through the KHBE as established by Section 1 of this administrative regulation; and

2. Is not eligible for minimum essential coverage, with the exception of coverage in the individual market, in accordance with 26 C.F.R. 1.36B-2(a)(2) and (c).

(2) A tax filer who is a non-citizen and lawfully present and ineligible for Medicaid for reason of immigration status shall be eligible for APTC if:

(a) The tax filer meets the requirement in subsection (1)(b) of this section;

(b) The tax filer is expected to have a household income of less than ***[~~one hundred (~~***100***[~~)~~]]*** percent of the FPL for the benefit year for which coverage is requested; and

(c) One (1) or more applicants for whom the tax filer expects to claim a personal exemption deduction on the tax filer's tax return for the benefit year is:

1. A non-citizen who is lawfully present; and

2. Not eligible for Medicaid for reason of immigration status.

(3) A tax filer shall attest that one (1) or more applicants for whom the tax filer attests that a personal exemption deduction for the benefit year shall be claimed is enrolled in a QHP that is not a catastrophic plan.

(4) A tax filer shall not be eligible for APTC if HHS notifies the KHBE that APTCs were made on behalf of the tax filer or tax filer's spouse for a year in accordance with 45 C.F.R. 155.305(f)(4).

(5) An APTC amount shall be:

(a) Calculated in accordance with 26 C.F.R. 1.36B-3; and

(b) Allocated between QHPs and stand-alone dental policies in accordance with 45 C.F.R. 155.340(e).

(6) An applicant for APTC may accept less than the full amount of APTC for which the applicant is determined eligible.

(7) An APTC shall be authorized by the KHBE on behalf of a tax filer only if the KHBE obtains necessary attestations from the tax filer that:

(a) The tax filer shall file an income tax return for the benefit year in accordance with 26 U.S.C. 6011 and 6012;

(b) If the tax filer is married, a joint tax return shall be filed for the benefit year;

(c) Another taxpayer shall not be able to claim the tax filer as a dependent for the benefit year; and

(d) The tax filer shall claim a personal exemption deduction on the tax filer's return for the applicants identified as members of the tax filer's family, including the tax filer and the spouse of the tax filer, in accordance with 45 C.F.R. 155.305(f)(4).

(8) An application filer who is not an applicant shall provide the Social Security number of a tax filer only if the applicant attests that the tax filer:

(a) Has a Social Security number; and

(b) Filed a tax return for the year for which tax data would be utilized for verification of household income and family size.

(9) The effective date for APTC shall be:

(a) For an initial eligibility determination, in accordance with the dates established by Section 5(1), (2), (3) and (4) ***of this administrative regulation***, as applicable; and

(b) For a redetermination, in accordance with the dates established by 45 C.F.R. 155.330(f) and 155.335(i), as applicable.

(10) An employer shall be notified of an employee's eligibility for APTC in accordance with 45 C.F.R. 155.310 (h).

Section 3. Eligibility Standards for Cost Sharing Reductions.

(1) An applicant shall be eligible for CSRs if the applicant:

(a) Meets the eligibility requirements for enrollment in a QHP as set forth in Section 1 of this administrative regulation;

(b) Meets the requirements for APTC as set forth in Section 2 of this administrative regulation;

(c) Is expected to have a household income that does not exceed the amount established by 45 C.F.R. 155.305(g)(1)(i)(C) for the benefit year for which coverage is requested; and

(d) Except for an enrollee who is an Indian, enrolls in a silver level QHP through the KHBE.

(2) An eligibility determination for CSRs shall be based on the categories as described in 45 C.F.R. 155.305(g)(2).

(3) If two (2) or more individuals enrolled in the individual market under a single policy would be eligible for different cost sharing amounts if enrolled in separate policies, the individuals under the single policy shall be ***found~~[deemed]~~*** by the KHBE to be collectively eligible only for the last category listed in 45 C.F.R. 155.305(g)(3) for which all the individuals covered by the policy would be eligible.

(4) The effective date for CSRs shall be:

(a) For an initial eligibility determination, in accordance with the dates established by Section 5(1), (2), (3), and (4) of this administrative regulation, as applicable; and

(b) For a redetermination, in accordance with the dates established by 45 C.F.R. 155.330(f) and 45 C.F.R. 155.335(i), as applicable.

(5) An employer shall be notified of an employee's eligibility for CSRs in accordance with 45 C.F.R. 155.310(h).

Section 4. Verification Processes.

(1) Verification of eligibility for an applicant seeking enrollment in a QHP shall be performed in accordance with:

(a) 45 C.F.R. 155.315; and

(b) ***The*** Kentucky QHP/APTC Eligibility Verification Plan.

(2) Verification of eligibility for an applicant or tax filer who requests an eligibility determination for an insurance affordability program shall be in accordance with:

(a) 45 C.F.R. 155.320; and

(b) ***The*** Kentucky QHP/APTC Eligibility Verification Plan.

Section 5. QHP Enrollment Periods and Effective Dates of Coverage.

(1) A qualified individual shall enroll in a QHP or an enrollee may change from one (1) QHP to another QHP during an open enrollment period.

(2) The timeframe for an open enrollment period shall be established by the Secretary of the Cabinet for Health and Family Services.

(3) A qualified individual or enrollee who selects a QHP during an open enrollment period shall have an effective date of coverage of:

(a) January 1, if a QHP selection is made on or before December 15 of the previous year;

(b) If after December 15, the first day of the following month, if a QHP selection is made between the first and the fifteenth of a month; or

(c) If after December 15, the first day of the second following month, if a QHP selection is made between the sixteenth and last day of a month.

(4)(a) A qualified individual shall enroll in a QHP or an enrollee may change from one (1) QHP to another QHP during a SEP as established by Section 6 of this administrative regulation.

(b) A qualified individual or an enrollee who selects a QHP during a SEP shall have an effective date of coverage as set forth in Section 6 of this administrative regulation.

(5) An initial enrollment in a QHP shall not be effective until the first month's premium is received by the QHP issuer.

Section 6. Special Enrollment Periods.

(1) Except as established by subsection (3) of this section, a qualified individual or enrollee shall have sixty (60) days from the date of a qualifying event as set forth in subsection (2) of this section to select a QHP.

(2) A qualified individual may enroll in a QHP or an enrollee or a dependent of an enrollee may change QHPs during a SEP if:

(a) The qualified individual or a dependent of the qualified individual:

1. Loses minimum essential coverage;

2. Is enrolled in any non-calendar year group health plan, individual health insurance coverage, or qualified small employer reimbursement arrangement even if the qualified individual or his or her dependent has the option to renew or reenroll in ***the~~[such]~~*** coverage;

3. Loses pregnancy-related coverage described in 45 C.F.R. 155.420(d)(1)(iii);

4. Loses medically needy coverage as described under 42 C.F.R. 435.320 only once per calendar year; or

5. Is enrolled in coverage under 26 C.F.R. 54.9801– 6(a)(3)(i) through (iii) for which an employer is paying all or part of the premiums and the employer ceases its contributions;

(b) The qualified individual gains a dependent or becomes a dependent through marriage, birth, adoption, placement for adoption, placement in foster care, a child support order, or other court order;

(c) The qualified individual, or a dependent of the qualified individual, who was not previously a citizen, national, or lawfully present gains status as a citizen, national, or lawfully present;

(d) The enrollee is determined newly eligible or newly ineligible for APTC;

(e) The enrollee or a dependent of the enrollee becomes newly eligible for CSRs and is not enrolled in a silver-level QHP;

(f) The enrollee or a dependent of the enrollee becomes newly ineligible for CSRs and is enrolled in a silver-level QHP;

(g) The qualified individual or a dependent of the qualified individual who is enrolled in qualifying coverage in an employer-sponsored plan is determined newly eligible for APTC in part on a finding that the individual ***shall[~~will~~]*** no longer be eligible for qualifying coverage in the employer-sponsored plan in the next sixty (60) days and is allowed to terminate existing coverage;

(h) The qualified individual or enrollee or a dependent of the qualified individual or the enrollee:

1. Gains access to new QHPs as a result of a permanent move; and

2. Had MEC for one (1) of more days during the sixty (60) days preceding the date of the permanent move;

(i) The qualified individual is an Indian who may enroll in a QHP or change from one (1) QHP to another QHP one (1) time per month;

(j) The qualified individual is or becomes a dependent of an Indian and is enrolled or is enrolling in a QHP on the same application as the Indian, and may change from one (1) QHP to another QHP one (1) time per month, at the same time as the Indian;

(k) The qualified individual or enrollee or a dependent of the qualified individual or enrollee is no longer incarcerated;

(l) The qualified individual or enrollee, or a dependent of the qualified individual or enrollee:

1. Gains access to an individual HRA; or

2. Is newly provided a QSEHRA arrangement;

(m) The plan in which the enrollee or a dependent of the enrollee is enrolled is decertified by the division;

(n) The enrollee loses a dependent or is no longer considered a dependent through divorce or legal separation;

(o) The enrollee or a dependent of the enrollee dies;

(p) The qualified individual or enrollee:

1. Is a victim of domestic abuse or spousal abandonment as defined by 26 C.F.R. 1.36B-2, or a dependent of the qualified individual or enrollee, or an unmarried victim of domestic abuse or spousal abandonment residing within the same household as the qualified individual or enrollee;

2. Is enrolled in MEC; and

3. Sought to enroll in coverage separate from the perpetrator of abuse or abandonment;

(q) The qualified individual or enrollee:

1. Is a dependent of an individual described in paragraph (i) of this subsection;

2. Is on the same application as the individual described in paragraph (i) of this subsection; and

3. Enrolls at the same time as the individual described in ***paragraph[~~subsection (2)~~]***(i) of this ***subsection[~~section~~]***;

(r) The qualified individual or enrollee:

1. Applies for coverage during:

a. An annual open enrollment period; or

b. If there is a qualifying event, a SEP; and

2. Is determined ineligible for Medicaid or KCHIP:

a. After open enrollment has ended; or

b. More than sixty (60) days after the qualifying event;

(s) The qualified individual or dependent of the qualified individual enrolls or fails to enroll in a QHP due to an error, misrepresentation, or inaction of an officer, employee, or representative of the KHBE;

(t) The enrollee or dependent of the enrollee demonstrates to the KHBE that the QHP in which the enrollee or the dependent of the enrollee is enrolled substantially violated a provision of its contract in relation to the enrollee or dependent;

(u) The qualified individual or enrollee, or a dependent of the qualified individual or enrollee, demonstrates to the KHBE that a material error related to a plan benefit, service area, or premium influenced the qualified individual's or enrollee's decision to purchase a QHP though KHBE; ***Material errors may include any incorrect premium, copay, co-insurance or deductible amount as well as services covered or providers included in network***;

(v) The qualified individual:

1. a. Was previously ineligible for APTC because of a household income below 100 percent of the FPL; and

b. Was ineligible for Medicaid due to living in a non-Medicaid expansion state during the same timeframe; and either

2. a. Experiences a change in household income; or

b. Makes a permanent move to the Commonwealth of Kentucky resulting in the individual becoming newly eligible for APTC;

(w) The qualified individual or a dependent of the qualified individual:

1. Experiences a decrease in household income;

2. Is newly determined eligible by the KHBE for APTC; and

3. Had MEC for one (1) or more days during the sixty (60) days preceding the date of the change in household income; or

(x) The qualified individual or a dependent of the qualified individual meets other exceptional circumstances as defined by 45 C.F.R. 155.420(d)(9).

(3) The date of the triggering event for the loss of minimum essential coverage shall be:

(a) For a decertification of a QHP as set forth in 900 KAR 10:115, the date of the notice of decertification;

(b) For an event described in subsection (2)(a)2. of this section, the last day of the plan year;

(c) For an event described in subsection (2)(a)5. of this section, the last day of the period for which COBRA continuation coverage is paid for, in part or in full, by an employer; or

(d) For all other cases, the date the qualified individual or dependent of the qualified individual loses eligibility for minimum essential coverage.

(4) Loss of minimum essential coverage shall include those circumstances described in 26 C.F.R. 54.9801–6(a)(3)(i) through (iii).

(5) Loss of minimum essential coverage shall not include termination or loss due to:

(a) Failure to pay premiums on a timely basis; or

(b) A situation allowing for a rescission as established by 45 C.F.R. 147.128.

(6) Except as established by subsection (7), (8), or (9) of this section, a qualified individual or enrollee who selects a QHP during a SEP shall have an effective date of coverage of:

(a) The first day of the following month for a selection made between the first and the fifteenth day of any month; or

(b) The first day of the second following month for a selection made between the sixteenth and last day of any month.

(7) A qualified individual or enrollee who selects a QHP:

(a) For a birth, adoption, placement for an adoption, placement in foster care, or child support or other court order, shall have an effective date of coverage of either:

1. The date of the birth, adoption, placement for adoption, placement in foster care, or effective date of court order; or

2. If the qualified individual or enrollee elects:

a. The first of the month following plan selection; or

b. In accordance with subsection (6) of this section;

(b) For a marriage, shall have an effective date of coverage of the first day of the month following plan selection;

(c) For a loss of coverage as described in subsection (2)(a) of this section, for a gain of access to a new QHP as a result of a permanent move as described in subsection (2)(h) of this

section, or for being newly eligible for enrollment in a QHP as described in subsection (2)(c) or (2)(k) of this section, if:

1. The plan selection is made on or before the day of the triggering event, shall have a coverage effective date of the first day of the month following the triggering event; or

2. The plan selection is made after the date of the triggering event, shall have a coverage effective date in accordance with this subsection; or

(d) For a death as described in subsection (2)(o) of this section, shall have a coverage effective date:

1. Of the first day of the month following a plan selection; or

2. In accordance with paragraph (c) of this subsection.

(8) A qualified individual, enrollee, or dependent of the qualified individual or enrollee who selects a QHP as described in subsection (2)(g) ***of this section*** shall have a coverage effective date:

(a) If the plan selection is made before the day of the triggering event:

1. On the first day of the month following the triggering event; or

2. If the triggering event is on the first day of a month, on the date of the triggering event; or

(b) If the plan selection is made on or after the day of the triggering event, on the first day of the month following plan selection.

(9) A qualified individual or enrollee who selects a QHP in accordance with subsection (2)(a)4.,(r), (s), (t), (u),or (v) of this section shall have a coverage effective date based on the circumstances of the SEP.

(10)(a) An individual described in subsection (2)(g) of this section may access a SEP sixty (60) days prior to the end of the individual's qualifying coverage in the employer-sponsored plan.

(b) An individual who accesses a SEP as set forth in paragraph (a) of this subsection shall not be eligible for APTCs until the end of the individual's qualifying coverage through the eligible employer-sponsored plan.

(11) If an existing enrollee becomes newly eligible for CSRs and is not enrolled in a silver plan, the enrollee may choose a silver plan.

(12) If an enrollee and a dependent of an enrollee become newly ineligible for CSRs and are enrolled in a silver-level QHP, the enrollee may change to a QHP one (1) metal level higher or lower.

(13) If an enrollee gains a dependent due to marriage, birth, adoption, foster care, or court order, the enrollee shall:

(a) Not change plans; and

(b) Either:

1. Add the new dependent to the enrollee's current enrollment; or

2. Enroll the new dependent in a plan of any plan category.

(14) Except for the qualifying events established by subsection (2)(i), (l), (p), (u), and (v) of this section and the events described in subsections (11), (12), and (13) of this section:

(a) If an enrollee qualifies for a SEP, the enrollee may change to a QHP within the same level of coverage;

(b) If a dependent of an enrollee qualifies for a SEP and the enrollee does not also qualify for a SEP, the enrollee shall add the dependent to the enrollee's current QHP; or

(c) If a qualified individual who is not an enrollee qualifies for a SEP and has a dependent who is an enrollee who does not qualify for a SEP, the qualified individual shall be added to the dependent's current QHP.

(15) For a qualified individual, enrollee, or dependent described in subsection (2)(l) of this section, the triggering event shall be:

(a) The first day on which coverage for the qualified individual, enrollee, or dependent under the individual coverage HRA can take effect; or

(b) The first day on which coverage under the QSEHRA takes effect.

(16) A qualified individual, enrollee, or dependent described in subsection (2)(l) of this section shall:

(a) Qualify for a SEP regardless of whether they were previously offered or enrolled in an individual HRA or previously provided a QSEHRA, if:

1. The qualified individual, enrollee, or dependent is not enrolled in the individual coverage HRA; or

2. The qualified individual, enrollee, or dependent is not covered by the QSEHRA on the day immediately prior to the triggering event; and

(b)1. Have sixty (60) days before the triggering event to select a QHP; or

2. Have sixty (60) days before or after the triggering event if the HRA or QSEHRA was not required to provide the notice described in 45 C.F.R. 146.123(c)(6), 26 C.F.R. 54.9802-4(c)(6), and 29 C.F.R. 2590.702-2(c)(6) or 26 U.S.C. 9831(d)(4).

Section 7. Verifications for Special Enrollment Periods.

(1) KHBE shall conduct pre-enrollment verification of newly enrolling individuals as established by this section.

(2) A QHP enrollment for an individual subject to verification shall not be submitted to the issuer pending verification for a SEP.

(3) For an enrollment subject to verification as described in this section, a new enrollee shall have thirty (30) days from the date of plan selection to provide requested documentation.

(4) A qualifying individual described in Section 6(2)(h) of this administrative regulation shall provide proof of:

(a) A permanent move during the past sixty (60) days; and

(b) Either:

1. Having had minimum essential coverage for one (1) or more days during the sixty (60) days preceding the date of the qualifying event; or

2. Having:

a. Lived in a foreign county or in a US territory for one (1) or more days during the sixty (60) days preceding the qualifying event;

b. Lived in a service area where no qualified health plan was available through KHBE for ***one*** (1) or more days during the sixty (60) days preceding the qualifying event or their most recent open enrollment or SEP; or

c. Status as an Indian.

(5) For a marriage, as described in Section 6(2)(b) of this administrative regulation, a qualified individual shall provide proof of marriage during the past sixty (60) days.

(6) Other than as described in subsections (4) and (5) of this section, a qualified individual described in Section 6(2)(b) of this administrative regulation shall provide proof of:

(a) The qualifying event during the past sixty (60) days; and

(b) Either:

1. Having minimum essential coverage as described in Section 6(2)(a) of this administrative regulation for one (1) or more days during the sixty (60) days preceding the date of the qualifying event; or

2. Meeting the requirements in subsection (4)(b) of this section.

(7) For a loss of minimum essential coverage as described in Section 6(2)(a) of this administrative regulation, a qualified individual shall provide proof of coverage for one (1) or more days during the past sixty (60) days.

(8) SEP verification shall not impact an enrollee's effective date of coverage except as provided in 45 C.F.R. 155.400(e)(1)(iii).

Section 8. Eligibility Redetermination During a Benefit Year.

(1) Eligibility shall be redetermined for an enrollee during a benefit year if the KHBE receives and verifies:

(a) New information reported by an enrollee; or

(b) Updated information obtained in accordance with 45 C.F.R. 155.330(d).

(2) Except as established by subsection (3) of this section, an enrollee or an application filer, on behalf of an enrollee, shall report within thirty (30) days:

(a) A change related to an eligibility standard in Section 1, 2, 3, 9, or 10 of this administrative regulation; and

(b) Via a method described in Section 1(5) of this administrative regulation.

(3) An enrollee who did not request an eligibility determination for an insurance affordability program shall not report a change related to income.

(4) If new information provided by an enrollee in accordance with subsection (1)(a) of this section is verified:

(a) Eligibility shall be redetermined in accordance with the standards in Section 1, 2, 3, 9, or 10 of this administrative regulation;

(b) The enrollee shall be notified of the redetermination in accordance with the requirements in 45 C.F.R. 155.310(g); and

(c) If applicable, the enrollee's employer shall be notified in accordance with the requirement established by 45 C.F.R. 155.310(h).

(5) If updated information obtained in accordance with subsection (1)(b) of this section regarding death or related to eligibility not regarding income, family size, or family composition is identified, an enrollee shall:

(a) Be notified by the KHBE of:

1. The updated information; and

2. The projected enrollees' eligibility determination after consideration of the information; and

(b) Have thirty (30) days from the date of the notice in paragraph (a) of this subsection to notify the KHBE if the information is inaccurate.

(6) If an enrollee responds to the notice in subsection (5)(a) of this section, contesting the updated information in the notice, the KHBE shall proceed in accordance with 45 C.F.R. 155.315(f).

(7) If an enrollee does not respond to the notice in subsection (5)(a) of this section within the thirty (30) day timeframe specified in subsection (5)(b) of this section, the KHBE shall:

(a) Redetermine eligibility in accordance with the standard in Section 1, 2, 3, 9, or 10 of this administrative regulation; and

(b) Notify the enrollee regarding the determination in accordance with the requirements established by 45 C.F.R. 155.310(g).

(8) With the exception of information regarding death, if updated information regarding income, family size, or family composition is identified, an enrollee shall:

(a) Be notified by the KHBE of:

1. The updated information regarding income, family size, and family composition obtained in accordance with subsection (1)(b) of this section; and

2. The projected eligibility determination after consideration of the information; and

(b) Have thirty (30) days from the date of the notice to:

1. Confirm the updated information; or

2. Provide additional information.

(9) If the enrollee responds to the notice in subsection (8)(a) of this section by confirming the updated information, the KHBE shall:

(a) Redetermine the enrollee's eligibility in accordance with Section 1, 2, 3, 9, or 10 of this administrative regulation; and

(b) Notify the enrollee regarding the determination in accordance with the requirements established by 45 C.F.R. 155.310(g).

(10) If the enrollee does not respond to the notice in subsection (8)(a) of this section within the thirty (30) day timeframe established by subsection (8)(b) of this section, the KHBE shall maintain the enrollee's existing eligibility determination without considering the updated information in subsection (8)(a) of this section.

(11) If the enrollee responds with more updated information, the KHBE shall verify the updated information in accordance with 45 C.F.R. 155.315 and 155.320.

(12) The effective date of a change resulting from a redetermination pursuant to this section shall be in accordance with 45 C.F.R. 155.330(f).

(13) The amount of an APTC or eligibility for a CSR as a result of an eligibility redetermination in accordance with this section shall be recalculated in accordance with 45 C.F.R. 155.330(g).

Section 9. Annual Eligibility Redetermination.

(1) A qualified individual shall:

(a) Have an annual redetermination of eligibility; and

(b) Be sent a notice of the annual redetermination that includes:

1. The data obtained under subsection (2) of this section;

2. The data used in the qualified individual's most recent eligibility determination; and

3. The projected eligibility determination for the following year, after considering the information in subparagraph 1. of this paragraph.

(2)(a) A qualified individual requesting an eligibility determination for an insurance affordability program shall authorize the release of updated tax return information, data regarding Social Security benefits, and data regarding MAGI-based income as described in 45 C.F.R. 155.320(c)(1) for use in the qualified individual's eligibility redetermination.

(b) Eligibility shall not be redetermined for a qualified individual requesting an eligibility determination for an insurance affordability program who does not authorize the release of updated tax return information.

(3) A qualified individual may authorize the release of tax return information for a period of no more than five (5) years based on a single authorization, if the authorization permits the qualified individual to:

(a)1. Decline to authorize the release of updated tax return information; or

2. Authorize the release of updated tax return information for fewer than five (5) years; and

(b) Discontinue, change, or renew the authorization at any time.

(4) A qualified individual, an application filer, or an authorized representative, on behalf of the enrollee, shall report any changes with respect to the information listed in the notice described in subsection (1)(b) of this section:

(a) Within thirty (30) days from the date of the notice; and

(b) Via a method listed in Section 1(5) of this administrative regulation.

(5) Any information reported by a qualified individual under subsection (4) of this section shall be verified as set forth in Section 4 of this administrative regulation.

(6) For a qualified individual who fails to act on the notice described in subsection (1)(b) of this section within the thirty (30) day period established by subsection (4) of this section, eligibility shall be redetermined as set forth in subsection (7)(a) of this section.

(7)(a) After the thirty (30) day period established by subsection (4) of this section:

1. Eligibility of a qualified individual shall be redetermined in accordance with the standards in Section 1, 2, 3, 9, or 10 of this administrative regulation using the information provided in the notice, as supplemented with any information reported by the qualified individual verified in accordance with Section 4 of this administrative regulation;

2. The qualified individual shall be notified in accordance with the requirements in 45 C.F.R. 155.310(g); and

3. If applicable, the qualified individual's employer shall be notified in accordance with 45 C.F.R. 155.310(h).

(b) If a qualified individual reports a change with respect to the information provided in the notice established by subsection (1)(b) of this section that has not been verified by the KHBE as of the end of the thirty (30) day period established by subsection (4) of this section, eligibility shall be redetermined after verification in accordance with Section 4 of this administrative regulation.

(8) The effective date of a redetermination in accordance with this section shall be the later of:

(a) The first day of the coverage year following the year in which the notice in subsection (1)(b) of this section is issued to the qualified individual; or

(b) The date determined in accordance with 45 C.F.R. 155.330(f)(1).

(9) If an enrollee remains eligible for coverage in a QHP upon annual redetermination and has not terminated coverage from the QHP in accordance with Section 10 of this administrative regulation, the enrollee shall:

(a) Remain in the QHP selected the previous year that may include modifications that shall be approved by the Department of Insurance; or

(b) Be enrolled by KHBE in a QHP that is substantially similar that shall be approved by the Department of Insurance.

(10) Eligibility shall not be redetermined if a qualified individual was redetermined eligible in accordance with this section during the prior year, and the qualified individual was not enrolled in a QHP ***when[***~~**at the time of**~~***]*** the redetermination and has not enrolled in a QHP since the redetermination.

Section 10. Eligibility to Enroll in a QHP that is a Catastrophic Plan.

(1) In addition to the requirements in Section 1 of this administrative regulation, to enroll in a QHP that is a catastrophic plan, an applicant shall:

(a) Not have attained the age of thirty (30) before the beginning of the plan year; or

(b) Have a certificate of exemption from the shared responsibility payment issued by the KHBE or HHS for a plan year in accordance with:

1. 26 U.S.C. 5000A(e)(1); or

2. 26 U.S.C. 5000A(e)(5).

(2) Verification related to eligibility for enrollment in a QHP that is a catastrophic plan shall be in accordance with 45 C.F.R. 155.315(j).

Section 11. Special Eligibility Standards and Processes for Indians.

(1) An applicant who is an Indian shall be eligible for the special cost sharing described in 45 C.F.R. 155.350(b) if the applicant:

(a) Meets the requirements established by 45 C.F.R.155.305(a) and (f);

(b) Is expected to have a household income that does not exceed the amount established by 45 C.F.R. 305(g)(3)(vi) for the benefit year for which coverage is requested; and

(c) Enrolls in a QHP through the KHBE.

(2) An applicant who is an Indian shall have an eligibility determination for the special cost sharing described in ***[***~~**section**~~***]*** 45 C.F.R. 155.350(b) without requesting an eligibility determination for an insurance affordability program.

Section 12. Eligibility Determination and Notification Standards.

(1) Eligibility shall be determined in accordance with 45 C.F.R. 155.310(e).

(2) Notifications regarding eligibility determinations shall be made in accordance with 45 C.F.R. 155.310(g).

Section 13. Termination of Coverage.

(1) An enrollee, including an enrollee who has obtained other minimum essential coverage, may terminate coverage in a QHP by submitting a request:

(a) Via the Web site ***at www.kynect.ky.gov***;

(b) By telephone;

(c) To the QHP issuer;

(d) By mail; or

(e) In person.

(2) An enrollee in a QHP may choose to remain in a QHP without financial assistance if the enrollee:

(a)1. Has been identified as eligible for other minimum essential coverage through the data matching described in 45 C.F.R. 155.330(d); or

2. Has been identified as eligible for Medicaid, KCHIP, or Medicare and has granted prior permission to KHBE; and

(b) Does not request termination in accordance with subsection (1) of this section.

(3) The last day of coverage of an enrollee who terminates coverage in accordance with subsection (1) of this section shall be:

(a) The termination date requested by the enrollee if the enrollee provides reasonable notice in accordance with subsection (7) of this section;

(b) Fourteen (14) days after the termination is requested by the enrollee, if the enrollee does not provide reasonable notice in accordance with subsection (7) of this section;

(c) A date determined by the issuer of an enrollee's QHP if the issuer is able to terminate coverage in fewer than fourteen (14) days and the enrollee requests an earlier termination effective date; or

(d) If the enrollee is newly eligible for Medicaid or KCHIP, the day before coverage in Medicaid or KCHIP begins.

(4) An enrollee's health coverage shall be terminated by an issuer if:

(a) The enrollee is no longer eligible for coverage in a QHP through the KHBE;

(b) The enrollee has failed to pay a premium; and

1. A three (3) month grace period required for an individual receiving an APTC has been exhausted as described in 45 C.F.R. 156.270(g); or

2. A thirty (30) day grace period required by KRS 304.17A-243 for an individual not receiving an APTC has been exhausted;

(c) The enrollee's coverage is rescinded in accordance with 45 C.F.R. 147.128 or KRS 304.14-110;

(d) The enrollee is enrolled in a QHP that:

1. Has been decertified pursuant to 900 KAR 10:115; or

2. Has withdrawn from participation in the KHBE; or

(e) The enrollee changes from one (1) QHP to another during an open enrollment period or SEP in accordance with Section 5 or 6 of this administrative regulation.

(5) The last day of coverage of an enrollee shall be:

(a) If terminated in accordance with subsection (4)(a) of this section, the last day of the month following the month in which the notice described in subsection (7) of this section is sent by KHBE, unless the enrollee requests an earlier termination date in accordance with subsection (3) of this section;

(b) If terminated in accordance with subsection (4)(b)1. of this section, the last day of the first month of the three (3) month grace period; or

(c) If terminated in accordance with subsection (4)(b)2. of this section, in accordance with KRS 304.17A-245.

(6) For an enrollee who is terminated in accordance with subsection (4)(e) of this section, the last day of coverage in an enrollee's prior QHP shall be the day before the effective date of coverage in the enrollee's new QHP.

(7) Reasonable notice shall be fourteen (14) calendar days from the requested date of termination of coverage.

Section 14. Authorized Representative.

(1) An individual may designate an authorized representative in accordance with 45 C.F.R. 155.227.

(2) An authorized representative shall comply with state and federal laws regarding:

(a) Conflict of interest; and

(b) Confidentiality of information.

(3) An applicant may authorize a representative to:

(a) Sign an application on behalf of the applicant;

(b) Submit an update or respond to a redetermination of eligibility for the applicant in accordance with Section 7 or 8 of this administrative regulation;

(c) Receive a copy of a notice or communication from the KHBE;

(d) Make an appeal request on behalf of an appellant; and

(e) Act on behalf of the individual in a matter with the KHBE.

(4) An authorization for an authorized representative shall be valid until:

(a) An applicant:

1. Changes the authorization; or

2. Notifies the KHBE and the authorized representative, through a method described in 45 C.F.R. 155.405(c), that the authorized representative is no longer authorized to act on behalf of the individual; or

(b) The authorized representative informs the KHBE and the individual that the authorized representative is no longer acting as the authorized representative.

Section 15. SHOP Employer Eligibility.

(1) An employer shall be a qualified employer and eligible to purchase coverage through SHOP if the employer meets the eligibility requirements established in 45 C.F.R. 155.710(b).

(2) An employer shall apply for an eligibility determination online to participate in SHOP ***at www.kynect.ky.gov***.

(3) ***Upon[~~At the time of~~]*** application, an employer shall provide:

(a) Employer name;

(b) Address of employer location;

(c) A valid federal employer identification number; and

(d) ***A statement from the employer attesting that[~~Information sufficient to confirm~~]*** the employer is:

1. A small employer; and

2. Offering at a minimum, all full-time employees coverage in a QHP through SHOP.

(4) Except as provided in 45 C.F.R. 147.104(b)(1)(i)(B), a qualified employer shall meet a minimum group participation rate of fifty (50) percent, calculated as described in 45 C.F.R. 155.706 (b)(10)(i).

(5) A qualified employer may purchase coverage for its qualified employees at any time during the year.

(6) An employer's plan year shall be the twelve (12) month period beginning with the effective date of coverage.

(7) An employer shall enroll in a QHP or SADP certified by the division by contacting an issuer or a participating agent.

(8) A qualified employer who ceases to be a small employer by reason of an increase in the number of employees shall be eligible to participate in SHOP until the employer:

(a) Fails to otherwise meet the eligibility criteria of this section; or

(b) Chooses to no longer purchase health coverage.

(9) An employer that fails to meet the requirements in subsection (1) of this section, shall be denied eligibility to participate in SHOP.

Section 16. SHOP Right to Formal Review.

(1) An employer applicant may request a formal review of a:

(a) Denial of eligibility as set forth in Section 15(9) of this administrative regulation; or

(b) Failure of the KHBE to make an eligibility determination to participate in SHOP within fifteen (15) calendars days of receiving an application from an employer.

(2) Within ninety (90) days of receipt of a notice of denial of eligibility, an employer may submit a formal review request to the division:

(a) By telephone;

(b) By mail; or

(c) By email.

(3) A formal review request shall clearly state a reason for the formal review in accordance with subsection (1) of this section.

(4) If an employer is notified that a formal review request does not meet the requirements of this section, the employer may amend the request to satisfy the requirements.

Section 17. SHOP Dismissal of a Formal Review.

(1) A formal review by an employer shall be dismissed if the employer:

(a) Withdraws the formal review request in writing; or

(b) Fails to submit a formal review request that meets the requirements in Section 16 of this administrative regulation.

(2) If a formal review is dismissed in accordance with subsection (1) of this section, the division shall provide written notice to the employer:

(a) Within three (3) business days of the dismissal; and

(b) That includes the reason for dismissal.

(3) The division may reverse a dismissal under subsection (2) of this section if an employer makes a written request within thirty (30) days of the date of the notice of dismissal in subsection (2) of this section ***and provides new information supporting a reversal of the previous decision*** ~~***[showing good cause why the dismissal shall be reversed]***~~.

Section 18. SHOP Desk Review.

(1) An employer shall have the opportunity to submit evidence to the division for review of an eligibility determination.

(2) The division shall consider:

(a) The information used to determine the employer's eligibility; and

(b) Any additional evidence provided by the employer under subsection (1) of this section.

(3) An applicant's formal review request shall be desk reviewed by one (1) or more impartial division officials who have not been directly involved in the eligibility determination implicated in the formal review.

Section 19. SHOP Formal Review Decision.

(1) A desk review by an official of the division shall result in a final formal review decision.

(2) A final formal review decision shall:

(a) Be in writing;

(b) Be based on the eligibility requirements in Section 15 of this administrative regulation;

(c) State the decision and the effect of the decision on the eligibility of the employer;
(d) Summarize the facts relevant to the formal review;
(e) Identify the legal and regulatory basis for the decision;
(f) State the effective date of the decision; and
(g) Be rendered within ninety (90) days of receipt by the division of an employer formal review request.

(3) The division shall issue written notice of the formal review decision to the employer within ninety (90) days of the date of receipt of a formal review request.

(4) If the formal review decision affects the employer's eligibility, the division shall implement the formal review decision.

Section 20. SHOP Formal Review Record. The formal review record shall be available and accessible to an employer:
(1) In a convenient format; and
(2) During regular business hours, which shall:
(a) Be Monday through Friday from 8:00 a.m. to 4:30 p.m.; and
(b) Exclude holidays.

Section 21. Incorporation by Reference.
(1) "Kentucky QHP/APTC Eligibility Verification Plan", Revised March, 2021, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Division of Health Benefit Exchange, 275 East Main Street 4WE, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m., or from its Web site at www.khbe.ky.gov.

CONTACT PERSON: Krista Quarles, Policy Advisor, 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
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Eric C. Friedlander
Secretary

June 2, 2021

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

RE: 900 KAR 10:120 - Agency Amendment

Dear Co-Chairs West and Hale:

After receiving guidance from the Centers for Medicare and Medicaid Services, the Office of Health Data and Analytics proposes the attached amendment to 900 KAR 10:120. If you have any questions, please feel free to contact David Verry at david.verry@ky.gov or Melea Rivera at meleaj.rivera@ky.gov.

Sincerely,
Sarah A Cooper
Sarah A. Cooper
Staff Assistant
Office of Legislative and Regulatory Affairs

Agency Amendment

Cabinet for Health and Family Services
Office of Health Data and Analytics
Division of Health Benefit Exchange

900 KAR 10:120. KHBE Eligibility and Enrollment in a Qualified Health Plan, SHOP, and SHOP Formal Resolution Process.

Page 6
Section 2(10)
Line 8

After "An employer", insert "may", delete "shall"

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Health Data and Analytics
Health Benefit Exchange
275 E Main St., Frankfort, KY 40621

Eric C. Friedlander
Secretary

Edith Slone
Director

Robert E. Putt
Executive Director

June 2, 2021

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: 900 KAR 10:120
900 KAR 10:125
900 KAR 10:130

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 900 KAR 10:120, 900 KAR 10:125, and 900 KAR 10:130, the Office of Health Data and Analytics proposes the attached suggested substitutes to 900 KAR 10:120, 900 KAR 10:125, and 900 KAR 10:130.

If you have any questions regarding this matter, please contact David Verry, Office of Health Data and Analytics, david.verry@ky.gov.

Sincerely,
Sarah A Cooper

Sarah A. Cooper
Staff Assistant
Office of Legislative and Regulatory Affairs

Final, 6-1-2021

SUGGESTED SUBSTITUTE

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Health Data and Analytics
Division of Health Benefit Exchange

900 KAR 10:125. KHBE Consumer Assistance Program, kynector Certification, and Individual Agent Participation with the KHBE.

RELATES TO: KRS Chapter 45A, ***Chapter 304,*** 304.2-310, ***29[~~Chapter 304, 26~~]*** U.S.C. 794, 42 U.S.C. 12101-12103, ***18022,*** 18031, ***18042, 18054,*** 45 C.F.R. Part 155***, 156***

STATUTORY AUTHORITY: KRS 194A.050(1)

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Office of Health Data and Analytics, Division of Health Benefit Exchange has responsibility to administer the Kentucky Health Benefit Exchange. KRS 194A.050(1) requires the secretary of the cabinet to promulgate administrative regulations necessary to protect, develop, and maintain the health, personal dignity, integrity, and sufficiency of the individual citizens of the Commonwealth; to operate the programs and fulfill the responsibilities vested in the cabinet; and to implement programs mandated by federal law. This administrative regulation establishes the policies and procedures relating to the registration of an individual agent and certification of a kynector, including a certified application counselor or navigator in accordance with 42 U.S.C. 18031 and 45 C.F.R. Part 155.

Section 1. KHBE Consumer Assistance Programs.

(1) The kynector program, in accordance with the accessibility standards of ***45[~~42~~]*** C.F.R. 155.205(c) and (d), shall include the following:

(a) The certified application counselor program described in Section 2 of this administrative regulation; and

(b) The navigator program described in Section 3 of this administrative regulation.

(2) A kynector shall:

(a) Receive training in accordance with 45 C.F.R. 155.215(b)(2) that shall be provided by the division or an approved vendor;

(b) Complete Medicaid, KCHIP, and other applicable training provided by CHFS;

(c) Complete all training required by the division within three (3) attempts;

(d) Enter into an agreement with the division to comply with the applicable standards of 45 C.F.R. 155.205, 155.210, 155.215, and 155.225 and this administrative regulation;

(e) Refer a consumer to other consumer assistance programs and community resources in Kentucky if available and appropriate;

(f) Be prepared to serve the individual exchange, Medicaid program, KCHIP, and other programs as designated by the secretary of CHFS; and

(g) Comply with the privacy and security standards consistent with 45 C.F.R. 155.260.

Section 2. Certified Application Counselor Program.

(1) The certified application counselor program shall comply with the provisions of 45 C.F.R. 155.225.

(2) An organization shall apply to the division to be designated as a certified application counselor.

(3) Upon designation by the division to participate in the certified application counselor program, an organization shall:

(a) Act in the best interest of an applicant;

(b) Provide information in a manner that is accessible to individuals with disabilities directly or through a referral to a kynector; and

(c) Provide quarterly reports of an activity to the division.

(4) A staff or a volunteer of a certified application counselor organization shall act as a kynector to:

(a) Provide information about an insurance affordability program and a QHP or SADP coverage option;

(b) Assist an individual to apply through the KHBE for coverage in a QHP, SADP, or an insurance affordability program; and

(c) Help to facilitate enrollment of a qualified individual in a QHP, SADP, or an insurance affordability program.

(5) An individual operating as a certified application counselor shall:

(a) Be identified by a designated organization described in subsection (2) of this section as an employee or a volunteer of the designated organization;

(b) Agree to act in the best interest of an applicant;

(c) Provide information with reasonable accommodation for an individual with a disability, as defined by 42 U.S.C. 12101 through 12103, if providing in-person assistance; and

(d) Register with the division through the KOG.

(6) A certified application counselor shall not:

(a) Impose any charge or fee on an applicant for application assistance;

(b) Receive compensation or a referral fee from an agent; or

(c) Enter into an exclusive referral agreement with an agent.

(7) In accordance with the procedures established in Section 4 of this administrative regulation, the division shall withdraw certification from a kynector or kynector entity if it finds noncompliance with the terms and conditions of the kynector or kynector entity agreement or this administrative regulation.

Section 3. Navigator Program.

(1) In accordance with 45 C.F.R. 155.205(d) and (e), ***[~~45 C.F.R.~~]***155.210, and ***[~~45 C.F.R.~~]*** 155.215, the division shall establish a navigator program to authorize an eligible public or private entity to carry out consumer assistance functions as described in 45 C.F.R. 155.205 and this section.

(2) An entity wishing to participate as a navigator shall:

(a) Be awarded a contract by the division pursuant to policies and procedures established by the Finance and Administration Cabinet and KRS Chapter 45A;

(b) Designate an individual as the participating entity representative who shall:

1. Register with the division through the KOG as the individual authorized by the agency;

2. Serve as a primary contact for the division;

3. Be responsible for ensuring that only an employee of the navigator agency is registered through KOG as a certified navigator;

4. Comply with 45 C.F.R. 155.210(b)(1) and (d) regarding a conflict of interest; and

5. As a navigator employee, comply with this subsection;

(c) Designate an individual employee who shall participate through the navigator entity and who shall register with the division through the KOG;

(d) Submit to the division a written plan to remain free of conflicts of interest while carrying out consumer assistance functions under 45 C.F.R. 155.205(d) and (e), and ***[~~45 C.F.R.~~]***155.210; and

(e) Provide a monthly report of activities to the division.

(3) An employee designated as a navigator by the kynector entity shall:

(a) Be eighteen (18) years of age or older;

(b) Provide an authorization to the navigator entity to conduct a state background check for evidence of good character; and

(c) Travel, if necessary, to assist an applicant with enrollment.

(4) A navigator entity and its employees shall:

(a) Inform an applicant of the functions and responsibilities of a navigator and a participating agent;

(b) Obtain authorization for the disclosure of applicant information prior to assisting an applicant with prescreening and completion of the application process; and

(c) Provide technical support to another navigator, navigator entity, or the division upon request.

(5) Upon authorization by the division, a navigator may assist:

(a) A qualified individual with enrollment in any QHP or SADP offered though the KHBE in the individual market;

(b) A small employer with applying for an eligibility determination online to participate on SHOP; or

(c) An individual with applying for insurance affordability programs, including Medicaid or KCHIP, and other public assistance programs as designated by KHBE.

(6) A navigator entity and its employees shall:

(a) Maintain expertise in eligibility, enrollment, and program specifications and conduct public education activities to raise awareness about a QHP, SADP, or an insurance affordability program; and

(b) Provide information and services in a fair, accurate, and impartial manner.

(7) A navigator entity and its employees shall not:

(a) Impose any charge or fee on an applicant for their assistance;

(b) Receive compensation or a referral fee from an agent; or

(c) Enter into an exclusive referral agreement with an agent.

(8) A navigator entity and its employees shall provide information in a manner that is culturally and linguistically appropriate to the needs of the population being served by the exchange, including individuals with limited English proficiency, and ensure accessibility and usability of navigator tools and functions for individuals with disabilities in accordance with the Americans with Disabilities Act, 42 U.S.C. 12101, Section 504 of the Rehabilitation Act, and 29 U.S.C. 794.

(9) A navigator entity or its employees shall provide a referral to the DOI for any enrollee or qualified individual with a grievance, complaint, or question regarding a health plan, coverage, or a determination under the plan or coverage.

(10) A navigator entity or its employees shall demonstrate to the division that the entity has existing relationships, or could readily establish relationships, with:

(a) Consumers, including uninsured and underinsured consumers; or

(b) Self-employed individuals eligible for a QHP, SADP, or another insurance affordability program.

(11)(a) In accordance with Section 4 of this administrative regulation, the division shall withdraw certification if it finds noncompliance with the terms and conditions of the agreement from:

1. An individual navigator; or

2. A navigator entity.

(b) In addition to withdrawal of certification, the division may enforce any penalty as specified in the contract.

Section 4. Withdrawal of Certification of a kynector and Appeals.

(1) If the division finds noncompliance with the terms and conditions of an agreement or this administrative regulation, the division shall:

(a) Provide the kynector entity or kynector with notice that the applicable certification shall be withdrawn as of the date on the notice;

(b) Allow the kynector entity or kynector an opportunity to submit evidence of compliance or additional information within ten (10) business days;

(c) Review any information submitted by the kynector entity or kynector; and

(d) Based on a review of the information provided, issue a final decision to withdraw or reinstate the applicable certification of the kynector entity or kynector.

(2) A kynector entity or kynector may appeal a final decision to withdraw the applicable certification by submitting a written request to the division within ten (10) business days of the final decision.

(3) After one (1) year following a decision to withdraw certification of a kynector entity or kynector, the kynector or kynector entity may reapply in accordance with this administrative regulation.

Section 5. Requirements to be a Participating Individual Agent. An agent wishing to participate on KHBE in accordance with 42 U.S.C. 18031 and 45 C.F.R. 155.220 shall:

(1) Be licensed by DOI with a health line of authority;

(2) Complete the agent training provided by the division in accordance with 45 C.F.R. 155.220(d)(2) within three (3) attempts;

(3) Enter into an agreement with the division to comply with the applicable standards of 45 C.F.R. 155.205 and 155.220 and this administrative regulation;

(4) Comply with the privacy and security standards of 45 C.F.R. 155.260;

(5) Except for an employee of an issuer or an individual agent directly contracted with an issuer, maintain:

(a) An appointment with at least one (1) QHP or SADP issuer participating on the KHBE; or

(b) A designation with a business entity having an appointment with at least one (1) QHP or SADP issuer participating on the KHBE;

(6) Register with the KHBE through the KOG; and

(7) Not serve as a web broker or consultant while assisting individuals with the activities described in Section 6 of this administrative regulation.

Section 6. Permitted Activities of a Participating Individual Agent.

(1) Upon completion of the registration requirements as set forth in Section 5 of this administrative regulation, a participating individual agent may:

(a) Enroll a qualified individual in any QHP or SADP offered by an issuer with which the individual agent has the appropriate designation or appointment as required by Section 5(5) of this administrative regulation through the KHBE in the individual market;

(b) Assist a qualified employer in selecting a QHP or SADP offered by an issuer with which the individual agent has the appropriate designation or appointment as required by Section 5(5) of this administrative regulation; or

(c) Assist an individual to apply through the KHBE for coverage in a QHP, SADP, or an insurance affordability program.

(2) A qualified individual may be enrolled in a QHP or SADP through the KHBE by a participating individual agent if the participating individual agent ensures the applicant's completion of an application as described in ***45[42]*** C.F.R. 155.405.

(3) A participating individual agent shall:

(a) Disclose to a potential applicant any relationships the individual agent has with a QHP or SADP issuer, insurance affordability program, or other potential conflicts of interest identified by the division; and

(b) Not:

1. Impose any charge or fee on an applicant for assistance in completing an application for, or enrolling in, a QHP, a SADP, or an insurance affordability program;

2. Provide compensation or a referral fee to a kynector; and

3. Enter into an exclusive referral agreement with a kynector.

(4) If the division finds noncompliance with this administrative regulation, the division shall withdraw an agent's registration and participation with the KHBE after giving:

(a) Notice to the participating individual agent; and

(b) An opportunity to respond to the notice required by paragraph (a) of this subsection in accordance with Section ***8[~~5~~]*** of this administrative regulation.

Section 7. Renewal of Participation and Registration with the Division. To maintain registration with the division, a participating individual agent shall:

(1) Comply with training provided by the division;

(2) Enter into an agreement with the division to comply with the applicable standards of 45 C.F.R. 155.205 and 155.220 and this administrative regulation;

(3) Maintain licensure, appointments, and designations as identified in Section 5 of this administrative regulation;

(4) Comply with the requirements of 45 C.F.R. 155.220; and

(5) Comply with 900 KAR Chapter 10.

Section 8. Withdrawal of Registration as an Individual Agent and Appeals.

(1)(a) Except as ***established[~~provided~~]*** in subsection (2) of this section, if the division finds noncompliance with the terms and conditions of an individual agent agreement or 900 KAR Chapter 10, the division shall:

1. Provide the participating individual agent with notice that the applicable registration shall be withdrawn as of the date of notice;

2. Allow the participating individual agent an opportunity to submit evidence of compliance or additional information within ten (10) business days;

3. Review any information submitted by the participating individual agent; and

4. Based on a review of the information provided, issue a decision to uphold the withdrawal or reinstate the applicable registration of a participating individual agent.

(b) A participating individual agent shall have the right to appeal a decision to withdraw registration in accordance with paragraph (a) of this subsection through the division.

(2)(a) If the health line of authority or licensure of an agent is suspended, revoked, or expired, the registration of the agent shall be withdrawn by the division based on DOI's administrative action.

(b) Any appeal or request of an action by DOI pursuant to paragraph (a) of this subsection shall be made to DOI in accordance with KRS 304.2-310(2)(b).

(3) After one (1) year following a decision to withdraw the registration of a participating individual agent, the individual agent may reapply in accordance with Section 5 of this administrative regulation.

CONTACT PERSON: Krista Quarles, Policy Advisor, 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
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June 2, 2021

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: 900 KAR 10:120
900 KAR 10:125
900 KAR 10:130

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 900 KAR 10:120, 900 KAR 10:125, and 900 KAR 10:130, the Office of Health Data and Analytics proposes the attached suggested substitutes to 900 KAR 10:120, 900 KAR 10:125, and 900 KAR 10:130.

If you have any questions regarding this matter, please contact David Verry, Office of Health Data and Analytics, david.verry@ky.gov.

Sincerely,

Sarah A. Cooper
Staff Assistant
Office of Legislative and Regulatory Affairs

Final 6-1-2021

SUGGESTED SUBSTITUTE

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Health Data and Analytics
Division of Health Benefit Exchange

900 KAR 10:130. Appeals of Eligibility for KHBE Participation and Insurance Affordability Programs.

RELATES TO: KRS 13B.050, 13B.080, 13B.090, 13B.110, 13B.120, 13B.140, 42 U.S.C. 18031, 26 C.F.R. 1.36B-4, 45 C.F.R. Parts 155, 156

STATUTORY AUTHORITY: KRS 194A.050(1)

NECESSITY, FUNCTION, AND CONFORMITY: The Cabinet for Health and Family Services, Office of Health Data and Analytics, Division of Health Benefit Exchange has responsibility to administer the Kentucky Health Benefit Exchange. KRS 194A.050(1) requires the secretary of the cabinet to promulgate administrative regulations necessary to protect, develop, and maintain the health, personal dignity, integrity, and sufficiency of the individual citizens of the Commonwealth; to operate the programs and fulfill the responsibilities vested in the cabinet; and to implement programs mandated by federal law. This administrative regulation establishes the policies and procedures relating to appeals of eligibility determinations for KHBE participation and insurance affordability programs on the Kentucky Health Benefit Exchange pursuant to and in accordance with 42 U.S.C. 18031 and 45 C.F.R. Parts 155 and 156.

Section 1. Right to Appeal an Individual Eligibility Determination or Redetermination.

(1) An applicant or an enrollee ***may*** ~~***[shall have the right to]***~~ make an appeal request of:

(a) An eligibility determination made in accordance with 45 C.F.R. 155.300 to 155.355 and 900 KAR 10:120, including:

1. An initial determination of eligibility for enrollment in a QHP or SADP, including the amount of APTC and CSR, made in accordance with the standards specified in 45 C.F.R. 155.305(a) through (h); or

2. A redetermination of eligibility, including the amount of APTC and CSR, made in accordance with 45 C.F.R. 155.330 and 155.335;

(b) A determination of eligibility for an enrollment period;

(c) A failure by the KHBE to provide ***within twenty (20) days*** ~~***[timely]***~~ notice of an eligibility determination pursuant to 45 C.F.R. 155.310(g), 155.330(e)(1)(ii), 155.335(h)(1)(ii), or 155.610(i); or

(d) A denial of a request to vacate dismissal made by DAH in accordance with 45 C.F.R. 155.530(d)(2), made pursuant to Section 8(3) of this administrative regulation.

(2) An appeal request that fails to meet the criteria in subsection (1) of this section shall not be considered an acceptable appeal request, and the division shall send written notice to the appellant to:

(a) State the appeal request has not been accepted and explain the nature of the defect in the appeal request; and

(b) Explain that the applicant or enrollee may cure the defect and resubmit the appeal request within ninety (90) days of the notice of action.

(3) Upon exhaustion of the appeal process established in this administrative regulation, an appellant ***may*** ~~***[shall have the right to]***~~:

(a) Appeal to HHS in accordance with 45 C.F.R. 155.520(c); and

(b) Seek a judicial review of an appeal decision pursuant to KRS 13B.140.

(4) The DAH shall conduct an appeal of an individual eligibility determination, except for an eligibility determination for an exemption made in accordance with 45 C.F.R. 155.605.

(5) An appeal of an eligibility determination of an exemption shall be conducted by HHS.

Section 2. Individual Appeal Designation of a Representative.

(1) An appellant may represent himself or herself or be represented during an appeal process by:

(a) Legal counsel;

(b) A relative;

(c) A friend; or

(d) Another individual not listed in paragraph (a), (b), or (c) of this subsection.

(2) The division shall designate a representative to act on behalf of the division for the hearing.

Section 3. Individual Appeal Notice of Appeal Rights.

(1) An applicant or an enrollee shall be notified of the right to appeal, timeframe to file an appeal, and how to file an appeal ***when~~[at the time]~~***:

(a) The applicant submits an application; and

(b) A notice of eligibility determination is sent by KHBE under 45 C.F.R. 155.310(g) or 155.330(e)(1)(ii), or by HHS under 45 C.F.R. 155.610(i).

(2) A notice described in subsection (1) of this section shall include:

(a) An explanation of the applicant or enrollee's appeal rights in accordance with this administrative regulation;

(b) A description of the procedure and timeframe within which to request an appeal;

(c) Information on the applicant or enrollee's right to represent himself or herself or to be represented by legal counsel or other authorized person as identified in Section 2 of this administrative regulation;

(d) An explanation of the circumstances under which the appellant's or enrollee's eligibility may be maintained or reinstated pending an appeal decision in accordance with Section 7 of this administrative regulation; and

(e) An explanation that an appeal decision for one (1) household member may result in a:

1. Change in eligibility for another household member; or

2. Redetermination of eligibility in accordance with 900 KAR 10:120.

Section 4. Individual Appeal Requests.

(1) An applicant or an enrollee may submit an appeal request:

(a) By phone;

(b) By mail;

(c) In person; or

(d) Via the internet.

(2) Upon request, the division or the DAH shall assist an applicant or enrollee in filing an appeal.

(3) An applicant or enrollee's right to appeal shall not be limited or interfered with by an employee or representative of the division.

(4) An applicant or enrollee shall have thirty (30) days from the date of notice of an eligibility determination or redetermination to submit an appeal request.

Section 5. Individual Appeal Informal Resolution Completed by the Division.

(1) After receiving an appeal request, the division shall:

(a) Conduct a desk review of an appeal prior to sending the appeal to the DAH; and

(b)1. Except ***established*** ~~***[as provided]***~~ in subparagraph 2. of this paragraph, complete the review within fifteen (15) calendar days of receipt of the appeal request; or

2. For an expedited appeal request submitted in accordance with Section 10 of this administrative regulation, complete the review within three (3) business days.

(2) An appellant shall:

(a) Have the right to a hearing if the appellant is dissatisfied with the outcome of the informal resolution process; and

(b) Not have to provide duplicative information or documentation previously provided during the application process.

(3) The outcome of an informal resolution shall be final and binding and the appeal shall not advance to a hearing if the appellant:

(a) Is satisfied with the outcome of the informal resolution process: and

(b) Withdraws his or her appeal request in accordance with Section 11 of this administrative regulation.

(4) If an appellant is dissatisfied with the outcome of the information resolution process, KHBE shall send:

(a) The appeal request and all documents utilized by the division in the desk review to DAH no later than five (5) business days after the completion of the informal resolution process; and

(b) A written notice to the appellant that includes:

1. Notification that the appeal request has been sent to DAH for a hearing;

2. Information regarding the appellant's eligibility pending appeal in accordance with Section 7 of this administrative regulation; and

3. An explanation that any APTCs paid on behalf of a tax filer pending appeal are subject to reconciliation under 26 C.F.R. 1.36B-4.

Section 6. Individual Appeal Acknowledgement of Appeal Request and Eligibility Record by DAH.

(1) A request for an appeal sent by KHBE to the DAH shall be reviewed by DAH to ensure that the appeal request is valid.

(2) Upon receipt of a valid appeal request, the DAH shall:

(a) Send ***within thirty (30) days*** ~~***[timely]***~~ notice to the appellant of receipt of the valid appeal, to include the hearing requirements contained in Section 9 of this administrative regulation; and

(b) Confirm receipt of the records transferred by KHBE pursuant to Section 5(4)(a) of this administrative regulation.

(3) The DAH shall consider an appeal request valid if the request:

(a) Was incorrectly delivered or mailed to a department or division of the Cabinet for Health and Family Services; and

(b) Is otherwise valid.

(4) Upon receipt of an appeal request that is not valid, the DAH shall:

(a) Send written notice to the appellant and KHBE that the appeal request has not been accepted and of the nature of the defect in the appeal request; and

(b) Accept an amended appeal request as valid that meets the requirements of this administrative regulation.

Section 7. Individual Eligibility Pending Appeal.

(1) An appellant who has submitted an acceptable request as described in Section 1 of this administrative regulation of a redetermination of eligibility in accordance with Section 4 of this administrative regulation shall be considered eligible while the appeal is pending.

(2) If a tax filer or appellant accepts eligibility pending an appeal of an eligibility redetermination, the appellant's eligibility for an APTC or CSR or enrollment in a QHP or SADP as applica-

ble shall be continued in accordance with the level of eligibility immediately before the redetermination being appealed.

(3) An appellant may waive receipt of APTCs pending the outcome of an appeal.

(4) The continued receipt of APTCs during an appeal may impact the amount owed or due by an appellant during the reconciliation process set forth in 26 C.F.R. 1.36B-4, depending upon the appeal decision.

(5) Eligibility pending appeal shall not be applicable to an appellant appealing an initial denial of eligibility for APTCs.

Section 8. Individual Dismissal of an Appeal.

(1) An appeal shall be dismissed by DAH if the appellant:

(a) Withdraws the appeal request in accordance with Section 11 of this administrative regulation;

(b) Fails to appear at a scheduled hearing without good cause;

(c) Fails to submit a valid appeal request as specified in Section 4 of this administrative regulation; or

(d) Dies while the appeal is pending.

(2) If an appeal is dismissed in accordance with subsection (1) of this section, DAH shall provide ***within thirty (30) days[~~timely~~]*** written notice to the appellant and the division that includes:

(a) The reason for the dismissal;

(b) An explanation of the effect of the dismissal on the appellant's eligibility;

(c) An explanation of how the appellant may show good cause why the dismissal should be vacated in accordance with subsection (3)(a) of this section;

(d) A statement of the eligibility determination to be implemented; and

(e) A statement discontinuing eligibility provided under Section 7 of this administrative regulation, if applicable.

(3) DAH shall:

(a) Vacate a dismissal under this section and proceed with the appeal if the appellant makes a written request within thirty (30) days of the date of the notice of the dismissal showing good cause why the dismissal should be vacated; and

(b) Provide ***within thirty (30) days[~~timely~~]*** written notice of the recommendation to the secretary of the Cabinet for Health and Family Services to deny the request to vacate a dismissal to the appellant, if the request is denied.

(4) Good cause for the purposes of this section shall include if the appellant:

(a) Was away from home during the entire filing period;

(b) Is unable to read or to comprehend the right to request a hearing on an adverse action notice;

(c) Moved, resulting in delay in receiving or failure to receive the adverse action notice;

(d) Had a household member who was seriously ill;

(e) Was not at fault for the delay of the request, as determined by the hearing officer; or

(f) Did not receive the notice.

Section 9. Individual Hearing Requirements.

(1) DAH shall provide written notice to the appellant and the division that:

(a) Acknowledges the appeal request as required by Section 6(2) of this administrative regulation; and

(b) Meets the notice requirements established by KRS 13B.050(3).

(2) An appellant ***may[~~shall have the opportunity to~~]***:

(a) Upon request, obtain from the division, copies of the appeal record, including all documents and records to be used at the hearing, prior to the date of the hearing, and during the hearing;

(b) Bring witnesses to testify;

(c) Establish all relevant facts and circumstances;

(d) Present an argument without undue interference; and

(e) Question or refute any testimony or evidence, including the opportunity to confront and cross-examine an adverse witness.

(3) The DAH shall:

(a) Consider the information used to determine an appellant's eligibility;

(b) Consider additional relevant evidence presented during the course of the appeal, including at the hearing; and

(c) Review the appeal without deference to a prior decision in the appeal case.

(4) A hearing shall be conducted:

(a) In accordance with the requirements of KRS 13B.080 and KRS 13B.090;

(b) At a reasonable date, time, and location or format;

(c) After notice of the hearing provided pursuant to subsection (1) of this section;

(d) Consistent with subsection (3) of this section; and

(e) By one (1) or more impartial hearing officers who have not been directly involved in the eligibility determination or any prior appeal decision in the same matter.

Section 10. Individual Expedited Appeals.

(1) An appellant ***may make[~~shall have the right to~~]*** an expedited appeal if:

(a) There is an immediate need for a health service; and

(b) The standard appeal process established in Section 9 of this administrative regulation ***may[~~could~~]*** seriously endanger the appellant's life, health, or ability to attain, maintain, or regain maximum function.

(2) An expedited appeal shall be requested in the same manner as a standard appeal as set forth in Section 4 of this administrative regulation.

(3) If an expedited appeal is requested, an appellant shall submit evidence of the reason for the expedited appeal.

(4) If an expedited appeal request under this section is denied by the DAH, the DAH shall:

(a) Conduct the appeal under the standard appeal process as set forth in Section 9 of this administrative regulation;

(b) Inform the appellant through electronic or oral notification, if possible, of the denial within the timeframes established by the secretary of HHS; and

(c) If notification is oral, follow up with the appellant by written notice.

(5) A written notice pursuant to subsection (4)(c) of this section shall include:

(a) The reason for the denial;

(b) An explanation that the appeal request shall be transferred to the standard process described in Section 9 of this administrative regulation; and

(c) An explanation of the appellant's rights under the standard process in Section 9 of this administrative regulation.

Section 11. Individual Withdrawal of an Appeal. If an appellant wants to withdraw an appeal, the appellant shall withdraw a request for an appeal:

(1) In writing;

(2) Orally to KHBE staff during an informal resolution process described in Section 5 of this administrative regulation; or

(3) Orally to the hearing officer during an appeal proceeding.

Section 12. Individual Hearing Decision.

(1) After the hearing is concluded or a decision is made not to reverse a dismissal of an appeal, the hearing officer shall issue a recommended order in accordance with the requirements of KRS 13B.110.

(2) A recommended order rendered by the DAH shall be based only on the:

(a) Information and evidence specified in 45 C.F.R. 155.535(e);

(b) Eligibility requirements in 900 KAR 10:120;

(c) Eligibility requirements under 45 C.F.R. 155.300 to 155.355; and

(d) Record of the appeal and hearing.

(3) A recommended order shall:

(a) Be sent to the appellant and the appellant's authorized representative, if applicable, and the division;

(b) State the decision;

(c) Include a plain language description of the effect of the decision on an appellant's eligibility;

(d) Summarize the facts relevant to the appeal;

(e) Identify the legal basis, including an administrative regulation that supports the decision; and

(f) State the effective date of the decision.

(4) If either the appellant or the division is dissatisfied with the recommended order, either party shall have fifteen (15) days from the date the recommended order is mailed to file exceptions to the recommendations with the secretary of the Cabinet for Health and Family Services.

(5) The secretary of the Cabinet for Health and Family Services shall consider the appeal record, including the recommended order and any exceptions filed to a recommended order, in accordance with KRS 13B.120.

(6) The secretary of the Cabinet for Health and Family Services shall:

(a) Accept the recommended order of the hearing officer and adopt it as the agency's final order;

(b) Reject or modify, in whole or in part, the recommended order; or

(c) Remand the matter, in whole or in part, to the hearing officer for further proceedings as appropriate.

(7) The secretary of the Cabinet for Health and Family Services shall:

(a) Issue written notice of the final order to the appellant and include in that notice the appellant rights to a judicial review afforded under KRS 13B.140 within ninety (90) days of the date an appeal request under Section 4 of this administrative regulation is received;

(b) If an appeal request is submitted under Section 10 of this administrative regulation that is determined to meet the criteria for an expedited appeal, issue the final order as expeditiously as:

1. The appellant's health condition requires; and

2. Reasonably possible, consistent with the timeframe established by the secretary of HHS; and

(c) Provide notice of the appeal decision and instructions to cease pended eligibility to:

1. The appellant, if applicable; and

2. The division.

(8) Upon receipt of a notice described in subsection (7)(a) of this section, the division shall:

(a) Implement the appeal decision:

1. Retroactive to the date the incorrect eligibility determination was made; or

2. At a time determined under 45 C.F.R. 155.330(f); and

(b) Redetermine the eligibility of a household member who has not appealed an eligibility determination, but whose eligibility may be affected by the appeal decision, in accordance with the standards described in:

1. 900 KAR 10:120; and
2. 45 C.F.R. 155.305.

Section 13. Individual Right to Appeal to HHS.

(1) If an appellant disagrees with an appeal decision made in accordance with Section 12 of this administrative regulation or notice of denial of a request to vacate a dismissal under Section 8(3)(b) of this administrative regulation, the appellant may request an appeal from HHS within thirty (30) days of the date of the appeal notice.

(2) Upon receipt of a notice of an appeal under subsection (1) of this section, DAH shall transmit via secure electronic interface the appellant's appeal record, including the appellant's eligibility record received from KHBE, to HHS.

(3) An applicant or an enrollee denied a request for an exemption by HHS under 45 C.F.R. 155.625(b) may appeal the decision to HHS.

Section 14. Individual Appeal Release of Records.

(1) An appellant shall have access to the information used by the KHBE to determine his or her eligibility.

(2) An appellant shall have access to his or her appeal record:

(a) Upon written request;

(b) At a place and time convenient to the appellant; and

(c) Subject to all applicable federal and state laws regarding privacy, confidentiality, disclosure, and personally identifiable information.

(3) The public shall have access to an appeal decision, subject to all applicable federal and state laws regarding privacy, confidentiality, disclosure, and personally identifiable information.

CONTACT PERSON: Krista Quarles, Policy Advisor, 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

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Eric C. Friedlander
Secretary

June 3, 2021

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 2:211E. Covering the Face in Response to Declared National or State Public Health Emergency.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 2:211E, the Department for Public Health proposes the enclosed suggested amendment to 902 KAR 2:211E If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at 564-3970, extension 4069.

Sincerely,

Sarah A. Cooper

Sarah A. Cooper
Staff Assistant
Office of Legislative and Regulatory Affairs

AGENCY AMENDMENT

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Epidemiology and Health Planning

902 KAR 2:211E. Covering the Face in Response to Declared National or State Public Health Emergency.

Page 2
Section 2(1)
Lines 7-9

After "public in Kentucky.", delete the following:

Existing sector-specific requirements mandating face coverings for employees of entities in the Commonwealth remain in effect and are available online at: https://healthyatwork.ky.gov.

Page 2
Section 2(2)
Line 10

After "by subsection", insert "(4)".
Delete "(3)".

Page 2
Section 2(2)(a)
Line 12

After "(a)", insert the following:

Is riding on public transportation or paratransit, including planes, buses, and trains, traveling into, within, or out of the United States and in U.S. transportation hubs, including airports and stations;
(b) Is in a K-12 educational, preschool, daycare, or other child care setting, including any student, employee, staff member, or visitor;
(c) Is in a healthcare setting; or
(d) Is in a long-term care setting.
(3) The following are strongly encouraged to cover their nose and mouth with a face covering:
(a) An inmate, employee, staff person, or visitor in a correctional facility;
(b) Any person who is in a homeless shelter, including employees of the shelter or volunteers; or
(c) Anyone who is immune-compromised, or who is exhibiting symptoms of COVID-19, or who has tested positive for COVID-19 in the prior ten (10) days.
(4)

Delete the following:

Is inside[~~, or waiting in line to enter,~~] any:

1. Retail establishment;
2. Grocery store;
3. Pharmacy;
4. Hair salon or barbershop;
5. Nail salon or spa;
6. Tattoo parlor;
7. Child care facility;
8. Restaurant or bar, if not seated and consuming food or beverage;
9. Gym, fitness studio, or any other indoor exercise or sports facility, including while actively engaged in exercise;
10. Health care setting; or
11. Other indoor public space in which it is difficult to maintain a physical distance of at least six (6) feet from all individuals who are not members of that person's household;
(b)1. Is [~~waiting for or~~] riding on public transportation or paratransit;
2. Is riding in a taxi, private car service, or ride-sharing vehicle; or
3. Is driving a vehicle described in subparagraph 1. or 2. of this paragraph while a customer is present; or
(c) Is in an outdoor public space or venue with 1,000 or more people in attendance [~~in which the person cannot maintain a physical distance of six (6) feet from all individuals who are not members of the person's household and is not otherwise covered by previously issued guidance~~].
(3)

Page 3
Section 2(3)
Line 12

After "(a)", insert the following:

A person who has received the final dose of a COVID-19 vaccine at least fourteen (14) days prior;
(b)

Delete the following:

1. Except as provided in subparagraph 2. of this paragraph,

Page 3
Section 2(3)
Line 15

Renumber paragraph "(b)" as paragraph "(c)".

After the newly inserted "(c)", delete the following:

or
2. A child who is younger than first grade while in attendance at a child care facility;
(b)

Page 3
Section 2(3)

Line 17

Renumber paragraph (c) as paragraph (d).

Page 3
Section 2(3)
Line 18

After "who is deaf or hard of hearing,", delete the following:

if the individual is able to maintain a safe distance of six (6) feet from all individuals who are not members of that person's household

Page 3
Section 2(3)
Line 21

Delete paragraph (d) in its entirety.

Page 4
Section 2(3)(e)
Line 1

After "or beverage service;", insert "or".

Page 4
Section 2(3)(f)
Line 2 through 13

After "(f)", delete the following:

Obtaining a service that requires temporary removal of the face covering in order to perform or receive the service;

(g) Required to temporarily remove the face covering to confirm the person's identity or for security or screening purposes;

(h)1. Giving a speech or broadcast to an audience; and

2. Able to maintain a safe distance of six (6) feet from all individuals who are not members of the person's household;

(i) In a swimming pool, lake, or other body of water;

(j) Exempt from wearing a face covering under guidance provided by the Kentucky High School Athletics Association or under guidance for athletic activities at an institution of higher education; or

(k)

Page 4
Section 3
Line15

After "Non-Compliance.", delete the following:

(1)(a) The requirements of this administrative regulation that pertain to a business or other public-facing entity shall be enforced by the Labor Cabinet, the Department for Public Health, another state regulatory agency, and each local health department.

(b)

Pages 4
Section 3
Line 22

Delete the remaining subsections of this section in their entirety.

Page 6
Section 6
Line 10

Delete this section in its entirety.

CABINET FOR HEALTH AND FAMILY SERVICES
Office of the Secretary

Andy Beshear
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Eric C. Friedlander
Secretary

June 1, 2021

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 4:150. Enhanced HANDS services in response to declared national or state public health emergency.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 4:150, the Department for Public Health proposes the enclosed suggested substitute to 902 KAR 4:150.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at 564-3970, extension 4069.

Sincerely,

Lucie Estill

Lucie Estill
Executive Staff Advisor
Office of Legislative and Regulatory Affairs

Final Version 4/23/2021 12:19 PM

SUGGESTED SUBSTITUTE TO *ORDINARY ONLY*

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Maternal and Child Health

902 KAR 4:150. Enhanced HANDS services in response to declared national or state public health emergency.

RELATES TO: KRS 13B.080 - 13B.160, 200.700, 211.090, 211.180, 211.689
STATUTORY AUTHORITY: KRS 194A.050, 211.690
NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.050(1) requires the Secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary to operate the programs and fulfill the responsibilities vested in the cabinet. KRS 211.690 authorizes the Cabinet for Health and Family Services to implement a voluntary statewide home visitation program for the purpose of providing assistance to at-risk parents. This administrative regulation establishes the provisions for providing home visitation through tele-service delivery methods if a national or state public health emergency has been declared.

Section 1. Definitions. (1) "Declared national or state public health emergency" means a formal declaration by the President of the United States or the Governor of Kentucky of an extraordinary event that is determined to constitute a public health risk through the spread of disease.
(2) "Tele-service" means a home visitation service provided through telephone or video communication with the HANDS provider, parent, and child present in real time.

Section 2. Enhanced Home Visitation Services in Response to a Declared National or State Public Health Emergency. (1) HANDS services and requirements may be enhanced to allow for tele-service delivery methods if a national or state public health emergency has been declared.
(2)(a) HANDS home visitation services that are otherwise designated as face-to-face in accordance with 902 KAR 4:120 may be provided through tele-service delivery methods with informed parental consent.
(b) These services ***shall*** include those listed in 902 KAR 4:120, ***Sections~~[Section]~~*** 2(4), 2(5), and 4.
(c) Verbal and written consent shall be provided for each child in a shared household. For example, if the family has twins, verbal and written consent shall be provided for each baby.
(3) Tele-service delivery methods shall be reimbursed at the usual and customary rate.
(4) Tele-service delivery methods in the manner ***established~~[prescribed]~~*** by this section shall only be utilized during a declared national or state public health emergency.

CONTACT PERSON: Krista Quarles, Policy Analyst, 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.

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Eric C. Friedlander
Secretary

June 1, 2021

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 30:210. Enhanced early intervention services in response to declared national or state public health emergency.

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 902 KAR 30:210, the Department for Public Health proposes the enclosed suggested substitute to 902 KAR 30:210.

If you have any questions regarding this matter, please contact Julie Brooks, Department for Public Health, at 564-3970, extension 4069.

Sincerely,

Lucie Estill

Lucie Estill
Executive Staff Advisor
Office of Legislative and Regulatory Affairs

Final Version 4/23/2021 2:07 PM

SUGGESTED SUBSTITUTE TO *ORDINARY ONLY*

CABINET FOR HEALTH AND FAMILY SERVICES
Department for Public Health
Division of Maternal and Child Health

902 KAR 30:210. Enhanced early intervention services in response to declared national or state public health emergency.

RELATES TO: KRS 200.650 - 200.676, 34 C.F.R. Part 99, 34 C.F.R. Part 303, 45 C.F.R. Part 160, 20 U.S.C. 1431-1444

STATUTORY AUTHORITY: KRS 194A.050, 200.660

NECESSITY, FUNCTION, AND CONFORMITY: KRS 200.660 requires the Cabinet for Health and Family Services to administer all funds appropriated to implement provisions of KRS 200.650 ***through*** ~~***to***~~ 200.676, to enter into contracts with service providers, and to promulgate administrative regulations. This administrative regulation establishes the provisions for providing tele-intervention services if a national or state public health emergency has been declared.

Section 1. Definitions. (1) "Declared national or state public health emergency" means a formal declaration by the President of the United States or the Governor of Kentucky of an extraordinary event that is determined to constitute a public health risk through the spread of disease.

(2) "Tele-intervention service" means early intervention services provided through the internet with both video and audio features and with the early intervention provider and family both present in real time.

Section 2. Enhanced Early Intervention Services in Response to a Declared National or State Public Health Emergency. (1) Early intervention services and requirements may be enhanced to allow for tele-intervention services if a national or state public health emergency has been declared.

(2) Early intervention services that are otherwise designated as face-to-face in accordance with 902 KAR 30:160 may be provided through tele-intervention with informed parental consent if:

(a) Informed parental consent is obtained verbally for the purposes of tele-intervention services;

(b) Written consent is received by the point of entry within ten (10) days of the verbal consent; and

(c) The date verbal consent is obtained is documented in the child's electronic record.

(3) ***Each provider*** ~~***Providers***~~ utilizing tele-intervention services shall take all necessary steps to maintain confidentiality with 34 C.F.R. Part 99, 34 C.F.R. 303.402, and 45 C.F.R. Part 160.

(4) Tele-intervention services shall be reimbursed at the usual and customary rate as established in 902 KAR 30:200, Section 2.

(5) Tele-intervention services shall revert to face-to-face service delivery methods following the end of the declared national or state public health emergency.

CONTACT PERSON: Krista Quarles, Policy Analyst, 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.