



KENTUCKY

PHARMACY LAWS



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UNOFFICIAL TEXT OF STATUTES AND ADMINISTRATIVE REGULATIONS
FOR INFORMATION ONLY
REVISED JUNE 2022

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Kentucky Controlled Substance Act Manual

Copies may be obtained from:

**Cabinet for Health and Family Services
Office of Inspector General
Drug Enforcement and Professional Practices Branch
275 East Main Street, 5ED
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Code of Federal Regulations

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315.002 Declarations of public policy -- Construction of chapter.

The practice of pharmacy within the Commonwealth is declared to be a professional practice affecting the public health, safety, and welfare, and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest and concern that the practice of pharmacy, as defined in this chapter, should merit and receive the confidence of the public, and only qualified persons shall be permitted to engage in the practice of pharmacy and ensure the quality of drugs and related devices distributed within the Commonwealth. This chapter shall be liberally construed to carry out these objectives and purposes. The persons entrusted through this chapter to engage in the practice of pharmacy shall be pharmacists. They shall be recognized by the Commonwealth as health care professionals, and, within their statutory scope of practice, providers of pharmacy-related primary care.

Effective: July 15, 1996

History: Created 1996 Ky. Acts ch. 257, sec. 1, effective July 15, 1996.

315.005 Purpose of chapter.

The purpose of this chapter is to promote, preserve, and protect public health, safety, and welfare by and through effective control and regulation of the practice of pharmacy; the licensure of pharmacists; the licensure, control, and regulation of all sites or persons who are required to obtain a license, certificate, or permit from the Board of Pharmacy, whether located in or outside the Commonwealth, that distribute, manufacture, or sell drugs within the Commonwealth.

Effective: July 15, 2016

History: Amended 2016 Ky. Acts ch. 103, sec. 16, effective July 15, 2016. -- Amended 2012 Ky. Acts ch. 73, sec. 10, effective July 12, 2012. -- Amended 2008 Ky. Acts ch. 148, sec. 6, effective July 15, 2008. -- Created 1996 Ky. Acts ch. 257, sec. 2, effective July 15, 1996.

315.010 Definitions for chapter.

As used in this chapter, unless the context requires otherwise:

- (1) "Administer" means the direct application of a drug to a patient or research subject by injection, inhalation, or ingestion, whether topically or by any other means;
- (2) "Administrative activities of a pharmacy" means the following functions performed by a pharmacy adhering to all local, state, and federal patient privacy laws:
 - (a) Investigating and researching a patient's insurance benefits and updating the patient profile regarding insurance coverage;
 - (b) Billing and collections activities, including:
 1. Contacting patients for copayments and coinsurance payments; and
 2. Communicating with insurance companies;
 - (c) Performing patient financial assistance activities and updating patient records accordingly;
 - (d) Opening faxes and accessing electronic prescriptions for the purposes of setting up patient demographic and insurance profiles, excluding height, weight, and allergy information, so long as the activity does not involve the entering of a prescription order into the dispensing or medication management system;

- (e) Initiating insurance prior authorizations for submission to the licensed pharmacy, including communications with the prescribing physician to collect, record, and transmit information to insurance companies, so long as the activity does not include the authorization or receipt of new or refill prescription orders;
 - (f) Answering and transferring telephone calls, whether or not such calls require accessing a patient record, so long as the call does not involve the interpretation, evaluation, or implementation of a drug order; and
 - (g) Communicating with patients via telephone or electronically regarding refill reminders, so long as the communication does not involve the interpretation, evaluation, or implementation of a drug order and a pharmacist is readily available for patient consultation;
- (3) "Association" means the Kentucky Pharmacists Association;
- (4) "Board" means the Kentucky Board of Pharmacy;
- (5) "Collaborative care agreement" means a written agreement between a pharmacist or pharmacists and a practitioner or practitioners that outlines a plan of cooperative management of patients' drug-related health care needs where:
- (a) Patients' drug-related health care needs fall within the practitioner's or practitioners' statutory scope of practice;
 - (b) Patients are referred by the practitioner or practitioners to the pharmacist or pharmacists; and
 - (c) The agreement:
 1. Identifies the practitioner or practitioners and the pharmacist or pharmacists who are parties to the agreement;
 2. Specifies the drug-related regimen to be provided, and how drug therapy is to be monitored; and
 3. Stipulates the conditions for initiating, continuing, or discontinuing drug therapy and conditions which warrant modifications to dose, dosage regimen, dosage form, or route of administration;
- (6) "Compound" or "compounding" means the preparation or labeling of a drug pursuant to or in anticipation of a valid prescription drug order, including but not limited to packaging, intravenous admixture or manual combination of drug ingredients. "Compounding," as used in this chapter, shall not preclude simple reconstitution, mixing, or modification of drug products prior to administration by nonpharmacists;
- (7) "Confidential information" means information which is accessed or maintained by a pharmacist in a patient's record, or communicated to a patient as part of patient counseling, whether it is preserved on paper, microfilm, magnetic media, electronic media, or any other form;

(8) "Continuing education unit" means ten (10) contact hours of board approved continuing pharmacy education. A "contact hour" means fifty (50) continuous minutes without a break period;

(9) "Dispense" or "dispensing" means to deliver one (1) or more doses of a prescription drug in a suitable container, appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug;

(10) "Drug" means any of the following:

- (a) Articles recognized as drugs or drug products in any official compendium or supplement thereto;
- (b) Articles, other than food, intended to affect the structure or function of the body of man or other animals;
- (c) Articles, including radioactive substances, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; or
- (d) Articles intended for use as a component of any articles specified in paragraphs (a) to (c) of this subsection;

(11) "Drug regimen review" means retrospective, concurrent, and prospective review by a pharmacist of a patient's drug-related history, including but not limited to the following areas:

- (a) Evaluation of prescription drug orders and patient records for:
 - 1. Known allergies;
 - 2. Rational therapy contraindications;
 - 3. Appropriate dose and route of administration;
 - 4. Appropriate directions for use; or
 - 5. Duplicative therapies;
- (b) Evaluation of prescription drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions;
- (c) Evaluation of prescription drug orders and patient records for adverse drug reactions; or
- (d) Evaluation of prescription drug orders and patient records for proper utilization and optimal therapeutic outcomes;

(12) "Immediate supervision" means under the physical and visual supervision of a pharmacist;

(13) "Manufacturer" or "virtual manufacturer" of a product means:

- (a) A person that holds an application approved under 21 U.S.C. sec. 355 or a license issued under 42 U.S.C. sec. 262 for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;
- (b) A co-licensed partner of the person described in paragraph (a) of this subsection

that obtains the product directly from a person described in this paragraph or paragraph (a) of this subsection;

(c) An affiliate of a person described in paragraph (a) or (b) of this subsection who receives the product directly from a person described in this paragraph or in paragraph (a) or (b) of this subsection; or

(d) Any person, except a pharmacist compounding in the normal course of professional practice;

(14) "Medical order" means a lawful order of a specifically identified practitioner for a specifically identified patient for the patient's health care needs. "Medical order" may or may not include a prescription drug order;

(15) "Nonprescription drugs" means nonnarcotic medicines or drugs which may be sold without a prescription and are prepackaged and labeled for use by the consumer in accordance with the requirements of the statutes and regulations of this state and the federal government;

(16) "Outsourcing facility" means a facility at one (1) geographic location or address that:

- (a) Is engaged in the compounding of human sterile drugs without a patient-specific prescription;
- (b) Has registered as an outsourcing facility with the secretary of the United States Department of Health and Human Services, Food and Drug Administration; and
- (c) Complies with all applicable state and federal requirements;

(17) "Pharmacist" means a natural person licensed by this state to engage in the practice of the profession of pharmacy;

(18) "Pharmacist intern" means a natural person who is:

- (a) Currently certified by the board to engage in the practice of pharmacy under the direction of a licensed pharmacist and who satisfactorily progresses toward meeting the requirements for licensure as a pharmacist;
- (b) A graduate of an approved college or school of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) certificate, who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;
- (c) A qualified applicant awaiting examination for licensure as a pharmacist or the results of an examination for licensure as a pharmacist; or
- (d) An individual participating in a residency or fellowship program approved by the board for internship credit;

(19) "Pharmacy" means every place where:

- (a) Drugs are dispensed under the direction of a pharmacist;

- (b) Prescription drug orders are compounded under the direction of a pharmacist; or
- (c) A registered pharmacist maintains patient records and other information for the purpose of engaging in the practice of pharmacy, whether or not prescription drug orders are being dispensed;

(20) "Pharmacy-related primary care" means the pharmacists' activities in patient education, health promotion, and assistance in the selection and use of over-the-counter drugs and appliances for the treatment of common diseases and injuries, as well as those other activities falling within their statutory scope of practice;

(21) "Pharmacy technician" means a natural person who works under the immediate supervision, or general supervision if otherwise provided for by statute or administrative regulation, of a pharmacist for the purpose of assisting a pharmacist with the practice of pharmacy;

(22) "Practice of pharmacy" means interpretation, evaluation, and implementation of medical orders and prescription drug orders; responsibility for dispensing prescription drug orders, including radioactive substances; participation in drug and drug-related device selection; administration of medications or biologics in the course of dispensing or maintaining a prescription drug order; the administration of adult immunizations pursuant to prescriber-approved protocols; the administration of immunizations to individuals nine (9) to seventeen (17) years of age pursuant to prescriber-approved protocols with the consent of a parent or guardian; the administration of immunizations to a child as defined in KRS 214.032, pursuant to protocols as authorized by KRS 315.500; drug evaluation, utilization, or regimen review; maintenance of patient pharmacy records; and provision of patient counseling and those professional acts, professional decisions, or professional services necessary to maintain and manage all areas of a patient's pharmacy-related care, including pharmacy-related primary care as defined in this section;

(23) "Practitioner" has the same meaning given in KRS 217.015(35);

(24) "Prescription drug" means a drug which:

(a) Under federal law is required to be labeled with either of the following statements:

1. "Caution: Federal law prohibits dispensing without prescription";
2. "Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian";
3. "Rx Only"; or
4. "Rx"; or

(b) Is required by any applicable federal or state law or administrative regulation to be dispensed only pursuant to a prescription drug order or is restricted to use by practitioners;

(25) "Prescription drug order" means an original or new order from a practitioner for drugs, drug-related devices or treatment for a human or animal, including orders issued through collaborative care agreements or protocols authorized by the board. Lawful prescriptions result from a valid practitioner-patient relationship, are intended to address a legitimate medical need, and fall within the prescribing practitioner's scope of professional practice;

(26) "Society" means the Kentucky Society of Health-Systems Pharmacists;

(27) "Supervision" means the presence of a pharmacist on the premises to which a pharmacy permit is issued, who is responsible, in whole or in part, for the professional activities occurring in the pharmacy; and

(28) "Wholesaler" means any person who legally buys drugs for resale or distribution to persons other than patients or consumers.

Effective: June 29, 2017

History: Amended 2017 Ky. Acts ch. 44, sec. 1, effective June 29, 2107; and ch. 136, sec. 1, effective June 29, 2017. -- Amended 2016 Ky. Acts ch. 105, sec. 1, effective July 15, 2016. -- Amended 2015 Ky. Acts ch. 118, sec. 1, effective June 24, 2015. -- Amended 2011 Ky. Acts ch. 81, sec. 1, effective June 8, 2011. -- Amended 2010 Ky. Acts ch. 22, sec. 5, effective July 15, 2010; and ch. 37, sec. 1, effective July 15, 2010. -- Amended 2007 Ky. Acts ch. 124, sec. 8, effective June 26, 2007. -- Amended 2005 Ky. Acts ch. 150, sec. 18, effective June 20, 2005. -- Amended 2004 Ky. Acts ch. 10, sec. 1, effective July 13, 2004. -- Amended 1998 Ky. Acts ch. 297, sec. 4, effective July 15, 1998; ch. 301, sec. 27, effective July 15, 1998; and ch. 531, sec. 3, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 3, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 1, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 1. -- Created 1960 Ky. Acts ch. 234, sec. 1.

Legislative Research Commission Note (6/29/2017). This statute was amended by 2017 Ky. Acts chs. 44 and 136, which do not appear to be in conflict and have been codified together.

Legislative Research Commission Note (7/13/2004). 2004 Ky. Acts ch. 10, sec. 2, states that 2004 Ky. Acts ch. 10, sec. 1, which amends this section, shall be known as the Robert L. Barnett, Jr. R. Ph. Act.

Legislative Research Commission Note (7/15/98). This section was amended by 1998 Ky. Acts chs. 297, 301, and 531 which do not appear to be in conflict and have been codified together. It is clear that the intent of both 1998 Ky. Acts ch. 297, sec. 4, and ch. 301, sec. 27, was to change the subsection reference in KRS 217.015 for the definition of practitioner. In codifying these Acts, that result has been effectuated. KRS 7.136(1)(e).

315.020 Only pharmacists to supervise manufacturing of pharmaceuticals or practice pharmacy -- Exceptions -- Persons employed to assist practice of pharmacy after April 1, 2009, to be registered pharmacy technicians or exempt under KRS 315.135.

(1) No owner of a pharmacy who is not a pharmacist shall fail to place a pharmacist in charge of his pharmacy or shall permit any person to compound or dispense prescription drugs, medicines, or pharmaceuticals in his place of business except in the presence and under the immediate supervision of a pharmacist.

(2) No manufacturer of pharmaceuticals who is not a pharmacist shall fail to place a pharmacist in charge of his place of business or shall permit any person to compound prescription drugs, medicines, or pharmaceuticals in his place of business, except as provided by the board through the promulgation of administrative regulations pursuant to KRS Chapter 13A.

(3) Except as provided in subsection (4) of this section, no person shall engage in the practice of pharmacy unless licensed to practice under the provisions of KRS Chapter 315.

(4) The provisions of subsection (3) of this section shall not apply to:

- (a) Pharmacist interns performing professional practice activities under the immediate supervision of a licensed pharmacist. The nature and scope of the activities referred to in this paragraph shall be determined by the board through administrative regulation promulgated pursuant to KRS Chapter 13A;
- (b) Pharmacist interns and pharmacy technicians performing specifically identified pharmacy practice activities while under the supervision of a pharmacist. The nature and scope of the activities referred to in this paragraph shall be determined by the board through administrative regulation promulgated pursuant to KRS Chapter 13A;
- (c) Other licensed health care professionals practicing within the statutory scope of their professional practices; or
- (d) Volunteer health practitioners providing services under KRS 39A.350 to 39A.366.

(5) (a) As used in this subsection:

- 1. "Order entry" means the process by which pharmacy personnel validate prescription data and enter that data into a pharmacy's dispensing or medication management system. Prescription data includes but is not limited to patient demographics, prescriber demographics, drug name, strength, dosage form, quantity, the directions for use, refill authorization, or any clarifications of the same; and
- 2. "Order entry verification" means the process by which a pharmacist verifies prescription data entered in a pharmacy's dispensing or medication management system after order entry has been completed.

(b) Nothing in this chapter shall prohibit a pharmacist licensed in Kentucky, or a pharmacy technician registered in Kentucky or a pharmacy intern certified in Kentucky who is working under the supervision of the pharmacist, from accessing the electronic database of the pharmacy, from inside or outside of the pharmacy, to perform order entry, order entry verification, or drug regimen review as defined in KRS 315.010, if:

- 1. The pharmacy has established controls to protect the confidentiality and integrity of protected health information;
- 2. No part of the pharmacy's database is duplicated, downloaded, or removed from the electronic database;
- 3. The pharmacy is located in Kentucky and is permitted by the board; and
- 4. All personnel who access the pharmacy's electronic database from outside of the pharmacy reside in Kentucky or within one hundred (100) miles of the pharmacy.

(c) Supervision required by paragraph (b) of this subsection may include electronic supervision.

- (d) This subsection shall only apply to pharmacies that are not open to the public and do not dispense to walk-in patients in a retail setting.
- (e) Nothing in this subsection shall be construed to authorize final product verification and dispensing of a prescription from a location outside of or other than a pharmacy.
- (f) Nothing in this subsection permits pharmacists, pharmacy technicians, or pharmacy interns to receive hard copy prescriptions outside of the premises of a permitted pharmacy.

(6) Effective April 1, 2009, an owner of a pharmacy shall not employ a person to assist in the practice of pharmacy unless the person is registered as a pharmacy technician by the board or exempt under KRS 315.135.

Effective: June 29, 2021

History: Amended 2021 Ky. Acts ch. 56, sec. 3, effective June 29, 2021. -- Amended 2008 Ky. Acts ch. 148, sec. 7, effective July 15, 2008. -- Amended 2007 Ky. Acts ch. 96, sec. 15, effective June 26, 2007. -- Amended 1996 Ky. Acts ch. 257, sec. 4, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 2, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 2. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. secs. 2619, 2620, 2628, 2631.

**315.030 Permit required -- License required to represent oneself as pharmacist --
Registration required to represent oneself as pharmacy technician.**

(1) No person shall take, use or exhibit the title of drug, drug store, pharmacy or apothecary, or any combination of such names or titles, or any title, name or description of like import, or any form designed to take the place of such a title, or use any place with respect to which any of those terms are used in any advertisement or telephone directory listing, unless the facility has been issued a permit by the board.

(2) No person shall call himself or hold himself out as or use the title of "pharmacist," "registered pharmacist," "licensed pharmacist," "druggist," or use the initials "R.Ph." or terms which would imply that he is a pharmacist, unless he is duly licensed under the provisions of KRS Chapter 315.

(3) Effective April 1, 2009, a person shall not call himself or herself or hold himself or herself out as a or use the title of "pharmacy technician" unless the person is duly registered under KRS 315.136 or 315.138.

Effective: July 15, 2008

History: Amended 2008 Ky. Acts ch. 148, sec. 9, effective July 15, 2008. -- Amended 1982 Ky. Acts ch. 191, sec. 3, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 3. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 1376t.

315.035 Permit required for operation of a pharmacy -- Application -- Fee -- Issuance -- Fee for failure to renew -- Premises covered by permit -- Rules and regulations -- Requirements for in-state pharmacy doing business through the Internet -- Board may waive permit requirements for out-of-state pharmacy -- Temporary operation of pharmacy during state of emergency.

(1) No person shall operate a pharmacy within this Commonwealth, physically or by means of the Internet, facsimile, phone, mail, or any other means, without having first obtained a

permit as provided for in KRS Chapter 315. An application for a permit to operate a pharmacy shall be made to the board upon forms provided by it and shall contain such information as the board requires, which may include affirmative evidence of ability to comply with such reasonable standards and rules and regulations as may be prescribed by the board. Each application shall be accompanied by a reasonable permit fee to be set by administrative regulation promulgated by the board pursuant to KRS Chapter 13A, not to exceed two hundred fifty dollars (\$250).

(2) Upon receipt of an application of a permit to operate a pharmacy, accompanied by the permit fee not to exceed two hundred fifty dollars (\$250), the board shall issue a permit if the pharmacy meets the standards and requirements of KRS Chapter 315 and the rules and regulations of the board. The board shall refuse to renew any permit to operate unless the pharmacy meets the standards and requirements of KRS Chapter 315 and the rules and regulations of the board. The board shall act upon an application for a permit to operate within thirty (30) days after the receipt thereof; provided, however, that the board may issue a temporary permit to operate in any instance where it considers additional time necessary for investigation and consideration before taking final action upon the application. In such event, the temporary permit shall be valid for a period of thirty (30) days, unless extended.

(3) A separate permit to operate shall be required for each pharmacy.

(4) Each permit to operate a pharmacy, unless sooner suspended or revoked, shall expire on June 30 following its date of issuance and be renewable annually thereafter upon proper application accompanied by such reasonable renewal fee as may be set by administrative regulation of the board, not to exceed two hundred fifty dollars (\$250) nor to increase more than twenty-five dollars (\$25) per year. An additional fee not to exceed the annual renewal fee may be assessed and set by administrative regulation as a delinquent renewal penalty for failure to renew by June 30 of each year.

(5) Permits to operate shall be issued only for the premises and persons named in the application and shall not be transferable; provided however, that a buyer may operate the pharmacy under the permit of the seller pending a decision by the board of an application which shall be filed by the buyer with the board at least five (5) days prior to the date of sale.

(6) The board may promulgate rules and regulations to assure that proper equipment and reference material is on hand considering the nature of the pharmaceutical practice conducted at the particular pharmacy and to assure reasonable health and sanitation standards for areas within pharmacies which are not subject to health and sanitation standards promulgated by the Kentucky Cabinet for Health and Family Services or a local health department.

(7) Each pharmacy shall comply with KRS 218A.202.

(8) Any pharmacy within the Commonwealth that dispenses more than twenty-five percent (25%) of its total prescription volume as a result of an original prescription order received or solicited by use of the Internet, including but not limited to electronic mail, shall, prior to obtaining a permit, receive and display in every medium in which it advertises itself a seal of approval for the National Association of Boards of Pharmacy certifying that it is a Verified Internet Pharmacy Practice Site (VIPPS) or a seal certifying approval of a substantially similar program approved by the Kentucky Board of Pharmacy. VIPPS, or any other substantially similar program approved by the Kentucky Board of Pharmacy, accreditation shall be maintained and remain current.

(9) Any pharmacy within the Commonwealth doing business by use of the Internet shall certify the percentage of its annual business conducted via the Internet and submit such supporting documentation as requested by the board, and in a form or application required by the board, when it applies for permit or renewal.

(10) A pharmacist may temporarily operate a pharmacy in an area not designated on the permit as authorized in KRS 315.500.

Effective: July 15, 2010

History: Amended 2010 Ky. Acts ch. 22, sec. 6, effective July 15, 2010. -- Amended 2007 Ky. Acts ch. 124, sec. 9, effective June 26, 2007. -- Amended 2005 Ky. Acts ch. 150, sec. 19, effective June 20, 2005; ch. 61, sec. 1, effective June 20, 2005; and ch. 99, sec. 597, effective June 20, 2005. -- Amended 1998 Ky. Acts ch. 426, sec. 548, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 5, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 4, effective July 15, 1982. -- Amended 1974 Ky. Acts ch. 310, sec. 1. -- Created 1966 Ky. Acts ch. 260, sec. 6.

315.0350 Administrative activities of a pharmacy.

Administrative activities of a pharmacy do not constitute the practice of pharmacy and shall be performed in the United States in a pharmacy or in a location other than a pharmacy.

Effective: July 15, 2016

History: Created 2016 Ky. Acts ch. 105, sec. 2, effective July 15, 2016.

315.0351 Out-of-state pharmacy -- Permit -- Requests for information -- Records -- Toll-free telephone service -- Pharmacist on duty -- Requirements for out-of-state pharmacy doing business through the Internet -- Application to sale or distribution of dialysate solution or devices.

(1) Except as provided in subsection (2) of this section:

(a) Every person or pharmacy located outside this Commonwealth which does business, physically or by means of the Internet, facsimile, phone, mail, or any other means, inside this Commonwealth within the meaning of KRS Chapter 315, shall hold a current pharmacy permit as provided in KRS 315.035(1) and (4) issued by the Kentucky Board of Pharmacy. The pharmacy shall be designated an "out-of-state pharmacy" and the permit shall be designated an "out-of-state pharmacy" and the permit shall be designated an "out-of-state pharmacy permit." The fee for the permit shall not exceed the current in-state pharmacy permit fee as provided under KRS 315.035;

- (b) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board shall disclose to the board the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs to residents of the Commonwealth. A report containing this information shall be made to the board on an annual basis and within thirty (30) days after any change of office, corporate officer, or pharmacist;
- (c) Every out-of-state pharmacy granted an out-of-state pharmacy permit shall comply with all statutorily-authorized directions and requests for information from any regulatory agency of the Commonwealth and from the board in accordance with the provisions of this section. The out-of-state pharmacy shall maintain at all times a valid unexpired permit, license, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction in which it is a resident. As a prerequisite to seeking a permit from the Kentucky Board of Pharmacy, the out-of-state pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. Thereafter, the out-of-state pharmacy granted a permit shall submit to the Kentucky Board of Pharmacy a copy of any subsequent inspection report on the pharmacy conducted by the regulatory or licensing body of the jurisdiction in which it is located;
- (d) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board shall maintain records of any controlled substances or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed;
- (e) Records for all prescriptions delivered into Kentucky shall be readily retrievable from the other prescription records of the out-of-state pharmacy;
- (f) Each out-of-state pharmacy shall, during its regular hours of operation, but not less than six (6) days per week and for a minimum of forty (40) hours per week, provide a toll-free telephone service directly to the pharmacist in charge of the out-of-state pharmacy and available to both the patient and each licensed and practicing in-state pharmacist for the purpose of facilitating communication between the patient and the Kentucky pharmacist with access to the patient's prescription records. A toll-free number shall be placed on a label affixed to each container of drugs dispensed to patients within the Commonwealth;
- (g) Each out-of-state pharmacy shall have a pharmacist in charge who is licensed to engage in the practice of pharmacy by the Commonwealth that shall be responsible for compliance by the pharmacy with the provisions of this section and for the distribution and sale of dialysate solutions and devices pursuant to subsection (2) of this section;
- (h) Each out-of-state pharmacy shall comply with KRS 218A.202;
- (i) Any out-of-state pharmacy that dispenses more than twenty-five percent (25%) of its total prescription volume as a result of an original prescription order received or solicited by use of the Internet, including but not limited to electronic mail, shall receive and display in every medium in which it advertises itself a seal of approval

for the National Association of Boards of Pharmacy certifying that it is a Verified Internet Pharmacy Practice Site (VIPPS) or a seal certifying approval of a substantially similar program approved by the Kentucky Board of Pharmacy. VIPPS, or any other substantially similar accreditation, shall be maintained and remain current;

(j) Any out-of-state pharmacy doing business in the Commonwealth of Kentucky shall certify the percentage of its annual business conducted via the Internet and electronic mail and submit such supporting documentation as requested by the board, and in a form or application required by the board, when it applies for permit or renewal;

(k) Any pharmacy doing business within the Commonwealth of Kentucky shall use the address on file with the Kentucky Board of Pharmacy as the return address on the labels of any package shipped into or within the Commonwealth. The return address shall be placed on the package in a clear and prominent manner; and

(l) The Kentucky Board of Pharmacy may waive the permit requirements of this chapter for an out-of-state pharmacy that only does business within the Commonwealth of Kentucky in limited transactions.

(2) (a) Only subsection (1)(g) of this section shall apply to the sale or distribution of dialysate solutions or devices necessary to perform home peritoneal kidney dialysis to patients with end-stage renal disease, if;

1. The dialysate solutions or devices are approved or cleared by the federal Food and Drug Administrations, as required by federal law;

2. The dialysate solutions or devices are lawfully held by a manufacturer or manufacturer's agent that is properly registered with or licensed by the board as a manufacturer, wholesale distributor, or third-party logistics provider under this chapter;

3. The dialysate solutions or devices are held and delivered in their original, sealed packaging from Food and Drug Administration-approved manufacturing facility;

4. The dialysate solutions or devices are only delivered upon receipt of a physician's prescription by a Kentucky licensed pharmacy and the transmittal of an order from the Kentucky licensed pharmacy to the manufacturer or manufacturer's agent; and

5. The manufacturer or manufacturer's agent delivers the dialysate solutions or devices directly to:

a. A patient with end-stage renal disease or the patient's designee for the patient's self-administration of dialysis therapy; or

b. A health-care provider or institution for administration or delivery of dialysis therapy to a patient with end-stage renal disease.

(b) 1. A manufacturer or manufacturer's agent who sells or distributes dialysate solutions or devices under this subsection shall employ or contract with a

pharmacist who is licensed to engage in the practice of pharmacy by the Commonwealth to conduct a retrospective audit on ten percent (10%) of the orders processed by that manufacturer or manufacturer's agent each month.

2. On or before February 1 of each year, an annual summary of the monthly audits shall be prepared and submitted to the board, in the form prescribed by the board.

3. On or before June 1 of each year, the board shall compile the summaries of monthly audits into a single report and submit that report to the Interim Joint Committee on Health and Welfare and Family Services.

(c) Prescriptions and records of delivery for dialysate solutions or devices sold or distributed under this subsection shall be maintained by the manufacturer or manufacturer's agent for a minimum of two (2) years and shall be made available to the board upon request.

(d) As used in this subsection, "dialysate solutions" means dextrose or icodextrin when used to perform home peritoneal dialysis.

(e) The Kentucky Board of Pharmacy will retain oversight of the distribution of dialysate solutions and devices under this section.

Effective: June 27, 2019

History: Amended 2019 Ky. Acts ch. 157, sec. 1, effective June 27, 2019. --Amended 2007 Ky. Acts ch. 124, sec. 10, effective June 26, 2007. -- Amended 2005 Ky. Acts ch. 150, sec. 20, effective June 20, 2005. -- Amended 2004 Ky. Acts ch. 107, sec. 4, effective July 13, 2004. -- Created 1990 Ky. Acts ch. 155, sec. 1, effective July 13, 1990.

315.036 Permit to be acquired by manufacturer -- Fee -- Records required -- Report -- Exception.

(1) Except as provided in subsection (4) of this section, each manufacturer of drugs shall be required to register with and obtain a permit from the board. Such permit shall be issued in accordance with policy and procedure prescribed by regulations of the board. Each application shall be accompanied by a reasonable permit fee to be set by administrative regulation of the board, not to exceed two hundred fifty dollars (\$250) annually or increase more than twenty-five dollars (\$25) per year.

(2) Manufacturers shall be required to maintain accurate records of all drugs manufactured, received and sold, as established by administrative regulation of the board. Such records shall be made available to agents of the board for inspection at reasonable times. The board may require by regulation that manufacturers periodically report to the board all drugs manufactured, received, and sold.

(3) Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under the provisions of KRS 315.131.

(4) The provisions of subsection (1) of this section do not apply to a pharmacist who, in the normal course of professional practice, compounds reasonable quantities of drugs pursuant to or in anticipation of a valid prescription drug order.

Effective: July 15, 2008

History: Amended 2008 Ky. Acts ch. 124, sec. 2, effective July 15, 2008. -- Amended 1996 Ky. Acts ch. 257, sec. 6, effective July 15, 1996. -- Created 1982 Ky. Acts ch. 191, sec. 5, effective July 15, 1982.

315.040 Exceptions to chapter.

(1) Nothing in this chapter shall be construed to prevent, restrict, or otherwise interfere with the sale of nonprescription drugs in their original packages by any retailer. No rule or regulation shall be adopted by the Board of Pharmacy under this chapter which shall require the sale of nonprescription drugs by a licensed pharmacist or under the supervision of a licensed pharmacist.

(2) Nothing in this chapter shall interfere with the professional activities of any licensed practicing physician, or prevent the physician from keeping any drug or medicine that he or she may need in his or her practice, from compounding the physician's own medications, or from dispensing or supplying to patients any article that seems proper to the physician.

(3) Nothing in this chapter pertaining to the use of collaborative care agreements shall apply in any hospital or other health facility operated by a hospital without the express written permission of the hospital's governing body. Collaborative care agreements may be restricted by the policies and procedures of the facility.

(4) Nothing in this chapter shall interfere with the activities of a physician assistant as authorized in KRS Chapter 311.

(5) Nothing in this chapter shall interfere with the activities of an advanced practice registered nurse as authorized in KRS Chapter 314.

(6) Nothing in this chapter shall be construed to prevent, restrict, or otherwise interfere with the sale or distribution of dialysate solutions as defined in KRS 315.0351(2) or devices necessary to perform home peritoneal dialysis to patients with end-stage renal disease, provided that the requirements established in KRS 315.0351(2) are satisfied. No rule or administrative regulation shall be adopted or promulgated by the board under this chapter that requires the sale or distribution of dialysate solutions as defined in KRS 315.0351 or devices necessary to perform home peritoneal dialysis by a licensed pharmacist or under the supervision of a licensed pharmacist.

Effective: June 27, 2019

History: Amended 2019 Ky. Acts ch. 157, sec. 2, effective June 27, 2019 -- Amended 2017 Ky. Acts ch. 80, sec. 23, effective June 29, 2017. -- Amended 2010 Ky. Acts ch. 85, sec. 67, effective July 15, 2010. -- Amended 2000 Ky. Acts ch. 391, sec. 22, effective July 14, 2000. -- Amended 1998 Ky. Acts ch. 228, sec. 6, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 7, effective July 15, 1996. -- Amended 1990 Ky. Acts ch. 482, sec. 12, effective July 13, 1990. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. secs. 1376t, 2625, 2632.

315.050 Qualifications of applicant for licensure -- Examination -- Standards for internship -- Certificate of internship.

(1) Every applicant for licensure as a pharmacist shall be not less than eighteen (18) years of age, of good mental health and moral character, a graduate of a school or college of

pharmacy program approved by the board, and shall file proof satisfactory to the board, substantiated by proper affidavits, of completion of an approved internship.

(2) After the applicant has passed a satisfactory examination conducted before the board under regulations prescribed by the board, he shall be entitled to a license as a pharmacist.

(3) The examination for licensure shall be given by the board at least two (2) times during each year. The examination shall be prepared to measure the competency of the applicant to engage in the practice of pharmacy. The board may employ and cooperate with any organization or consultant in the preparation and grading of an appropriate examination, but shall retain the sole discretion and responsibility of determining which applicants have successfully passed such an examination.

(4) The board shall by regulation establish standards for pharmacist intern certification and an approved internship program and shall determine appropriate qualifications for pharmacists supervising approved internship programs.

(5) The board shall issue certificates of internship which shall be valid for six (6) years from date of issuance. The fee for a certificate shall be set by administrative regulation of the board, not to exceed fifty dollars (\$50).

Effective: June 24, 2015

History: Amended 2015 Ky. Acts ch. 113, sec. 17, effective June 24, 2015. -- Amended 1996 Ky. Acts ch. 257, sec. 8, effective July 15, 1996. -- Amended 1990 Ky. Acts ch. 443, sec. 23, effective July 13, 1990. -- Amended 1982 Ky. Acts ch. 191, sec. 6, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 120, sec. 8; and ch. 221, sec. 4. -- Amended 1946 Ky. Acts ch. 161, sec. 1. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2625.

315.060 Examination fee.

A reasonable examination fee shall be fixed by administrative regulation of the board, not to exceed three hundred dollars (\$300) or increase more than twenty-five dollars (\$25) per year, and shall be collected for each examination taken by an applicant.

Effective: July 15, 1996

History: Amended 1996 Ky. Acts ch. 257, sec. 9, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 7, effective July 15, 1982. -- Amended 1974 Ky. Acts ch. 310, sec. 2. -- Amended 1970 Ky. Acts ch. 221, sec. 5. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2625.

315.065 Continuing education requirements.

(1) Because of the continuous introduction of new therapeutic and diagnostic agents and changing concepts in the practice of pharmacy, it is essential that a pharmacist undertake a program of continuing education to maintain his professional competency to practice in the public interest.

(2) No pharmacist's license shall be renewed until the license holder is able to submit written proof to the board that he has satisfactorily completed, in the previous renewal period, a continuing education program acceptable to the board. Such continuing education requirements shall be determined by regulation of the board, but they shall not require

more than an average of one and one-half (1-1/2) continuing education units (CEU) per year.

(3) The board shall adopt rules and regulations to carry out the provisions of this section, to include guidelines and criteria for reviewing and approving continuing education programs.

Effective: June 24, 2015

History: Amended 2015 Ky. Acts ch. 113, sec. 18, effective June 24, 2015. -- Amended 2001 Ky. Acts ch. 61, sec. 11, effective June 21, 2001. -- Amended 1998 Ky. Acts ch. 531, sec. 4, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 10, effective July 15, 1996. -- Amended 1990 Ky. Acts ch. 443, sec. 10, effective July 13, 1990. -- Created 1982 Ky. Acts ch. 191, sec. 9, effective July 15, 1982.

315.110 License expiration date -- Renewal fee -- Application and requirements -- Certificate -- Display -- Pocket certificate.

(1) Each license to practice pharmacy, unless sooner suspended or revoked, shall expire on February 28 following its date of issuance. Every pharmacist who desires to continue to practice pharmacy shall pay to the executive director of the board a reasonable renewal fee to be set by administrative regulation of the board, but not to exceed one hundred seventy-five dollars (\$175) annually or increase more than twenty-five dollars (\$25) per year, and shall file with the board an application in such form and containing such data as the board may require for renewal of the license. A delinquent renewal penalty fee not to exceed the renewal fee may be assessed and set by administrative regulation for each renewal period the licensee fails to renew the license after expiration.

(2) Every pharmacist shall keep his current certificate conspicuously displayed in his primary place of practice.

(3) In addition to a current renewal certificate, each pharmacist shall be issued upon renewal a pocket certificate which shall be in the licensee's possession at all times when the licensee is engaged in the practice of pharmacy and which shall be exhibited by the licensee upon request from any member, inspector or agent of the board.

Effective: June 20, 2005

History: Amended 2005 Ky. Acts ch. 61, sec. 2, effective June 20, 2005. -- Amended 1996 Ky. Acts ch. 257, sec. 11, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 8, effective July 15, 1982. -- Amended 1974 Ky. Acts ch. 310, sec. 3. -- Amended 1970 Ky. Acts ch. 221, sec. 7. -- Amended 1966 Ky. Acts ch. 260, sec. 2. -- Created 1960 Ky. Acts ch. 234, sec. 2. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2627.

315.115 Renewal fees suspended for persons in Armed Forces.

All persons who are required to pay renewal fees to the board as registered pharmacists shall not be required to pay such fees during the time such persons are actively serving in the Armed Forces of the United States.

Effective: July 15, 1996

History: Amended 1996 Ky. Acts ch. 257, sec. 12, effective July 15, 1996. -- Amended 1970 Ky. Acts ch. 221, sec. 8. -- Created 1942 Ky. Acts ch. 98, sec. 2.

315.120 Notification of failure to renew license -- Procedure for renewal of expired license -- Renewal after lapse of five or more years -- Inactive license.

(1) Within thirty (30) days after the renewal period, the executive director shall notify all pharmacists who have failed to comply with license renewal requirements.

(2) Any pharmacist who has failed to timely renew his license for any consecutive period up to five (5) years may renew his license only upon satisfying the continuing education regulations of the board and paying the cumulative penalty and renewal fees provided for in KRS 315.110.

(3) Any pharmacist who has failed to timely renew his license for five (5) or more consecutive years may renew his license only upon satisfying the continuing education regulations of the board, passing a satisfactory examination before the board and paying the renewal and penalty fees provided for in KRS 315.110.

(4) Any pharmacist not currently holding an active pharmacist's license in another jurisdiction who does not desire to meet the qualifications for active license renewal shall, upon application, be issued an inactive license. Such license shall entitle the license holder to use the term "pharmacist" but the license holder shall not be permitted to engage in the practice of pharmacy. An inactive license holder may apply for an active license as provided for by the regulations of the board. The inactive license renewal fee shall be set by administrative regulation of the board, not to exceed fifty dollars (\$50) annually.

Effective: June 20, 2005

History: Amended 2005 Ky. Acts ch. 61, sec. 3, effective June 20, 2005. -- Amended 1996 Ky. Acts ch. 257, sec. 13, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 10, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 9. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2627.

315.121 Grounds for acting against licensee -- Notification to board of conviction required -- Petition for reinstatement -- Expungement.

(1) The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons:

(a) Unprofessional or unethical conduct;

(b) Mental or physical incapacity that prevents the licensee, permit holder, or certificate holder from engaging or assisting in the practice of pharmacy or the wholesale distribution or manufacturing of drugs with reasonable skill, competence, and safety to the public;

(c) Being convicted of, or entering an "Alford" plea or plea of nolo contendere to, irrespective of an order granting probation or suspending imposition of any sentence imposed following the conviction or entry of such plea, one (1) or more of the following, if in accordance with KRS Chapter 335B:

1. A crime as defined in KRS 335B.010; or

2. A violation of the pharmacy or drug laws, rules, or administrative regulations of this state, any other state, or the federal government;

(d) Knowing or having reason to know that a pharmacist, pharmacist intern, or pharmacy technician is incapable of engaging or assisting in the practice of

- pharmacy with reasonable skill, competence, and safety to the public and failing to report any relevant information to the board;
- (e) Knowingly making or causing to be made any false, fraudulent, or forged statement or misrepresentation of a material fact in securing issuance or renewal of a license, permit, or certificate;
- (f) Engaging in fraud in connection with the practice of pharmacy or the wholesale distribution or manufacturing of drugs;
- (g) Engaging in or aiding and abetting an individual to engage or assist in the practice of pharmacy without a license or falsely using the title of "pharmacist," "pharmacist intern," "pharmacy technician," or other term which might imply that the individual is a pharmacist, pharmacist intern, or pharmacy technician;
- (h) Being found by the board to be in violation of any provision of this chapter, KRS Chapter 217, KRS Chapter 218A, or the administrative regulations promulgated pursuant to these chapters;
- (i) Violation of any order issued by the board to comply with any applicable law or administrative regulation;
- (j) Knowing or having reason to know that a pharmacist, pharmacist intern, or pharmacy technician has engaged in or aided and abetted the unlawful distribution of legend medications, and failing to report any relevant information to the board;
- (k) Failure to notify the board within fourteen (14) days of a change in one's home address; or
- (l) As provided in KRS 311.824(2), being convicted of a violation of KRS 311.823(2).

(2) Unprofessional or unethical conduct includes but is not limited to the following acts of a pharmacist, pharmacist intern, or pharmacy technician:

- (a) Publication or circulation of false, misleading, or deceptive statements concerning the practice of pharmacy;
- (b) Divulging or revealing to unauthorized persons patient information or the nature of professional services rendered without the patient's express consent or without order or direction of a court. In addition to members, inspectors, or agents of the board, the following are considered authorized persons:
 1. The patient, patient's agent, or another pharmacist acting on behalf of the patient;
 2. Certified or licensed health-care personnel who are responsible for care of the patient;
 3. Designated agents of the Cabinet for Health and Family Services for the purposes of enforcing the provisions of KRS Chapter 218A;
 4. Any federal, state, or municipal officer whose duty is to enforce the laws of this state or the United States relating to drugs and who is engaged in a specific investigation involving a designated person; or
 5. An agency of government charged with the responsibility of providing medical care for the patient, upon written request by an authorized representative of the agency requesting such information;

- (c) Selling, transferring, or otherwise disposing of accessories, chemicals, drugs, or devices found in illegal traffic when the pharmacist, pharmacy intern, or pharmacy technician knows or should have known of their intended use in illegal activities;
- (d) Engaging in conduct likely to deceive, defraud, or harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct which substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist or pharmacy intern, with or without established proof of actual injury;
- (e) Engaging in grossly negligent professional conduct, with or without established proof of actual injury;
- (f) Except as provided in KRS 315.500, selling, transferring, dispensing, ingesting, or administering a drug for which a prescription drug order is required, without having first received a prescription drug order for the drug;
- (g) Willfully or knowingly failing to maintain complete and accurate records of all drugs received, dispensed, or disposed of in compliance with federal and state laws, rules, or administrative regulations;
- (h) Obtaining any remuneration by fraud, misrepresentation, or deception;
- (i) Accessing or attempting to access confidential patient information for persons other than those with whom a pharmacist has a current pharmacist-patient relationship and where such information is necessary to the pharmacist to provide pharmacy care;
- (j) Failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful;
- (k) Violating KRS 304.39-215; or
- (l) Engaging in conduct that is subject to the penalties under KRS 304.99-060(4) or (5).

(3) Any licensee, permit holder, or certificate holder entering an "Alford" plea, pleading nolo contendere, or who is found guilty of a violation prescribed in subsection (1)(c) of this section shall within thirty (30) days notify the board of that plea or conviction. Failure to do so shall be grounds for suspension or revocation of the license, certificate, or permit.

(4) Any person whose license, permit, or certificate has been revoked in accordance with the provisions of this section, may petition the board for reinstatement. The petition shall be made in writing and in a form prescribed by the board. The board shall investigate all reinstatement petitions, and the board may reinstate a license, permit, or certificate upon showing that the former holder has been rehabilitated and is again able to engage in the practice of pharmacy with reasonable skill, competency, and safety to the public. Reinstatement may be on the terms and conditions that the board, based on competent evidence, reasonably believes necessary to protect the health and welfare of the citizens of the Commonwealth.

(5) Upon exercising the power of revocation provided for in subsection (1) of this section, the board may reasonably prohibit any petition for reinstatement for a period up to and including five (5) years.

(6) Any licensee, permit holder, or certificate holder who is disciplined under this section for a minor violation may request in writing that the board expunge the minor violation from the licensee's, permit holder's, or certificate holder's permanent record.

(a) The request for expungement may be filed no sooner than three (3) years after the date on which the licensee, permit holder, or certificate holder has completed disciplinary sanctions imposed and if the licensee, permit holder, or certificate holder has not been disciplined for any subsequent violation of the same nature within this period of time.

(b) No person may have his or her record expunged under this section more than once. The board shall promulgate administrative regulations under KRS Chapter 13A to establish violations which are minor violations under this subsection. A violation shall be deemed a minor violation if it does not demonstrate a serious inability to practice the profession; assist in the practice of pharmacy; provide home medical equipment and services; adversely affect the public health, safety, or welfare; or result in economic or physical harm to a person; or create a significant threat of such harm.

Effective: January 22, 2021

History: Amended 2021 Ky. Acts ch. 1, sec. 12, effective January 22, 2021. -- Amended 2019 Ky. Acts ch. 143, sec. 14, effective June 27, 2019. -- Amended 2017 Ky. Acts ch. 158, sec. 60, effective June 29, 2017. -- Amended 2016 Ky. Acts ch. 103, sec. 13, effective July 15, 2016. -- Amended 2012 Ky. Acts ch. 73, sec. 11, effective July 12, 2012. -- Amended 2010 Ky. Acts ch. 22, sec. 7, effective July 15, 2010. -- Amended 2008 Ky. Acts ch. 148, sec. 8, effective July 15, 2008. -- Amended 2005 Ky. Acts ch. 99, sec. 598, effective June 20, 2005. -- Amended 2003 Ky. Acts ch. 51, sec. 4, effective June 24, 2003. -- Amended 2002 Ky. Acts ch. 335, sec. 1, effective July 15, 2002. -- Amended 1998 Ky. Acts ch. 426, sec. 549, effective July 15, 1998. -- Amended 1996 Ky. Acts ch. 257, sec. 14, effective July 15, 1996. -- Created 1982 Ky. Acts ch. 191, sec. 11, effective July 15, 1982.

Legislative Research Commission Note (7/12/2012). Under the authority of KRS 7.136(1), the Reviser of Statutes has corrected manifest clerical or typographical errors in this statute during codification. The meaning of the text was not changed.

315.125 Mental or physical examination ordered by board -- Effect of failure to submit to examination.

(1) When the board has probable cause to believe a pharmacist, pharmacy technician, licensee, certificate holder, or permit holder is suffering from a mental or physical condition that might impede that person's ability to practice competently, the board may order the individual to undergo a mental or physical examination by an appropriately-trained professional designated by the board.

(2) Failure of a pharmacist, pharmacy technician, licensee, or permit holder to submit to such an examination when directed, unless the failure was due to circumstances beyond his or her control, shall constitute an admission that he or she has developed such a mental or physical disability, or other condition, that continued practice is dangerous to patients or to the public. Failure to attend the examination shall constitute a default, and a final order suspending, limiting, restricting, or revoking the license or permit may be entered without

the taking of testimony or presentation of evidence.

(3) A pharmacist, pharmacy technician, licensee, or permit holder whose license has been suspended, limited, restricted, or revoked pursuant to this section shall at reasonable intervals be afforded an opportunity, pursuant to KRS 315.121(4), to demonstrate that he can resume the competent practice of pharmacy with reasonable skill and safety to patients.

Effective: July 15, 2016

History: Amended 2016 Ky. Acts ch. 103, sec. 15, effective July 15, 2016. -- Amended

2012 Ky. Acts ch. 73, sec. 12, effective July 12, 2012. -- Amended 2008 Ky. Acts ch. 148, sec. 5, effective July 15, 2008. -- Created 1996 Ky. Acts ch. 257, sec. 15, effective July 15, 1996.

Legislative Research Commission Note (7/12/2012). Under the authority of KRS 7.136(1), the Reviser of Statutes has corrected manifest clerical or typographical errors in this statute during codification. The meaning of the text was not changed.

315.126 Pharmacist recovery network committee -- Administrative regulations -- Assessment -- Confidentiality -- Reporting restrictions.

(1) The board shall establish a pharmacist recovery network committee to promote the early identification, intervention, treatment, and rehabilitation of pharmacists and pharmacist interns who may be impaired by reason of illness, alcohol or drug abuse, or as a result of any other physical or mental condition.

(2) The board may enter into a contractual agreement with a nonprofit corporation, pharmacy professional organization, or similar organization for the purpose of creating, supporting, and maintaining a pharmacist recovery network committee.

(3) The board may promulgate administrative regulations pursuant to KRS Chapter 13A to effectuate and implement the provisions of this section.

(4) Beginning July 15, 1998, the board shall collect an assessment of ten dollars (\$10) to be added to each licensure renewal application fee payable to the board. This assessment shall be expended by the board on the operation of the pharmacist recovery network committee.

(5) Members of a pharmacist recovery network committee, any administrator, staff member, consultant, agent, volunteer, or employee of the committee acting within the scope of his or her duties and without actual malice and all other persons who furnish information to the committee in good faith and without actual malice shall not be liable for any claim or damages as a result of any statement, decision, opinion, investigation, or action taken by the committee or by any individual member of the committee.

(6) All information, interviews, reports, statements, memoranda, or other documents furnished to or produced by the pharmacist recovery network committee, all communications to or from the committee, and all proceedings, findings, and conclusions of the committee, including those relating to intervention, treatment, or rehabilitation, that in any way pertain or refer to a pharmacist or pharmacist intern who is or may be impaired

shall be privileged and confidential.

(7) All records and proceedings of the committee that pertain or refer to a pharmacist or pharmacist intern who is or may be impaired shall be privileged and confidential, used by the committee and its members only in the exercise of the proper function of the committee, not be considered public records, and not be subject to court subpoena, discovery, or introduction as evidence in any civil, criminal, or administrative proceedings, except as described in subsection (8) of this section.

(8) The committee may only disclose the information relative to an impaired pharmacist or pharmacist intern if:

- (a) It is essential to disclose the information to persons or organizations needing the information in order to address the intervention, treatment, or rehabilitation needs of the impaired pharmacist or pharmacist intern;
- (b) The release is authorized in writing by the impaired pharmacist or pharmacist intern; or
- (c) The committee is required to make a report to the board pursuant to KRS 315.121.

Effective: June 20, 2005

History: Amended 2005 Ky. Acts ch. 61, sec. 5, effective June 20, 2005. -- Created 1998 Ky. Acts ch. 531, sec. 1, effective July 15, 1998.

315.131 Proceedings before fine, probation, suspension, revocation of license, permit, or certificate -- Appeals -- Emergency suspension prior to disciplinary hearing.

(1) Every proceeding imposing a fine or for probation, suspension, or revocation of a license, permit, or certificate issued pursuant to this chapter shall be conducted in accordance with KRS Chapter 13B. Upon failure of the licensee, permit holder, or certificate holder to respond to the complaint at or before the time of the hearing, the allegations set forth in the complaint shall be taken by the board as confessed.

(2) All decisions revoking or suspending a license, permit, or certificate or placing a licensee, permit holder, or certificate holder on probation or imposing a fine shall be made by the board.

(3) The board may when in its opinion the continued practice of the licensee or certificate holder or the continued operation of the permit holder would be dangerous to the health, welfare, and safety of the general public, issue an emergency order as provided in KRS 13B.125.

(4) A licensee, permit holder, or certificate holder aggrieved by a final order of the board may within ten (10) days after notice thereof move the board to reconsider this order. A motion to reconsider based on newly-discovered material evidence must be made within one (1) year of the entry of the order.

(5) A licensee, permit holder, or certificate holder aggrieved by a final order of the board may appeal to the Franklin Circuit Court in accordance with KRS Chapter 13B.

(6) The board may, without benefit of a hearing, temporarily suspend a license, certificate, or permit for not more than sixty (60) days if the president of the board finds on the basis of reasonable evidence that a licensee, certificate holder, or permit holder:

- (a) Has violated a statute or administrative regulation the board is empowered to enforce, and continued practice or operation by the licensee, certificate holder, or permit holder would create imminent risk of harm to the public; or
- (b) Suffers a mental or physical condition that through continued practice or operation could create an imminent risk of harm to the public.

The emergency suspension shall take effect upon receipt by the licensee, certificate holder, or permit holder of written notice, delivered by certified mail or in person, specifying the statute or administrative regulation violated. At the time the emergency suspension order issues, the board shall schedule a disciplinary hearing to be held in accordance with the provisions of KRS Chapter 13B within sixty (60) days thereafter.

Effective: July 15, 1996

History: Amended 1996 Ky. Acts ch. 257, sec. 16, effective July 15, 1996; and ch. 318, sec. 271, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 12, effective July 15, 1982. -- Created 1966 Ky. Acts ch. 260, sec. 8.

Legislative Research Commission Note (10/16/96). The initial 1996 codification of the amendments to this statute from the 1996 Regular Session has been revised with respect to subsection (5) of the statute. 1996 Ky. Acts ch. 257, sec. 16, made the venue for appeals "the Franklin Circuit Court" while 1996 Ky. Acts ch. 318, sec. 271, changed "permittee" to "permit holder," in existing language that set the venue for appeals as "the Circuit Court of the county in which the licensee, permittee or certificate holder conducts his practice or place of business." The changing of the word "permittee" to "permit holder" in this phrase was purely stylistic. Therefore, although Acts ch. 318 was a later enactment than Acts ch. 257 for purposes of KRS 446.250, the substantive amendment on this point in Acts ch. 257 prevails over the nonsubstantive, stylistic amendment in Acts ch. 318 pursuant to 1996 Ky. Acts ch. 318, sec. 358. The text of subsection (5) has been altered to reflect this determination.

Legislative Research Commission Note (7/15/96). This section was amended by 1996 Ky. Acts chs. 257 and 318. Where these Acts are not in conflict, they have been codified together. Where a conflict exists, Acts ch. 318, which was last enacted by the General Assembly, prevails under KRS 446.250.

315.135 Registration as pharmacy technician required to assist in the practice of pharmacy -- Exemptions.

(1) Effective April 1, 2009, a person shall not assist in the practice of pharmacy unless he or she is duly registered as a pharmacy technician under the provisions of this chapter or is exempt under subsection (2) of this section.

(2) A person may assist in the practice of pharmacy without obtaining the registration required by this section if the person:

- (a) Has filed an application with the board in accordance with KRS 315.136 and no more than thirty (30) days has elapsed since the date the applicant was first employed by the pharmacy. The exemption shall not apply if:
 - 1. The application has been denied;
 - 2. The person is less than sixteen (16) years of age; or
 - 3. The person has previously been denied a registration or has had a registration revoked or suspended in any jurisdiction and the registration has not yet been issued or reinstated;
- (b) Is in the employ of a son, daughter, spouse, parent, or legal guardian; or

(c) Is participating in a work-study program through an accredited secondary or postsecondary educational institution.

Effective: July 15, 2008

History: Created 2008 Ky. Acts ch. 148, sec. 1, effective July 15, 2008.

315.136 Requirements for registration as pharmacy technician.

(1) Every applicant for registration as a pharmacy technician shall be sixteen (16) years of age and of good mental health and moral character and shall file with the board an application in such form and containing such data as the board may reasonably require.

(2) The application fee shall be twenty-five dollars (\$25). All applicants for registration as a pharmacy technician who serve only on a voluntary basis as a pharmacy technician with a pharmacy operated by a charitable provider as defined in KRS 142.301 shall not be required to pay the application fee.

(3) The board shall issue a certificate of registration and a pocket registration card to an applicant who meets the requirements for registration.

Effective: July 15, 2010

History: Amended 2010 Ky. Acts ch. 11, sec. 1, effective July 15, 2010. -- Created 2008 Ky. Acts ch. 148, sec. 2, effective July 15, 2008.

315.137 Denial of application for registration as pharmacy technician -- Hearing.

(1) The board may deny an application for registration filed under KRS 315.136 if the applicant:

- (a) Submits an incomplete application;
- (b) Fails to submit the application fee; or
- (c) Violates or is deemed to be in violation of any of the provisions of KRS 315.121.

(2) After denying an application for registration, the board shall set the matter for a hearing in accordance with KRS Chapter 13B, upon the written request of the applicant. The applicant's request shall be submitted to the board no later than thirty (30) days immediately following the date the letter of denial is postmarked.

Effective: July 15, 2008

History: Created 2008 Ky. Acts ch. 148, sec. 3, effective July 15, 2008.

315.138 Renewal of registration as pharmacy technician -- Display of registration certificate.

(1) Every pharmacy technician who wishes to renew his or her registration shall pay to the executive director of the board an annual renewal fee of twenty-five dollars (\$25) and shall file with the board an application in such form and containing such information that the board reasonably determines necessary to renew the registration. Each pharmacy technician's registration shall expire on March 31 of each year. A delinquent renewal penalty fee not to exceed twenty-five dollars (\$25) may be assessed for each renewal period the registrant fails to remove his or her registration after the expiration of the registration.

(2) Every pharmacy technician shall keep his or her current certificate of registration conspicuously displayed in the technician's primary place of employment.

(3) In addition to a current certificate of registration, each pharmacy technician shall be issued, upon renewal, a pocket registration card which shall be in the registrant's possession when the registrant is assisting in the practice of pharmacy. The pocket registration card shall be exhibited upon the request of any member, inspector, or agent of the board.

Effective: July 15, 2008

History: Created 2008 Ky. Acts ch. 148, sec. 4, effective July 15, 2008.

315.150 Board membership -- Appointment -- Term -- Vacancy -- Oath -- Quorum.

(1) The board shall consist of six (6) members appointed by the Governor. Five (5) members shall be pharmacists licensed in this state. One (1) member shall be a citizen at large, who is not associated with or financially interested in the practice of pharmacy.

(2) In any calendar year scheduled to be the last full calendar year of a member's regular term in office, the association shall select and submit to the Governor a list of five (5) pharmacists, each of whom has had at least five (5) years' experience in the practice of pharmacy, is a resident of the state and in good standing with the board. On or before March 1 of the same year, the society, other state pharmacy organizations, or individuals may submit recommendations to the association for its consideration in selecting the list to be submitted. The Governor shall, before October 1 of the same year, appoint no more than two (2) persons from each list so submitted, to take office on January 1 following. The citizen member shall be appointed by the Governor. No two (2) pharmacist members of the board shall be residents of the same county.

(3) Beginning January 1, 2005, the term of each board member shall be four (4) years. Each member shall serve until his or her successor is appointed and qualified, unless removed for cause. No member shall be appointed to serve for more than two (2) full terms.

(4) The Governor shall fill any vacancy of a pharmacist member from the names last submitted within sixty (60) days after such a vacancy occurs. Any member so appointed shall commence service at the next regularly-scheduled board meeting and shall serve for the remainder of the term vacated.

(5) Each member shall take and subscribe to an oath before a competent officer to perform the duties of the office faithfully and impartially. The oath shall be inscribed upon the member's commission.

(6) Four (4) members of the board shall constitute a quorum.

Effective: July 13, 2004

History: Amended 2004 Ky. Acts ch. 96, sec. 4, effective July 13, 2004. -- Amended 1996 Ky. Acts ch. 257, sec. 17, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 13, effective July 15, 1982. -- Amended 1976 Ky. Acts ch. 206, sec. 8. -- Amended 1970 Ky. Acts ch. 221, sec. 12. -- Amended 1948 Ky. Acts ch. 222, sec. 6. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. secs. 2621, 2622.

315.155 Removal of board members.

(1) The Governor may remove a member of the board for any of the following reasons:

- (a) Refusal or inability of a board member to perform his duties as a member of the board in an efficient, responsible and professional manner;
- (b) Misuse of the office by a member of the board to obtain personal, pecuniary, or material gain or advantage for himself or another;
- (c) Willful violation of any provision of KRS Chapter 315 or any rule or regulation promulgated thereunder.

(2) Any person may file a complaint with the executive director of the board against a board member alleging specific facts which constitute grounds for removal from the board. The executive director shall transmit a copy of any such complaint to the Governor, the president of the board and the accused board member. Upon a written recommendation of the Governor or two-thirds (2/3) of the members of the board, a hearing shall be conducted before an impartial hearing officer pursuant to KRS Chapter 13B.

(3) The hearing officer shall submit a transcript of the hearing to the Governor with a recommendation based on evidence presented in the hearing. The Governor shall review the transcript to determine if the evidence supports the recommendation, and he shall enter a finding in accordance with such determination.

(4) In the event a board member is removed, his removal shall be effective as of the date of the Governor's finding and a vacancy shall be deemed to exist. Any board member so removed shall be entitled to appeal the removal in the Franklin Circuit Court.

Effective: July 15, 1996

History: Amended 1996 Ky. Acts ch. 257, sec. 18, effective July 15, 1996. -- Created 1982 Ky. Acts ch. 191, sec. 19, effective July 15, 1982.

315.160 Election of officers -- Executive director -- Meetings.

(1) The board shall elect annually from its membership a president and such other officers as it deems necessary. These officers shall serve for a term of one (1) year and perform the duties prescribed by the board. No officer shall serve more than two (2) consecutive full terms in each office to which he is elected.

(2) The board shall employ a pharmacist to serve as a full time employee of the board in the position of executive director. The executive director shall be responsible for the performance of the administrative functions of the board and such other duties as the board may direct. The board may employ, upon recommendation of the executive director, such additional assistance as necessary for the proper conduct of board business and in accordance with the rules and regulations of the Kentucky Personnel Cabinet.

(3) The board shall meet at least four (4) times a year to transact business, at such place as it may determine. The board may also meet at the call of the president or a majority of the

board members. Each board member shall be given adequate prior notice of any board meeting.

Effective: July 15, 1998

History: Amended 1998 Ky. Acts ch. 154, sec. 89, effective July 15, 1998. -- Amended 1982 Ky. Acts ch. 191, sec. 14, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 13. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2622.

315.171 Compensation of board members and executive director.

(1) Beginning January 1, 1998, each member of the board shall receive not more than one hundred dollars (\$100) for each day actively engaged in the service of the board. During the period between July 15, 1996, and January 1, 1998, each board member shall receive not more than seventy-five dollars (\$75) for each day actively engaged in the service of the board. Each member shall receive his traveling expenses and all necessary expenses incurred in the performance of his official duties.

(2) The executive director of the board shall receive a reasonable salary determined by the board. He shall also receive his traveling expenses and all necessary expenses incurred in the performance of his official duties.

Effective: July 15, 1996

History: Amended 1996 Ky. Acts ch. 257, sec. 19, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 15, effective July 15, 1982. -- Created 1966 Ky. Acts ch. 260, sec. 5.

315.180 Executive director to keep record of persons issued licenses, permits or certificates.

The executive director shall keep a register of the names of those persons to whom a license, permit or certificate has been issued and the dates thereof.

Effective: July 15, 1982

History: Amended 1982 Ky. Acts ch. 191, sec. 16, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 15. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2627.

315.191 Powers and duties of board -- Advisory council.

(1) The board is authorized to:

- (a) Promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters set forth in this chapter relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers, to the extent that regulation and control of same have not been delegated to some other agency of the Commonwealth, but administrative regulations relating to drugs shall be limited to the regulation and control of drugs sold pursuant to a prescription drug order. However, nothing contained in this chapter shall be construed as authorizing the board to promulgate any administrative regulations relating to prices or fees or to advertising or the promotion of the sales or use of commodities or services;
- (b) Issue subpoenas, schedule and conduct hearings, or appoint hearing officers to schedule and conduct hearings on behalf of the board on any matter under the jurisdiction of the board;
- (c) Prescribe the time, place, method, manner, scope, and subjects of examinations, with at least two (2) examinations to be held annually;

- (d) Issue and renew all licenses, certificates, and permits for all pharmacists, pharmacist interns, pharmacies, pharmacy technicians, wholesale distributors, and manufacturers engaged in the manufacture, distribution, or dispensation of drugs;
- (e) Investigate all complaints or violations of the state pharmacy laws and the administrative regulations promulgated by the board, and bring all these cases to the notice of the proper law enforcement authorities;
- (f) Promulgate administrative regulations, pursuant to KRS Chapter 13A, that are necessary and to control the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders within and between pharmacists and pharmacies licensed or issued a permit by it;
- (g) Perform all other functions necessary to carry out the provisions of law and the administrative regulations promulgated by the board relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers;
- (h) Establish or approve programs for training, qualifications, and registration of pharmacist interns;
- (i) Assess reasonable fees, in addition to the fees specifically provided for in this chapter and consistent with KRS 61.870 to 61.884, for services rendered to perform its duties and responsibilities, including, but not limited to, the following:
 - 1. Issuance of duplicate certificates;
 - 2. Mailing lists or reports of data maintained by the board;
 - 3. Copies of documents; or
 - 4. Notices of meetings;
- (j) Seize any drug or device found by the board to constitute an imminent danger to public health and welfare;
- (k) Establish an advisory council to advise the board on administrative regulations and other matters, within the discretion of the board, pertinent to the regulation of pharmacists, pharmacist interns, pharmacy technicians, pharmacies, drug distribution, and drug manufacturing. The council shall consist of nine (9) members selected by the board for terms of up to four (4) years. No member shall serve on the council for more than eight (8) years. Membership of the council shall include nine (9) individuals broadly representative of the profession of pharmacy and the general public. Members shall be selected by the board from a list of qualified candidates submitted by the association, society, or other interested parties; and
- (l) Promulgate administrative regulations establishing the qualifications that pharmacy technicians are required to attain prior to engaging in pharmacy practice activities outside the immediate supervision of a pharmacist.

(2) The board shall have other authority as may be necessary to enforce pharmacy laws and administrative regulations of the board including, but not limited to:

- (a) Joining or participating in professional organizations and associations organized exclusively to promote improvement of the standards of practice of pharmacy for

the protection of public health and welfare or facilitate the activities of the board;
and

(b) Receiving and expending funds, in addition to its biennial appropriation, received from parties other than the state, if:

1. The funds are awarded for the pursuit of a specific objective which the board is authorized to enforce through this chapter, or which the board is qualified to pursue by reason of its jurisdiction or professional expertise;
2. The funds are expended for the objective for which they were awarded;
3. The activities connected with or occasioned by the expenditure of the funds do not interfere with the performance of the board's responsibilities and do not conflict with the exercise of its statutory powers;
4. The funds are kept in a separate account and not commingled with funds received from the state; and
5. Periodic accountings of the funds are maintained at the board office for inspection or review.

(3) In addition to the sanctions provided in KRS 315.121, the board or its hearing officer may direct any licensee, permit holder, or certificate holder found guilty of a charge involving pharmacy or drug laws, rules, or administrative regulations of the state, any other state, or federal government, to pay to the board a sum not to exceed the reasonable costs of investigation and prosecution of the case, not to exceed twenty-five thousand dollars (\$25,000).

(4) In an action for recovery of costs, proof of the board's order shall be conclusive proof of the validity of the order of payment and any terms for payment.

Effective: July 15, 2016

History: Amended 2016 Ky. Acts ch. 103, sec. 14, effective July 15, 2016. -- Amended 2015 Ky. Acts ch. 56, sec. 3, effective June 24, 2015. -- Amended 2012 Ky. Acts ch. 73, sec. 13, effective July 12, 2012. -- Amended 2008 Ky. Acts ch. 148, sec. 10, effective July 15, 2008. -- Amended 2005 Ky. Acts ch. 61, sec. 4, effective June 20, 2005. -- Amended 1996 Ky. Acts ch. 257, sec. 20, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 17, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 16. -- Created 1966 Ky. Acts ch. 260, sec. 1.

Legislative Research Commission Note (7/12/2012). The internal format of subsection (1)(d) of this statute has been modified by the Reviser of Statutes from the way it appeared in 2012 Ky. Acts ch. 73, sec. 13, under the authority of KRS 7.136(1). The words in the text were not changed.

315.193 Board members' immunity for official acts.

(1) Members of the board, its agents, and employees shall be immune from suit in any action, civil, or criminal, which is based upon any official act or acts performed by them in good faith.

(2) Any pharmacist, whose duty it is to review or evaluate the acts of other pharmacists and who serves on any committee, board, commission or other entity affiliated with a governmental or quasi-governmental agency or with a medical facility, shall not be required to respond in damages for any official action taken by him in good faith as a member thereof.

Effective: July 15, 1996

History: Amended 1996 Ky. Acts ch. 257, sec. 21, effective July 15, 1996. -- Created 1974 Ky. Acts ch. 310, sec. 4.

315.195 Agency fund -- Use.

(1) All license, permit, and certificate fees, charges, fines, and other moneys collected by the board under the provisions of this chapter, and the administrative regulations of the board, shall be deposited into the State Treasury and credited to a trust and agency fund to be used by the board in carrying out the provisions of this chapter, and are hereby appropriated for those purposes.

(2) Notwithstanding KRS 45.229, any moneys remaining in the fund at the close of the fiscal year shall not lapse but shall be carried forward into the succeeding fiscal year.

Effective: July 12, 2012

History: Amended 2012 Ky. Acts ch. 73, sec. 14, effective July 12, 2012. -- Amended 1996 Ky. Acts ch. 257, sec. 22, effective July 15, 1996. -- Amended 1982 Ky. Acts ch. 191, sec. 18, effective July 15, 1982. -- Created 1966 Ky. Acts ch. 260, sec. 11.

315.200 For whom prescriptions to be refilled.

No prescription shall be knowingly refilled except for the person for whom it was written.

Effective: October 1, 1942

History: Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2060a-6.

315.202 Exercise of judgment by pharmacist to dispense varying quantities of prescription drug per fill.

(1) Notwithstanding any statute to the contrary, unless the practitioner has specified on the prescription drug order that dispensing a prescription for a noncontrolled maintenance drug in an initial amount followed by periodic refills is medically necessary, a pharmacist may exercise professional judgment to dispense varying quantities of the prescribed drug per fill up to the total number of dosage units as authorized by the practitioner on the prescription drug order, including any refills, up to a ninety (90) day supply.

(2) This section does not apply to controlled substances or to any drugs for which a report is required to the electronic system for monitoring controlled substances established in KRS 218A.202.

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 113, sec. 1, effective June 29, 2017.

315.205 Notification of immunization to minor's primary care provider.

Upon the request of an individual or his or her parent or guardian, a pharmacist who administers an immunization to an individual who is nine (9) to seventeen (17) years of age, as authorized in KRS 315.010(22), shall provide notification of the immunization to the individual's primary care provider.

Effective: June 29, 2017

History: Amended 2017 Ky. Acts ch. 44, sec. 2, effective June 29, 2017; and ch. 136, sec. 11, effective June 29, 2017. -- Amended 2016 Ky. Acts ch. 105, sec. 3, effective July 15, 2016. -- Amended 2011 Ky. Acts ch. 81, sec. 2, effective June 8, 2011. -- Created 2010 Ky. Acts ch. 37, sec. 2, effective July 15, 2010.

Legislative Research Commission Note (6/29/2017). This statute was amended by 2017 Ky. Acts chs. 44 and 136, which do not appear to be in conflict and have been codified together.

315.210 Reciprocity.

The board may exchange license certificates with other states so as to allow registered pharmacists of other states to practice pharmacy in this state under regulations prescribed by the board.

History: Amended 1970 Ky. Acts ch. 221, sec. 17.--Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. sec. 2619a-1.

315.220 Powers of representatives of board.

(1) For the purpose of enforcing the provisions of this chapter, officers, agents, and inspectors of the board shall have the power and authority to:

- (a) Administer oaths;
- (b) Enter upon premises of all facilities issued a permit or license by the board, at all reasonable times for the purpose of:
 - 1. Making inspections and carrying out the provisions of this chapter;
 - 2. Conducting investigations;
 - 3. Requiring production of books, papers, documents, records, or other evidence for inspection or copying;
 - 4. Seizing evidence; or
 - 5. Securing oral or written statements;
- (c) Employ special investigators;
- (d) Expend funds for the purpose of obtaining evidence; and
- (e) Issue subpoenas.

(2) As used in subsection (1) of this section, "records" includes, but is not limited to, patient records.

(3) Any decision to inspect, copy, or seize books, papers, documents, records, or other evidence shall be at the discretion of the officer, agent, or inspector of the board.

(4) Inspection, copying, or seizure of books, papers, documents, records, or other evidence does not affect the confidential nature of those records, and the board shall maintain the records so as to protect the confidentiality of the records.

Effective: July 12, 2012

History: Amended 2012 Ky. Acts ch. 73, sec. 15, effective July 12, 2012. -- Amended 1996 Ky. Acts ch. 257, sec. 23, effective July 15, 1996. -- Created 1966 Ky. Acts ch. 260, sec. 9.

315.230 Restraint of violations -- Legal representation.

(1) Notwithstanding the existence or pursuit of any other remedy (civil or criminal) the board is hereby authorized to institute and maintain actions to restrain and enjoin any violation of this chapter, or the rules and regulations of the board.

(2) City, county and Commonwealth's attorneys, and the Attorney General, shall within their respective jurisdictions represent the board, its officers, agents, and inspectors, in the enforcement of the provisions of this chapter, and the rules and regulations of the board, but when the board deems it necessary, it may employ at its discretion, special attorneys to

assist the board, or its officers, agents, or inspectors, and may pay reasonable compensation, fees and other costs from any unexpended funds.

History: Created 1966 Ky. Acts ch. 260, sec. 10.

315.235 Attorney General's jurisdiction to investigate and prosecute violators of pharmacy laws.

(1) The Attorney General has concurrent jurisdiction with the Commonwealth's attorneys of this state for the enforcement of the provisions of this chapter.

(2) The Attorney General may investigate and prosecute a practitioner or any other person who violates the provisions of:

- (a) This chapter; and
- (b) Any other statute if the violation is committed by the practitioner or person in the course of committing a violation described in paragraph (a) of this subsection.

(3) When acting pursuant to this section, the Attorney General may commence his investigation and file a criminal action without leave of court, and the Attorney General has exclusive charge of the conduct of the prosecution.

Effective: June 20, 2005

History: Created 2005 Ky. Acts ch. 150, sec. 16, effective June 20, 2005.

315.295 Automated pharmacy system in residential hospice facilities.

(1) As used in this section and KRS 315.300:

- (a) "Automated pharmacy system" means a mechanical system that delivers prescribed over-the-counter and legend drugs, and controlled substances received from a pharmacy licensed in Kentucky that maintains transaction information; and
- (b) "Residential hospice facility" means a facility licensed under KRS Chapter 216B that provides residential skilled nursing care, pain management, and treatment for acute and chronic conditions for terminally ill patients.

(2) A pharmacy may provide pharmacy services to a residential hospice facility through the use of an automated pharmacy system under the supervision of a licensed pharmacist pursuant to the policies, procedures, and protocol established by the Kentucky Board of Pharmacy. The supervising pharmacist shall not be required to be physically present at the location of the automated pharmacy system and supervision may be provided electronically.

(3) Drugs stored in bulk or unit dose in an automated pharmacy system in a residential hospice facility shall be considered the inventory of the pharmacy providing services to the facility and drugs delivered through the automated pharmacy system shall be considered dispensed by the pharmacy.

(4) The Kentucky Board of Pharmacy shall promulgate administrative regulations pursuant to KRS Chapter 13A to implement the provisions of this section that shall include but not be limited to:

- (a) Accuracy of the automated pharmacy system;
- (b) Security of the system;
- (c) Recordkeeping, including but not limited to electronic signatures of authorized users;
- (d) Inventory management;
- (e) Labeling or reporting requirements that include identification of the dispensing pharmacy, the prescription number, the name of the patient, and the name of the prescriber; and
- (f) Training for authorized users.

(5) Nothing in this section shall be construed to limit or impede pharmacy practice in Kentucky.

Effective: July 12, 2006

History: Created 2006 Ky. Acts ch. 153, sec. 1, effective July 12, 2006.

315.300 Placement of drugs by pharmacy with authorized employees of home health agencies and hospices -- Protocol -- Allowable legend drugs -- Administrative regulations.

(1) A pharmacy shall be allowed to place drugs with a home health agency's authorized employees and with a hospice's authorized employees for the betterment of public health. The pharmacy shall remain the legal owner of the drugs.

(2) A written agreement between the pharmacy and home health agency or hospice shall document the protocol for the handling and storage of the drugs by authorized employees and shall be approved by the pharmacist in charge.

(3) The pharmacist in charge shall review the protocol to assure that safe, secure and accountable handling of controlled legend drugs is maintained under the protocol before giving approval.

(4) The pharmacist in charge or a pharmacist designee shall physically inspect and review the drug storage and handling at the home health agency and the hospice not less than annually.

(5) The home health agency and the hospice protocol shall include but not be limited to the following:

- (a) Safe and secure storage of drugs;
- (b) Access to drugs limited to authorized employees;
- (c) Records of drugs checked out to authorized employees and records of drugs, amounts, and to whom and by whom administered;

- (d) Prompt notification of the pharmacy when a drug is used, including the prescriber, patient, drug, dosage form, directions for use and other pertinent information;
- (e) Billing information;
- (f) Procedures for handling drugs beyond their expiration date; and
- (g) Inventory control.

(6) The following legend drugs shall be allowed under these agreements:

- (a) Sterile water for injection or irrigation;
- (b) Sterile saline solution for injection or irrigation;
- (c) Heparin flush solution;
- (d) Diphenhydramine injectable;
- (e) Epinephrine injectable;
- (f) Glucagon;
- (g) Influenza vaccine; and
- (h) Pneumonia vaccine.

(7) As used in this section:

- (a) "Authorized employee" means any employee of a home health agency or hospice who, in the course of the employee's duties, is licensed by the employee's appropriate licensing agency to administer legend drugs;
- (b) "Home health agency" means an entity required to be licensed under KRS Chapter 216; and
- (c) "Hospice" means an entity authorized to hold itself out to the public as a hospice or as a licensed hospice pursuant to KRS Chapter 216.

(8) The cabinet shall promulgate administrative regulations to implement the provisions of this section.

(9) Nothing in this section shall preclude or prevent a pharmacy from providing pharmacy services through an automated pharmacy system to a residential hospice facility in accordance with KRS 315.295.

Effective: July 12, 2006

History: Amended 2006 Ky. Acts ch. 153, sec. 2, effective July 12, 2006. -- Created 1998 Ky. Acts ch. 531, sec. 5, effective July 15, 1998.

315.310 Duty of treating pharmacist utilizing telehealth to ensure patient's informed consent and maintain confidentiality -- Board to promulgate administrative regulations -- Definition of "telehealth".

- (1) A treating pharmacist who provides or facilitates the use of telehealth shall ensure:
- (a) That the informed consent of the patient, or another appropriate person with authority to make the health care treatment decision for the patient, is obtained before services are provided through telehealth; and

(b) That the confidentiality of the patient's medical information is maintained as required by this chapter and other applicable law. At a minimum, confidentiality shall be maintained through appropriate processes, practices, and technology as designated by the board and that conform to applicable federal law.

(2) The board shall promulgate administrative regulations in accordance with KRS Chapter 13A to implement this section and as necessary to:

- (a) Prevent abuse and fraud through the use of telehealth services;
- (b) Prevent fee-splitting through the use of telehealth services; and
- (c) Utilize telehealth in the provision of pharmacy services and in the provision of continuing education.

(3) For purposes of this section, "telehealth" means the use of interactive audio, video, or other electronic media to deliver health care. It includes the use of electronic media for diagnosis, consultation, treatment, transfer of health or medical data, and continuing education.

Effective: July 14, 2000

History: Created 2000 Ky. Acts ch. 376, sec. 15, effective July 14, 2000.

315.320 Illegal operation of out-of-state pharmacy -- Exemption for lapsed license or permit -- Penalty -- Exceptions from section.

(1) A person or pharmacy is guilty of a Class C felony if the person or pharmacy, located inside or outside this Commonwealth, is not licensed by the Commonwealth of Kentucky to engage in the practice of pharmacy and knowingly:

- (a) Communicates with a person in this Commonwealth; and
- (b) Uses or attempts to use such communication or information, in whole, or in part, to:
 1. Fill or refill a prescription for a prescription drug for the other person; or
 2. Deliver, cause, allow, or aid in the delivery of a controlled substance, imitation controlled substance, counterfeit substance or prescription drug to the other person.

(2) A person or pharmacy is guilty of a Class B felony if the substance or drug dispensed in subsection (1) of this section:

- (a) Is classified in Schedule I; or
- (b) Proximately causes serious physical injury or the death of the intended recipient of the substance or drug or any other person.

(3) The court shall not grant probation to or suspend the sentence of a person punished pursuant to subsection (2) of this section.

(4) A person who knowingly aids another in any act or transaction that violates the provisions of subsection (1) of this section is guilty of a Class C felony.

(5) A person who knowingly aids another in any act or transaction that violates the provisions of subsection (2) of this section is guilty of a Class B felony.

(6) A person or pharmacy may be prosecuted, convicted, and punished for a violation of this section whether or not the person is prosecuted, convicted, or punished for a violation of any other statute based upon the same act or transaction.

(7) This section shall not apply to a licensed pharmacist or permitted pharmacy that inadvertently allows its license or permit issued by the Kentucky Board of Pharmacy to lapse for a period of less than thirty (30) days.

(8) This section shall not apply to authorized agents of a pharmacy with a valid permit issued by the Kentucky Board of Pharmacy.

(9) This section shall not apply to an authorized agent of a pharmacy that inadvertently allows its permit issued by the Kentucky Board of Pharmacy, to lapse for a period of less than thirty (30) days.

(10) Unless a more specific penalty applies within this chapter, anyone who uses the Internet to communicate and facilitate the sale of controlled substances, except as specifically provided for in this chapter, may be prosecuted under KRS Chapter 218A.

Effective: June 26, 2007

History: Amended 2007 Ky. Acts ch. 124, sec. 11, effective June 26, 2007. -- Created 2005 Ky. Acts ch. 150, sec. 14, effective June 20, 2005.

315.325 Exemption from pharmacy licensing requirements for common carriers transporting drugs.

The provisions of KRS 315.320 do not apply to a person who is:

(1) A common or contract carrier or warehouseman, or any employee thereof, unless the person is acting outside of the usual course of his business or employment or knows or has reasonable cause to believe that the act or transaction is unlawful; or

(2) An employee or agent of a pharmacist or pharmacy licensed or permitted pursuant to this chapter and acting in accordance with KRS Chapter 218A, unless the person is acting outside of the usual course of his business or employment or knows or has reasonable cause to believe that the act or transaction is unlawful; or

(3) The intended recipient of a substance or drug, unless the intended recipient knows or has reasonable cause to believe that the act or transaction is unlawful.

Effective: June 20, 2005

History: Created 2005 Ky. Acts ch. 150, sec. 15, effective June 20, 2005.

315.330 Seizure and forfeiture of illegal drug shipments.

(1) Any drug which is ordered or shipped in violation of any provision of this chapter or KRS Chapter 218A shall be considered as contraband and may be seized by any peace officer or

any employee of the Board of Pharmacy designated to enforce the provisions of this chapter or KRS Chapter 218A.

(2) The officer, prior to seizing the drug, shall make a reasonable effort to determine:

- (a) The person who ordered the drug;
- (b) The pharmacy from which the drug was ordered;
- (c) The shipper of the drug;
- (d) The intended recipient of the drug; and
- (e) Whether or not the shipment was legal.

(3) Unless the matter is the subject of a criminal prosecution, if, after thirty (30) days of investigation, the officer seizing the drug cannot adequately determine the information required by subsection (2) of this section, the drug that has been seized shall be considered as abandoned and escheat to the Commonwealth.

(4) If a drug seized pursuant to this section is the subject of a criminal investigation, the drug shall be retained as evidence and, if there is a conviction of any person or pharmacy relating to the ordering or shipment of the drug, the drug shall be forfeited to the Commonwealth. If the defendant is found not guilty or the charges are dismissed with prejudice, the drug shall be returned to the defendant.

(5) Drugs which have been seized and which have been forfeited or abandoned and escheat to the Commonwealth shall be destroyed.

Effective: June 20, 2005

History: Created 2005 Ky. Acts ch. 150, sec. 17, effective June 20, 2005.

315.335 Reporting of robbery, theft, or missing shipment of controlled substances.

(1) A pharmacy located in Kentucky which has a robbery or theft of a controlled substance shall immediately following the robbery or discovery of the theft report the incident to a law enforcement agency serving the geographic area in which the pharmacy is located.

(2) A pharmacy which has mailed or shipped a controlled substance to a location in Kentucky and learns that the mailing or shipment did not arrive shall within three (3) business days report that nonreceipt to:

- (a) The Department of Kentucky State Police; and
- (b) If applicable, the United States Postal Inspection Service.

(3) (a) The reports required pursuant to subsections (1) and (2) of this section shall contain at a minimum, if known and applicable:

- 1. The name, National Drug Code, and quantity of each controlled substance involved;
- 2. A description of the circumstances of the loss;
- 3. The names and contact information of any witnesses; and

4. The name and description of any person suspected of committing the offense or causing the loss.

(b) The Board of Pharmacy may by administrative regulation authorize a pharmacy to submit a completed DEA 106 form or a successor form in lieu of the data elements required by this subsection.

Effective: March 4, 2013

History: Amended 2013 Ky. Acts ch. 2, sec. 5, effective March 4, 2013. – Created 2012 (1st Extra. Sess.) Ky. Acts ch. 1, sec. 11, effective July 20, 2012.

315.340 Permit for operation of in-state outsourcing facility doing business in Kentucky -- Requirements -- Administrative regulations.

- (1) (a) A person shall not operate an outsourcing facility within this Commonwealth, physically or by means of the Internet, facsimile, phone, mail, or any other means, without first obtaining a permit from the board.
- (b) An application for a permit to operate an outsourcing facility shall be made to the board upon forms provided by the board and shall contain such information as the board requires, which may include affirmative evidence of the ability to comply with the requirements of this chapter and the administrative regulations promulgated by the board.
- (c) Each application shall be accompanied by a nonrefundable permit fee to be set by administrative regulation promulgated by the board, not to exceed five hundred dollars (\$500).
- (2) (a) As a prerequisite to obtaining or renewing a permit from the board, the outsourcing facility shall:
1. Register as an outsourcing facility with the United States Secretary of Health and Human Services in accordance with 21 U.S.C. sec. 353b; and
 2. Submit a copy of a current inspection report resulting from an inspection conducted by the United States Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the United States Food and Drug Administration.
- (b) 1. The inspection report required pursuant to paragraph (a)2. of this subsection shall be deemed current for the purposes of this section if the inspection was conducted no more than:
- a. One (1) year prior to the date of submission of an application for a permit to the board; or
 - b. Two (2) years prior to the date of submission of an application for renewal of a permit to the board.
2. If the outsourcing facility has not been inspected by the United States Food and Drug Administration within the period required under subparagraph 1. of this paragraph, the board may:
- a. Accept an inspection report or other documentation from another entity that is satisfactory to the board; or

- b. Cause an inspection to be conducted by its duly authorized agent and charge an inspection fee in an amount sufficient to cover the costs of the inspection.
- (3) (a) Upon receipt of an application for a permit to operate an outsourcing facility accompanied by the permit fee prescribed by administrative regulation, the board shall:
1. Issue a permit if the outsourcing facility meets the requirements of this chapter and the administrative regulations promulgated by the board; or
 2. Refuse to issue or renew any permit to operate if the outsourcing facility fails to meet the requirements of this chapter and the administrative regulations promulgated by the board.
- (b) The board shall act upon an application for a permit to operate within thirty (30) days after the receipt of the application. The board may issue a temporary permit to operate in any instance where it considers additional time necessary for investigation and consideration before taking final action upon the application. The temporary permit shall be valid for a period of thirty (30) days, unless extended.
- (4) A separate permit to operate shall be required for each outsourcing facility.
- (5) (a) Each permit to operate an outsourcing facility, unless suspended or revoked, shall expire on June 30 following its date of issuance and be renewable annually thereafter upon proper application accompanied by the renewal fee as established by administrative regulations promulgated by the board. The renewal fee shall not exceed five hundred dollars (\$500).
- (b) An additional nonrefundable fee not to exceed the annual renewal fee may be assessed and set by administrative regulation as a delinquent renewal penalty for failure to renew by June 30 of each year.
- (6) Permits to operate shall be issued only for the premises and persons named in the application and shall not be transferable, except that a buyer may operate the outsourcing facility under the permit of the seller pending a decision by the board on an application, which shall be filed by the buyer with the board at least five (5) days prior to the date of sale.
- (7) The board may promulgate administrative regulations to ensure:
- (a) That proper equipment and reference material is on hand considering the nature of the pharmaceutical practice conducted at the particular outsourcing facility; and
 - (b) Health and sanitation standards for areas within outsourcing facilities that adhere to Current Good Manufacturing Practices published by the United States Food and Drug Administration.

(8) Each outsourcing facility shall comply with KRS 218A.202.

(9) Each outsourcing facility shall compound in compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the United States Food and Drug Administration.

(10) A pharmacist may temporarily operate an outsourcing facility in an area not designated on the permit as authorized in KRS 315.500.

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 136, sec. 2, effective June 29, 2017.

315.342 Permit for operation of out-of-state outsourcing facility doing business in Kentucky -- Requirements -- Administrative regulations.

- (1) (a) Each out-of-state outsourcing facility that does business physically or by means of the Internet, facsimile, phone, mail, or any other means, inside this Commonwealth, shall hold a current outsourcing facility permit issued by the board.
- (b) An application for a permit to operate an out-of-state outsourcing facility shall be made to the board upon forms provided by it and shall contain such information as the board requires, which may include affirmative evidence of ability to comply with reasonable standards and regulations as may be prescribed by the board.
- (c) Each application shall be accompanied by a permit fee to be set by administrative regulation promulgated by the board. The fee shall not exceed:
1. Two hundred fifty dollars (\$250); or
 2. The current in-state outsourcing facility permit.
- (2) (a) As a prerequisite to obtaining or renewing a permit from the board, the out-of-state outsourcing facility shall:
1. Register as an outsourcing facility with the United States Secretary of Health and Human Services in accordance with 21 U.S.C. sec. 353b; and
 2. Submit a copy of a current inspection report resulting from an inspection conducted by the United States Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the United States Food and Drug Administration.
- (b) 1. The inspection report required pursuant to paragraph (a)2. of this subsection shall be deemed current for the purposes of this section if the inspection was conducted no more than:
- a. One (1) year prior to the date of submission of an application for a permit to the board; or
 - b. Two (2) years prior to the date of submission of an application for renewal of a permit to the board.

2. If the out-of-state outsourcing facility has not been inspected by the United States Food and Drug Administration within the required period required under subparagraph 1. of this paragraph, the board may:

- a. Accept an inspection report or other documentation from another entity that is satisfactory to the board; or
- b. Cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

- (3) (a) Upon receipt of an application for a permit to operate an out-of-state outsourcing facility, accompanied by the permit fee required by subsection (1) of this section, the board shall:
1. Issue a permit if the out-of-state outsourcing facility meets the requirements of this chapter and the administrative regulations promulgated by the board; or
 2. Refuse to renew any permit to operate unless the out-of-state outsourcing facility meets the requirements of this chapter and the administrative regulations promulgated by the board.
- (b) The board shall act upon an application for a permit to operate within thirty (30) days after the receipt thereof. The board may issue a temporary permit to operate in any instance where it considers additional time necessary for investigation and consideration before taking final action upon the application. The temporary permit shall be valid for a period of thirty (30) days, unless extended.

(4) A separate permit to operate shall be required for each out-of-state outsourcing facility.

(5) Each out-of-state outsourcing facility granted an out-of-state outsourcing facility permit by the board shall disclose to the board the location, names, and titles of all its principal corporate officers and all its pharmacists who are dispensing prescription drugs to entities within the Commonwealth. A report containing this information shall be made to the board on an annual basis and within thirty (30) days after any change of office, corporate officer, or pharmacist.

- (6) (a) An out-of-state outsourcing facility granted an out-of-state outsourcing facility permit shall comply with all requests for information within three (3) business days of a written request by the board or its agents.
- (b) An out-of-state outsourcing facility shall maintain at all times a valid unexpired permit, license, or registration to conduct the outsourcing facility in compliance with the laws of the jurisdiction in which it is a resident.
- (c) As a prerequisite to seeking a permit from the board, the out-of-state outsourcing facility shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. Thereafter, the out-of-state outsourcing facility granted a permit shall submit to the board a copy of any subsequent inspection report of the outsourcing facility conducted by the regulatory or licensing body of the jurisdiction in which it is located.

(7) Each out-of-state outsourcing facility granted an out-of-state outsourcing facility permit by the board shall maintain records of any controlled substances or dangerous drugs.

(8) Each out-of-state outsourcing facility shall, during its regular hours of operation, but not less than five (5) days per week and for a minimum of forty (40) hours per week, provide a toll-free telephone service directly to the pharmacist in charge of the out-of-state outsourcing facility for the purpose of facilitating communication. A toll-free number shall be placed on a label affixed to each container of drugs dispensed to an entity within the Commonwealth.

(9) An out-of-state outsourcing facility shall comply with KRS 218A.202.

(10) An out-of-state outsourcing facility doing business within the Commonwealth of Kentucky shall use the address on file with the board as the return address on the labels of any package shipped into or within the Commonwealth. The return address shall be placed on the package in a clear and prominent manner.

(11) (a) A permit to operate an out-of-state outsourcing facility, unless suspended or revoked, shall expire on June 30 following its date of issuance and be renewable annually thereafter upon proper application accompanied by the nonrefundable renewal fee established by subsection (1) of this section.

(b) An additional nonrefundable fee not to exceed the annual renewal fee may be assessed and set by administrative regulation as a delinquent renewal penalty for failure to renew by June 30 of each year.

(12) Permits to operate shall be issued only for the premises and persons named in the application and shall not be transferable, except that a buyer may operate the out-of-state outsourcing facility under the permit of the seller pending a decision by the board on an application which shall be filed by the buyer with the board at least five (5) days prior to the date of sale.

(13) The board may promulgate administrative regulations to ensure that proper equipment and reference material is on hand considering the nature of the pharmaceutical practice conducted at the particular out-of-state outsourcing facility.

(14) Each out-of-state outsourcing facility shall compound in compliance with the requirements of state and federal law and regulations, to include all applicable guidance documents and Current Good Manufacturing Practices published by the United States Food and Drug Administration.

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 136, sec. 3, effective June 29, 2017.

315.350 License required for medical gas wholesaler operating within state -- Fee -- Recordkeeping -- Penalty for noncompliance -- Administrative regulations.

(1) A medical gas wholesaler, whether located within the Commonwealth or operating within the Commonwealth from a location outside the Commonwealth, shall be licensed by the board. Each license application shall be accompanied by a fee which shall:

- (a) Be prescribed by administrative regulation promulgated by the board in an amount not to exceed two hundred fifty dollars (\$250); and
- (b) Not be increased by more than twenty-five dollars (\$25) per year.

(2) A medical gas wholesaler shall be required to maintain accurate records of all drugs handled. Records shall be made available to agents of the board for inspection upon request.

(3) Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under KRS 315.121.

(4) The board shall promulgate administrative regulations to specify the criteria for licensure and discipline of a medical gas wholesaler.

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 136, sec. 10, effective June 29, 2017. Legislative Research Commission Note (6/29/2017). In codification, the Reviser of Statutes has corrected a manifest clerical or typographical error by inserting the inadvertently omitted words "accompanied by" in subsection (1) of this statute as created in 2017 Ky. Acts ch. 136, sec. 10 under the authority of KRS 7.136(1)(h).

315.400 Definitions for KRS 315.400 to 315.412.

As used in KRS 315.400 to 315.412:

(1) "Authorized distributor of record" means a wholesale distributor that:

- (a) Has established an ongoing relationship with a manufacturer to distribute the manufacturer's prescription drug. An ongoing relationship exists between a wholesale distributor and a manufacturer if the wholesale distributor, including any affiliated group of the wholesale distributor as defined in Section 1504 of the Internal Revenue Code, has a written agreement for distribution in effect; and
- (b) Is listed on the manufacturer's current list of authorized distributors of record;

(2) "Co-licensed product" means a prescription drug manufactured by two (2) or more co-licensed partners;

(3) "Counterfeit prescription drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed the drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, the other drug manufacturer, processor, packer, or distributor;

(4) "Dispenser" means:

- (a) A retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouse distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; but

(b) Does not include a person who dispenses only products to be used in animals in accordance with 21 U.S.C. sec. 360b(a)(4) and (5);

(5) "Distribution" or "distribute" means the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with Section 503(b)(1) of the federal Drug Quality and Security Act or the dispensing of a product approved under Section 512(b) of the federal Drug Quality and Security Act;

(6) "Drop shipment" means a product not physically handled or stored by a wholesale distributor and that is exempt from Section 582 of the federal Drug Quality and Security Act, except the notification requirements under clauses (ii), (iii), and (iv) of subsection (c)(4)(B) of Section 582 of the federal Drug Quality and Security Act, provided that the manufacturer, repackager, or other wholesale distributor that distributes the product to the dispenser by means of a drop shipment for the wholesale distributor includes on the transaction information and transaction history to the dispenser the contact information of the wholesale distributor and provides the transaction information, transaction history, and transaction statement directly to the dispenser. Providing administrative services, including the processing of orders and payments, shall not by itself be construed as being involved in the handling, distribution, or storage of a product;

(7) "Emergency medical reasons" includes but is not limited to:

- (a) Transfers of a prescription drug between health-care entities or between a health-care entity and a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruptions of the regular distribution schedules;
- (b) Sales of drugs for use in the treatment of acutely ill or injured persons to nearby emergency medical services providers, firefighting organizations, or licensed health-care practitioners in the same marketing or service area;
- (c) The provision of emergency supplies of drugs to nearby nursing homes, home health agencies, or hospice organizations for emergency use when necessary drugs cannot be obtained; or
- (d) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;

(8) "End user" means a patient or consumer that uses a prescription drug as prescribed by an authorized health-care professional;

(9) "Exclusive distributor" means the wholesale distributor that directly purchased the product from the manufacturer and is the sole distributor of that manufacturer's product to a subsequent repackager, wholesale distributor, or dispenser;

(10) "FDA" means the United States Food and Drug Administration and any successor agency;

(11) "Illegitimate product" means a product for which credible evidence shows that the product:

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

- (b) Is intentionally adulterated so that the product would result in serious adverse health consequences or death to humans;
- (c) Is the subject of a fraudulent transaction; or
- (d) Appears otherwise unfit for distribution so that the product would be reasonably likely to result in serious adverse health consequences or death to humans;

(12) "Manufacturer" means the same as defined in KRS 315.010;

(13) "Medical gas wholesaler" means a person licensed to distribute, transfer, wholesale, deliver, or sell medical gases on drug orders to suppliers or other entities licensed to use, administer, or distribute medical gas;

(14) "Pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of prescription drugs to a group of pharmacies under common ownership and control;

(15) "Prescription drug" means the same as defined in KRS 315.010;

(16) "Repackager" means a person who owns or operates an establishment that repacks and relabels a product or package for further sale, or distribution without a further transaction;

(17) "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, manufacturers, or other entities by receiving, taking inventory, and managing the disposition of outdated or nonsalable drugs;

(18) "Third-party logistics provider" means an entity that contracts with a manufacturer, wholesale distributor, repackager, or dispenser to provide and coordinate warehousing or other logistics services on behalf of a manufacturer, wholesale distributor, repackager, or dispenser, but does not take title to the drug or have responsibility to direct the sale of the drug. A third-party logistics provider shall be considered as part of the normal distribution channel;

(19) "Transaction" means the transfer of product between persons in which a change of ownership occurs, with the following exemptions:

- (a) Intracompany distribution of any product between members of an affiliate or within a manufacturer;
- (b) The distribution of a product among hospitals or other health care entities that are under common control;
- (c) The distribution of a product for emergency medical reasons, including a public health emergency declaration pursuant to Section 319 of the federal Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;
- (d) The dispensing of a product pursuant to a prescription executed in accordance with Section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act;

- (e) The distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with Section 503(d) of the Federal Food, Drug, and Cosmetic Act;
- (f) The distribution of blood or blood components intended for transfusion;
- (g) The distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;
- (h) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- (i) The distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;
- (j) The dispensing of a product approved under Section 512(c) of the Federal Food, Drug, and Cosmetic Act;
- (k) Products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by the state pursuant to an agreement with the commission under Section 274 of the federal Atomic Energy Act, 42 U.S.C. sec. 2021;
- (l) A combination product that is not subject to approval under Section 505 of the federal Drug Quality and Security Act or licensure under Section 351 of the federal Public Health Service Act, and that is:
 - 1. A product composed of a device and one (1) or more other regulated components such as a drug or drug device, a biologic or biologic device, or a drug and biologic or drug and biologic device that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
 - 2. Two (2) or more separate products packaged together in a single package or as a unit and composed of a drug and device or device and biological product; or
 - 3. Two (2) or more finished medical devices plus one (1) or more drug or biological products that are packaged together in what is referred to as a medical convenience kit as described in paragraph (m) of this subsection;
- (m) The distribution of a medical convenience kit or collection of finished medical devices which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user, if:
 - 1. The medical convenience kit is assembled in an establishment that is registered with the federal Food and Drug Administration as a device manufacturer in accordance with Section 510(b)(2) of the Federal Food, Drug, and Cosmetic Act;
 - 2. The medical convenience kit does not contain a controlled substance that appears in a schedule contained in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970;
 - 3. In the case of a medical convenience kit that includes a product, the person that manufactures the kit:
 - a. Purchased the product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

- b. Does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and
- 4. In the case of a medical convenience kit that includes a product, the product is:
 - a. An intravenous solution intended for the replenishment of fluids and electrolytes;
 - b. A product intended to maintain the equilibrium of water and minerals in the body;
 - c. A product intended for irrigation or reconstitution;
 - d. An anesthetic;
 - e. An anticoagulant;
 - f. A vasopressor; or
 - g. A sympathomimetic;
- (n) The distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes such as sodium, chloride, and potassium, or calories such as dextrose and amino acids;
- (o) The distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;
- (p) The distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;
- (q) The distribution of a medical gas as defined in Section 575 of the Federal Food, Drug, and Cosmetic Act; or
- (r) The distribution or sale of any licensed product under Section 351 of the federal Public Health Service Act that meets the definition of a device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act;

(20) "Wholesale distribution" means the distribution of a prescription drug to persons other than an end user, but does not include:

- (a) Intracompany sales or transfers;
- (b) The sale, purchase, distribution, trade, or transfer of a prescription drug for emergency medical reasons;
- (c) The distribution of prescription drug samples by a manufacturer or authorized distributor;
- (d) Drug returns or transfers to the original manufacturer, original wholesale distributor, or transfers to a reverse distributor or third-party returns processor;
- (e) The sale, purchase, or trade of a drug pursuant to a prescription;
- (f) The delivery of a prescription drug by a common carrier;
- (g) The purchase or acquisition by a health-care entity or pharmacy that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization, or health-care entities or pharmacies that are members of the group organization;
- (h) The sale, purchase, distribution, trade, or transfer of a drug by a charitable health-care entity to a nonprofit affiliate of the organization as otherwise permitted by law;
- (i) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy with another pharmacy or pharmacies; or

(j) The distribution of a prescription drug to a health-care practitioner or to another pharmacy if the total number of units transferred during a twelve (12) month period does not exceed five percent (5%) of the total number of all units dispensed by the pharmacy during the immediate twelve (12) month period; and

(21) "Wholesale distributor" or "virtual wholesale distributor" means a person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager engaged in wholesale distribution as defined by 21 U.S.C. sec. 353(e)(4) as amended by the federal Drug Supply Chain Security Act.

Effective: June 27, 2019

History: Amended 2019 Ky. Acts ch. 157, sec 3, effective June 27, 2019 – Amended 2017 Ky. Acts ch. 136, sec. 4, effective June 29, 2017. -- Created 2008 Ky. Acts ch. 124, sec. 3, effective July 15, 2008

315.402 Licensure of wholesale distributors of prescription drugs -- Record retention -- Administrative regulations -- Confidentiality.

(1) A wholesale distributor shall be licensed by the board under this section prior to engaging in the wholesale distribution of prescription drugs in the Commonwealth. Each license application shall be accompanied by a reasonable fee prescribed by administrative regulation not to exceed two hundred fifty dollars (\$250) annually or increase more than twenty-five dollars (\$25) per year.

(2) A wholesale distributor shall be required to maintain accurate records of all drugs handled in accordance with KRS 315.400 to 315.412, and records shall be made available to agents of the board for inspection upon request.

(3) Licensing requirements that exceed the requirements of federal law shall not apply to a manufacturer distributing its own FDA-approved drugs or co-licensed products, unless there is reasonable cause to believe that the manufacturer presents a special risk of distributing counterfeit prescription drugs in the Commonwealth.

(4) Failure to report to the board or willful submission of inaccurate information shall be grounds for disciplinary action under the provisions of KRS 315.131.

(5) The board shall promulgate an administrative regulation pursuant to KRS Chapter 13A to specify the criteria for licensure in conformity with the guidelines for state licensure of a wholesale prescription drug distributor issued by the FDA.

(6) Pursuant to KRS 61.878, information provided by an applicant under this section and any related administrative regulation shall not be disclosed to any person or entity other than the board.

Effective: July 15, 2008

History: Created 2008 Ky. Acts ch. 124, sec. 4, effective July 15, 2008.

315.404 Returns or exchanges of prescription drugs.

(1) (a) A wholesale distributor may receive prescription drug returns or exchanges from a pharmacy, pharmacy warehouse, or other person authorized to distribute a

prescription drug to an end user under the terms and conditions of an agreement between the parties.

(b) Returns of expired, damaged, recalled, or otherwise nonsalable prescription drugs shall be distributed by the receiving wholesale distributor only to the original manufacturer, a third-party returns processor, or a reverse distributor licensed as a wholesale distributor.

(c) Returns or exchanges of prescription drugs that may or may not be salable, including any redistribution by a receiving wholesaler, shall not be subject to the requirements of KRS 315.406 if they are exempt from the pedigree requirements of the federal regulations for the federal Prescription Drug Marketing Act of 1987 as amended by the Prescription Drug Amendments of 1992 and any amendments thereto.

(2) A manufacturer or wholesale distributor shall supply prescription drugs only to a person or entity licensed to possess or distribute prescription drugs to an end user.

(3) Prescription drugs supplied by a manufacturer or wholesale distributor shall be delivered only to the business address of the licensee or the address listed on the license, to the address of a health-care entity authorized by the licensee, or to an authorized person or agent of the licensee at the premises of the manufacturer or wholesale distributor if the identity and authority of the authorized agent is established.

(4) A licensed wholesale distributor, pharmacy, or other person authorized by law to furnish prescription drugs to an end user shall be accountable for their returns process and shall ensure that all aspects of their operations are secure and do not permit the entry of adulterated or counterfeit prescription drugs.

Effective: July 15, 2008

History: Created 2008 Ky. Acts ch. 124, sec. 5, effective July 15, 2008.

315.406 Prescription drug pedigree for drugs leaving normal distribution channel -- Administrative regulations.

(1) (a) As of the date specified by an administrative regulation promulgated by the board pursuant to KRS Chapter 13A, each person or entity engaged in the wholesale distribution of prescription drugs that leave or that have ever left the normal distribution channel shall, prior to the distribution of the prescription drug, provide a pedigree to the person receiving the prescription drug.

(b) A retail pharmacy or a pharmacy warehouse shall comply with paragraph (a) of this subsection only if it engages in wholesale distribution of prescription drugs.

(2) The board shall specify the requirements for the contents and maintenance of a pedigree that are consistent with the federal requirements.

(3) The board shall promulgate an administrative regulation pursuant to KRS Chapter 13A to implement the provisions of this section no later than one hundred eighty (180) days after July 15, 2008.

Effective: July 15, 2008

History: Created 2008 Ky. Acts ch. 124, sec. 6, effective July 15, 2008.

315.408 Electronic track and trace system.

(1) The board shall not require the use of an electronic track and trace system to initiate, provide, receive, or maintain a pedigree by a person or entity licensed to possess, distribute, dispense, or administer prescription drugs for use by an end user until the FDA develops and implements standards for identification, validation, authentication, and tracking and tracing of prescription drugs pursuant to 21 U.S.C. sec. 355e. The electronic track and trace system requirements by the board shall meet the FDA's standards for all prescription drugs covered by the FDA standards.

(2) Upon implementation of FDA standards for an electronic track and trace system, the requirements relating to a pedigree in KRS 315.406 shall be superseded by the FDA standards and shall not apply to any prescription drugs specified in the FDA standards.

(3) Prior to promulgation of any administrative regulation under KRS Chapter 13A that requires the use of an electronic track and trace system, the board shall consult with manufacturers, wholesale distributors, and pharmacies regarding implementation of the electronic track and trace system requirements and publish a report on its Web site about implementation issues, including but not limited to universal availability, technical and operational feasibility, and reliability for manufacturers, wholesale distributors, and pharmacies.

Effective: July 15, 2008

History: Created 2008 Ky. Acts ch. 124, sec. 7, effective July 15, 2008.

315.410 Order to cease distribution of prescription drugs -- Hearing.

(1) The board shall issue an order to the appropriate person or entity, including but not limited to wholesale distributors or retailers, to immediately cease distribution of prescription drugs within the Commonwealth if there are reasonable grounds to believe:

- (a) 1. The distribution of the prescription drug is in violation of KRS 315.406;
 2. The prescription drug is accompanied by a falsified pedigree in violation of KRS 315.406; or
 3. The prescription drug is a counterfeit prescription drug; and
- (b) Other procedures to intercede would result in an unreasonable delay.

(2) A person in receipt of an order to cease distribution shall be notified in writing of the right to an administrative hearing to be conducted in accordance with KRS Chapter 13B no later than ten (10) days, excluding weekends and holidays, after the date of the order. If, after a hearing is conducted, the hearing officer determines that there are inadequate grounds to support the order, the order shall be vacated.

Effective: July 15, 2008

History: Created 2008 Ky. Acts ch. 124, sec. 8, effective July 15, 2008.

315.4102 License required for each facility of a third-party logistics provider.

(1) Each facility of a third-party logistics provider located within Kentucky shall be licensed by the board prior to shipping a prescription drug:

- (a) Within the borders of Kentucky; or
- (b) To a location outside the borders of Kentucky.

(2) Licenses issued under subsection (1) of this section shall be renewed annually upon:

- (a) Completion of an application; and
- (b) Payment of a renewal fee as established by administrative regulations promulgated by the board.

(3) A third-party logistics provider located in another state seeking to ship a prescription drug into Kentucky shall provide documentation upon request by the board or its staff that the third-party logistics provider is licensed as a third-party logistics provider by:

- (a) The state from which the third-party logistics provider ships, if that state licenses third-party logistics providers; or
- (b) The United States Food and Drug Administration.

(4) A third-party logistics provider license shall be valid only for the name, ownership, and location listed on the license. Changes of name, ownership, or location shall require a new third-party logistics provider license.

(5) Changes in information required for licensure shall be reported to the board, in writing, within ten (10) days of the change.

(6) A third-party logistics provider shall not operate from a place of residence.

(7) A third-party logistics provider facility shall be located apart and separate from any retail pharmacy licensed by the board.

(8) A third-party logistics provider shall publicly display all licenses and have the most recent state and federal inspection reports readily available.

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 136, sec. 5, effective June 29, 2017.

315.4104 Required license application information and fee for third-party logistics provider.

(1) An applicant for licensure as a third-party logistics provider shall submit a satisfactorily completed board-approved application along with the required fee. New applicants shall provide, at minimum, the following:

- (a) The applicant's full name, all trade or business names used, full business address, and telephone number;

- (b) Type of ownership, whether individual, partnership, limited liability company, or corporation;
- (c) Name of the owner or owners, including:
 - 1. If a person, the name, address, Social Security number, and date of birth;
 - 2. If other than a person, the name, address, Social Security number, and date of birth of each partner, limited liability company member, or corporate officer and corporate director, and the federal employer identification number;
 - 3. If a corporation, the state of incorporation; and
 - 4. If a publicly traded corporation, the information described in subparagraph 2 of this paragraph is not required for corporate officers and corporate directors;and
- (d) Upon the board's written request, a list of all manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services.

(2) The board may use a board-approved outside agency, if permitted by federal law, to inspect third-party logistics providers.

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 136, sec. 6, effective June 29, 2017.

315.4106 Eligibility factors for initial licensure and renewal for third-party logistics provider.

- (1) The board shall consider, at a minimum, the following factors in determining the eligibility for initial licensure and renewal of third-party logistics providers:
- (a) A finding by a law enforcement agency or regulatory agency that the applicant or any owners of an applicant has violated federal, state, or local laws;
 - (b) Suspension, revocation, or any other sanction against a license currently or previously held by the applicant or any of its owners for a violation of federal or state law;
 - (c) A finding that the applicant or any of its owners are guilty of or pleaded guilty or nolo contendere to violating federal, state, or local laws;
 - (d) The furnishing by the applicant of false or fraudulent material in any application;
 - (e) Failure to maintain or make available to the board or to federal, state, or local law enforcement officials the records required to be maintained by third-party logistics providers; and
 - (f) Any other factors or qualifications that the board considers relevant to and consistent with the public health and safety. Any factors inconsistent with federal standards shall not be applied.

(2) A licensee who has no record of providing third-party logistics services involving prescription drugs during a routine inspection may have its subsequent renewal application referred to the board for review and possible discipline, and the board may require the licensee to appear before the board at the review.

(3) A third-party logistics provider shall have and follow a diversion detection and loss prevention plan that includes all prescription drugs, which shall be immediately available to the board or its agents upon request.

(4) The board shall have the right to deny licensure if it determines that granting the license would not be consistent with public health and safety.

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 136, sec. 7, effective June 29, 2017.

315.4108 List of owners and designated representatives of third-party logistics provider subject to board inspection -- Persons disqualified from being owner or designated representative.

(1) Third-party logistics providers shall establish and maintain for board inspection a list of each partner, limited liability company member, and corporate officer and director, including a description of the duties and the qualifications of each.

(2) A third-party logistics provider shall not have as an owner or designated representative anyone convicted of a felony for conduct relating to:

- (a) Providing third-party logistics services involving prescription drugs;
- (b) A violation of 21 U.S.C. sec. 331(i) or (k); or
- (c) A violation of 18 U.S.C. sec. 1365 relating to product tampering.

(3) A third-party logistics provider shall not have, as an owner or designated representative, anyone who has violated federal or state requirements for third-party logistics provider licensure and presented a threat of serious adverse health consequences or death to humans.

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 136, sec. 8, effective June 29, 2017.

315.4110 Third-party logistics provider must comply with all laws and regulations -- Inspection access required -- Penalty for noncompliance.

(1) A third-party logistics provider shall operate in compliance with all applicable federal, state, and local laws and regulations, including but not limited to:

- (a) The Drug Supply Chain Security Act of 2013 and rules promulgated thereunder; and
- (b) The storage practices set out in 21 U.S.C. sec. 360eee-3(d)(2)(C).

(2) A third-party logistics provider shall allow the board and authorized federal, state, and local law enforcement officials to enter and inspect its premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records to the extent authorized by law, rule, or regulation.

(3) Failure to operate in compliance with all applicable federal, state, and local laws and regulations shall constitute unprofessional conduct pursuant to KRS 315.121(1)(a).

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 136, sec. 9, effective June 29, 2017.

315.412 Penalties for violation of KRS 315.400 to 315.410.

(1) A person engaged in the wholesale distribution of prescription drugs who unknowingly violates any provision of KRS 315.400 to 315.410 may be fined not more than five thousand dollars (\$5,000).

(2) A person engaged in the wholesale distribution of prescription drugs who acts with gross negligence and violates any provision of KRS 315.400 to 315.410 may be fined not more than fifteen thousand dollars (\$15,000).

(3) A person engaged in the wholesale distribution of prescription drugs who knowingly violates any provision of KRS 315.400 to 315.410 may be fined not more than one hundred thousand dollars (\$100,000).

Effective: July 15, 2008

History: Created 2008 Ky. Acts ch. 124, sec. 9, effective July 15, 2008.

315.450 Definitions for KRS 315.450 to 315.460.

For the purposes of KRS 315.450 to 315.460:

(1) "Controlled substance" has the same meaning as in KRS 218A.010;

(2) "Dispense" has the same meaning as in KRS 217.015;

(3) "Health care provider" has the same meaning as in KRS 304.17A-005;

(4) "Health facility" has the same meaning as in KRS 216B.015;

(5) "Legend drug" has the same meaning as in KRS 217.015;

(6) "Pharmacist" has the same meaning as in KRS 315.010; and

(7) "Prescription drug" has the same meaning as in KRS 315.010.

Effective: June 29, 2017

History: Repealed, reenacted, and renumbered 2017 Ky. Acts ch. 136, sec. 12, effective June 29, 2017 -- Created 2005 Ky. Acts ch. 136, sec. 1, effective June 20, 2005.

Formerly codified as KRS 194A.450.

**315.452 Legend Drug Repository Program to be established -- Purpose -- Permitted donations -
- Voluntary participation -- Handling fee -- Distribution.**

(1) The board shall establish and maintain a legend drug repository program to support the donation of a legend drug or supplies needed to administer a legend drug for use by an individual who meets the eligibility criteria specified by an administrative regulation promulgated by the board. The repository program shall not accept any controlled substance.

(2) Donations may be made on the premises of a health facility or pharmacy that elects to participate in the program and meets requirements specified by the board by an administrative regulation promulgated by the board.

(3) The health facility may charge a handling fee to an individual who received a legend drug or supplies under the program established under this section, except that the fee shall not exceed the amount established by an administrative regulation promulgated by the board.

(4) A health facility or pharmacy that receives a donated legend drug under this section may distribute the legend drug or supplies to another eligible health facility or pharmacy for use under the program created under this section.

(5) Nothing in this section or KRS 315.454 shall require a health facility, pharmacy, pharmacist, or practitioner to participate in the program established in this section.

Effective: June 29, 2017

History: Repealed, reenacted, and renumbered 2017 Ky. Acts ch. 136, sec. 13, effective June 29, 2017 -- Created 2005 Ky. Acts ch. 136, sec. 2, effective June 20, 2005.

Legislative Research Commission Note (6/20/2015). 2005 Ky. Acts chs. 11, 85, 95, 97, 98, 99, 123, and 181 instruct the Reviser of Statutes to correct statutory references to agencies and officers whose names have been changed in 2005 legislation confirming the reorganization of the executive branch. Such a correction has been made in this section.

Formerly codified as KRS 194A.452.

315.454 Requirements for accepting and dispensing legend drug or administration supplies.

(1) A legend drug or supplies used to administer a legend drug may be accepted and dispensed under the program established in KRS 315.452 only if the following requirements are met:

- (a) The legend drug or supplies needed to administer the legend drug is in its original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened;
- (b) The legend drug is not classified as a controlled substance;
- (c) The legend drug or supplies needed to administer a legend drug is not adulterated or misbranded, as determined by a pharmacist employed by, or under contract with, the health facility or pharmacy, who shall inspect the drug or supplies needed to administer a legend drug before the drug or supplies are dispensed; and
- (d) The legend drug or supplies needed to administer a legend drug are prescribed by a physician, advanced practice registered nurse, or physician assistant and dispensed by a pharmacist.

(2) No legend drug or supplies needed to administer a legend drug that are donated for use under this section may be resold.

Effective: June 29, 2017

History: Repealed, reenacted, and renumbered 2017 Ky. Acts ch. 136, sec. 14, effective June 29, 2017 -- Amended 2010 Ky. Acts ch. 85, sec. 32, effective July 15, 2010 -- Created 2005 Ky. Acts ch. 136, sec. 3, effective June 20, 2005.

Formerly codified as KRS 194A.454.

315.456 Immunity from civil liability -- Exceptions.

(1) Unless the manufacturer of a legend drug or supply needed to administer a legend drug exercises bad faith or fails to exercise ordinary care, the manufacturer of a legend drug or supply shall not be subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of the drug or supply under the

legend drug repository created under KRS 315.452, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

(2) Health facilities, pharmacies, and health care providers shall be immune from civil liability for injury to or the death of an individual to whom a legend drug or supply is dispensed and shall not be subject to disciplinary action for unprofessional conduct for their acts or omissions related to donating, accepting, distributing, or dispensing a legend drug or supply under KRS 315.450 to 315.460, unless the act or omission involves reckless, wanton, or intentional misconduct or the act or omission results from failure to exercise ordinary care.

Effective: June 29, 2017

History: Repealed, reenacted, and renumbered 2017 Ky. Acts ch. 136, sec. 15, effective June 29, 2017 -- Created 2005 Ky. Acts ch. 136, sec. 4, effective June 20, 2005.

Formerly codified as KRS 194A.456

315.458 Required administrative regulations.

The board shall promulgate administrative regulations to establish:

(1) The requirements for health facilities and pharmacies to accept and dispense donated legend drugs or supplies needed to administer legend drugs under KRS 315.452 and 315.454, including all of the following:

- (a) Eligibility criteria for health facilities;
- (b) Standards and procedures for accepting, safely storing, and dispensing donated legend drugs or supplies needed to administer legend drugs;
- (c) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine if these are in their original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened; and
- (d) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine that these are not adulterated or misbranded;

(2) Eligibility criteria for individuals to receive donated legend drugs or supplies needed to administer legend drugs dispensed under KRS 315.452 and 315.454;

(3) Standards for prioritizing the dispensation to individuals who are uninsured or indigent, or to others if an uninsured or indigent individual is unavailable;

(4) A means by which an individual who is eligible to receive a donated legend drug or supplies needed to administer a legend drug may indicate that eligibility;

(5) Necessary forms for administration of the legend drug repository program;

(6) The maximum handling fee that a health facility may charge for accepting, distributing, or dispensing donated legend drugs or supplies needed to administer legend drugs;

(7) A list of legend drugs and supplies needed to administer legend drugs that the legend drug repository program may accept for dispensing; and

(8) A list of legend drugs and supplies needed to administer legend drugs that the legend drug repository program shall not accept for dispensing, including the reason why the legend drug or supply is ineligible for donation.

Effective: June 29, 2017

History: Repealed, reenacted, and renumbered 2017 Ky. Acts ch. 136, sec. 16, effective June 29, 2017 -- Created 2005 Ky. Acts ch. 136, sec. 5, effective June 20, 2005.

Legislative Research Commission (6/20/2015). 2005 Ky. Acts chs. 11, 85, 95, 97, 98, 99, 123, and 181 instruct the Reviser of Statutes to correct statutory references to agencies and officers whose names have been changed in 2005 legislation confirming the reorganization of the executive branch. Such a correction has been made in this section. Formerly codified as KRS 194A.458.

315.460 Restriction on acceptance or distribution of certain drugs.

Drugs that shall only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements shall not be accepted or distributed under the provisions of the program.

Effective: June 29, 2017

History: Created 2017 Ky. Acts ch. 136, sec. 17, effective June 29, 2017.

315.500 Emergency authority for pharmacists during state of emergency -- Executive order -- Time limit -- Actions authorized -- Extension.

(1) When the Governor declares a state of emergency pursuant to KRS 39A.100, the Governor may issue an executive order for a period of up to thirty (30) days giving pharmacists emergency authority. The executive order shall designate the geographical area to which it applies. In the executive order, the Governor may vest pharmacists with the authority to:

- (a) Dispense up to a thirty (30) day emergency supply of medication;
- (b) Administer immunizations to children pursuant to protocols established by the Centers for Disease Control and Prevention, the National Institutes of Health, or the National Advisory Committee on Immunization Practices or determined to be appropriate by the commissioner of public health or his or her designee;
- (c) Operate temporarily, a pharmacy in an area not designated on the pharmacy permit; and
- (d) Dispense drugs as needed to prevent or treat the disease or ailment responsible for the emergency pursuant to protocols established by the Centers for Disease Control and Prevention or the National Institutes of Health or determined to be appropriate by the commissioner of public health or his or her designee to respond to the circumstances causing the emergency.

(2) The provisions of this section may be extended, in writing, by the Governor if necessary to protect the lives or welfare of the citizens.

(3) Nothing in this section shall be affected by the requirements of KRS 39A.090

Effective: February 2, 2021.

History: Amended 2021 Ky. Acts ch. 6, sec. 8, effective February 2, 2021. -- Created 2010 Ky. Acts ch. 22, sec. 1, effective July 15, 2010.

315.505 Administrative regulations to effectuate authority granted in KRS 315.500(1).

The Kentucky Board of Pharmacy may promulgate administrative regulations in accordance with KRS Chapter 13A to allow pharmacists to effectuate the authority granted in KRS 315.500(1).

Effective: July 15, 2010

History: Created 2010 Ky. Acts ch. 22, sec. 2, effective July 15, 2010.

315.990 Penalties.

(1) Except for the provisions of KRS 315.320, any person violating any provision of KRS Chapter 315 shall be fined for each offense not less than one hundred dollars (\$100) nor more than one thousand dollars (\$1,000) or imprisoned in the county jail for not more than six (6) months, or both. Each week that any provision of KRS 315.020, 315.030, or 315.035 is violated shall also constitute a separate offense.

(2) Any person convicted of willfully resisting, preventing, impeding, obstructing, threatening, or interfering with the officers, agents, or inspectors of the board in the administration of the provisions of this chapter shall be guilty of a Class A misdemeanor.

(3) The board may levy an administrative fine not to exceed five thousand dollars (\$5,000) for each offense, for any violation of KRS 315.121. All such fines shall be deposited to the credit of the licensing board to be used by the board in carrying out the provisions of this chapter.

(4) The board may refuse to issue or renew a permit, or may suspend, temporarily suspend, revoke, fine, or reasonably restrict any permit holder for any violation of KRS 315.0351. Any administrative fine levied by the board shall not exceed five thousand dollars (\$5,000) for any violation of KRS 315.0351. All such fines shall be deposited to the credit of the licensing board to be used by the Board of Pharmacy in carrying out the provisions of this chapter.

(5) For a violation of KRS 315.320, the Board of Pharmacy may, in addition to any other civil or criminal penalty, levy an administrative fine not exceeding one hundred thousand dollars (\$100,000). All such fines shall be deposited to the credit of the Board of Pharmacy in carrying out the provisions of this chapter.

Effective: June 20, 2005

History: Amended 2005 Ky. Acts ch. 150, sec. 21, effective June 20, 2005. -- Amended 1996 Ky. Acts ch. 257, sec. 24, effective July 15, 1996. -- Amended 1990 Ky. Acts ch. 155, sec. 2, effective July 13, 1990. -- Amended 1982 Ky. Acts ch. 191, sec. 20, effective July 15, 1982. -- Amended 1970 Ky. Acts ch. 221, sec. 18. -- Amended 1950 Ky. Acts ch. 16, sec. 1. -- Recodified 1942 Ky. Acts ch. 208, sec. 1, effective October 1, 1942, from Ky. Stat. secs. 1376t-1, 2619, 2620, 2625, 2628.

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TITLE 201 - GENERAL GOVERNMENT CABINET
Chapter 2 Board of Pharmacy

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201 KAR 2:010. Schools approved by the board.

RELATES TO: KRS 315.050

STATUTORY AUTHORITY: KRS 315.050, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.050(1) authorizes the board to promulgate administrative regulations to regulate and control all matters set forth in KRS Chapter 315 relating to pharmacists. KRS 315.050 (1) requires the board to approve the schools or colleges of pharmacy whose curricula or course of studies are acceptable. This administrative regulation establishes the educational standards for an applicant for licensure as a pharmacist in Kentucky and identifies the acceptable and approved colleges or schools of pharmacy from which an applicant shall graduate.

Section 1. An applicant for licensure as a pharmacist, shall have graduated and received a degree in an accredited pharmacy degree program which has been approved by the Board of Pharmacy. A program shall be considered approved if the program's standards are equivalent to the minimum standards for accreditation for a similar program established by:

- (1) The Accreditation Council on Pharmaceutical Education, Accreditation Standards and Key Elements for Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree; or
- (2) The Canadian Council for Accreditation of Pharmacy Programs, Accreditation Standards for Canadian First Professional Degree in Pharmacy Programs.

Section 2. An applicant for licensure as a pharmacist who shall have graduated and received a degree in a foreign pharmacy degree program, other than from a college or school accredited by the Canadian Council for Accreditation of Pharmacy Programs shall be deemed to be a graduate of a pharmacy degree program which has been approved by the Board of Pharmacy if the applicant has obtained a Foreign Pharmacy Graduate Examination Committee Certificate through the Foreign Pharmacy Graduate Examination Committee Certification Program, which is administered by the National Association of Boards of Pharmacy Foundation.

Section 3. Incorporation by Reference.

- (1) The following material is incorporated by reference:
 - (a) "Accreditation Standards and Key Elements for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree", January 25th, 2015, Accreditation Council on Pharmaceutical Education; and
 - (b) "Accreditation Standards for Canadian First Professional Degree in Pharmacy Programs", January 2018, Canadian Council for Accreditation of Pharmacy Programs.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601-8204, Monday through Friday 8 a.m. to 4:30 p.m.

(4 Ky.R. 218; eff. 1-4-78; 11 Ky.R. 1612; eff. 6-4-85; 12 Ky.R. 498; eff. 12-10-85; 16 Ky.R. 791; eff. 1-12-90; 18 Ky.R. 1911; eff. 2-19-92; 19 Ky.R. 443; eff. 10-8-92; 25 Ky.R. 2925; 26 Ky.R. 718; eff. 10-20-99; 45 Ky.R. 3447; 46 Ky.R. 410; eff. 8-19-2019.)

201 KAR 2:015. Continuing education.

RELATES TO: KRS 315.065, 315.120

STATUTORY AUTHORITY: KRS 315.065, 315.110(1), 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.065(2) and (3) require the Board of Pharmacy to establish continuing education requirements for pharmacists. This

administrative regulation establishes requirements for the continuing pharmacy education of registered pharmacists and requires all registered pharmacists holding a license issued by the board to participate in continuing pharmacy education as a means of renewal of their licenses.

Section 1. Definitions.

- (1) "Continuing education unit" or "CEU" is defined by KRS 315.010(8).
- (2) "Sponsor" means a person, school, association, company, corporation, or group who wishes to develop a continuing education program.

Section 2. (1) Continuing education hours for credit shall be relevant to the practice of pharmacy and free of commercial bias.

- (2) Continuing education hours shall be approved if approved by:
 - (a) The Accreditation Council for Pharmacy Education (ACPE); or
 - (b) The board.

Section 3. (1) Continuing education sponsors shall submit an Application for Provider CE Approval to the board:

- (a) At least sixty (60) days prior to the presentation date, if pre-approval is sought; or
 - (b) Between sixty (60) days prior and thirty (30) days after the presentation date, if pre-approval is not sought.
- (2) Program changes shall be submitted to and approved by the board, or the approval of the program shall be void.
 - (3) Continuing education credit shall be given only once for each program per participant.
 - (4) Sponsors shall retain a file of each participant's program completion for three (3) years.
 - (5) Board approval of each program shall expire three (3) years after the date of approval.

Section 4. (1) Pharmacists requesting approval of individually obtained continuing pharmacy education shall submit an Application for Pharmacist CE Approval to the board within thirty (30) days of completion of the educational presentation.

- (2) The board shall notify the requesting pharmacist whether the application request has been approved or denied.
- (3) Continuing education that has not been approved by ACPE or the board shall not be used to meet continuing education requirements for renewal or issuance of a license.

Section 5. (1) A pharmacist shall:

- (a) Complete a minimum of one and five-tenths (1.5) CEU (fifteen (15) contact hours) annually between January 1 and December 31; and
 - (b) Not transfer or apply excess hours or units for future years.
- (2) A pharmacist may be granted a deferral on a year-to-year basis at the discretion of the board for illness, incapacity, or other extenuating circumstances.

(3) A pharmacist first licensed by the board within twelve (12) months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions for that year.

(4) Pharmacists shall:

(a) Keep valid records, receipts, and certifications of continuing pharmacy education programs completed for three (3) years; and

(b) Submit that documentation to the board upon request.

(5) Submission of a fraudulent statement or certificate concerning continuing pharmacy education shall subject the pharmacist to discipline as provided in KRS 315.121.

Section 6. All pharmacists shall keep the board informed of their correct addresses.

Section 7. CEU may be transferred from another state to Kentucky if the transfer state recognizes Kentucky CEU.

Section 8. A licensee who failed to timely renew his or her license shall:

(1) Comply with the applicable provisions of KRS 315.120(2) or (3); and

(2) Complete fifteen (15) hours of continuing education for each year the applicant failed to renew his or her license, up to a maximum of seventy-five (75) hours.

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

(a) "Application for Provider CE Approval", June 2018; and

(b) "Application for Pharmacist CE Approval", June 2018.

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

(4 Ky.R. 218; eff. 1-4-1978; Am. 11 Ky.R. 1612; eff. 6-4-1985; 16 Ky.R. 791; eff. 1-12-1990; 28 Ky.R. 1906; 2192; eff. 3-28-2002; 37 Ky.R. 2041; 2376; eff. 5-6-2011; 41 Ky.R. 2609; 42 Ky.R. 272; eff. 9-4-2015; 45 Ky.R. 146, 650; eff. 9-19-2018.)

201 KAR 2:020. Examination.

RELATES TO: KRS 218A.205(7), 315.050

STATUTORY AUTHORITY: KRS 218A.205(7), 315.050(2), 315.191(1), (2), (4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.050(2) and 315.191(1)(c) authorize the board to promulgate administrative regulations to prescribe the time, place, method, manner, scope, and subjects of examinations. KRS 218A.205 (7) requires the board to establish requirements for background checks for licensees. This administrative regulation establishes the examination and application requirements for obtaining a license to practice pharmacy in Kentucky.

Section 1. The examination for licensure shall include:

(1) The North American Pharmacist Licensure Examination (NAPLEX); and

(2) The Multistate Pharmacy Jurisprudence Examination (MPJE).

Section 2. The passing score on the required examinations shall be:

(1) At least seventy-five (75) on the basis of the NAPLEX and the MPJE grades shall not be used in computing the NAPLEX; and

(2) At least seventy-five (75) on the basis of the MPJE.

Section 3. If an applicant fails to obtain the necessary scores in any of the tests described in Section 2 of this administrative regulation, the applicant may upon proper application retake the tests upon the payment of the fee set forth in 201 KAR 2:050 plus any direct costs for test materials and supplies. An applicant who has failed any test may retake that test within one (1) year of the date the applicant first failed the test without having to reapply.

Section 4. All results of examinations shall be preserved according to the Board of Pharmacy Record Retention Schedule.

Section 5. Fees submitted with an application shall be nonrefundable.

Section 6. Prior to approval for examination, an applicant shall:

- (1) Submit to a nation-wide criminal background investigation by means of fingerprint check by the Department of Kentucky State Police and the Federal Bureau of Investigation; and
- (2) Submit to a query to the National Practitioner Data Bank of the United States Department of Health and Human Services.

Section 7. License, Fee. An applicant shall submit:

- (1) An Initial Application for Pharmacist Licensure pursuant to KRS 315.050; and
- (2) As appropriate, the fee established by 201 KAR 2:050, Section 1(1).

Section 8. Incorporation by Reference. (

- 1) "Initial Application for Pharmacist Licensure", Form 1, 12/2019, is incorporated by reference.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday 8:00 a.m. to 4:30p.m.

(1 Ky.R. 9; eff. 9-11-1974; Am. 7 Ky.R. 403; eff. 12-3-1980; 9 Ky.R. 11; eff. 8-11-1982; 11 Ky.R. 1614; eff. 6-4-1985; 16 Ky.R. 793; eff. 1-12-1990; 19 Ky.R. 443; eff. 10-8-1992; 26 Ky.R. 866; 1117; eff. 12-15-1999; 32 Ky.R. 1462; 1879; eff. 5-5-2006; 39 Ky.R. 501; eff. 2-1-2013; 39 Ky.R. 2377; eff. 8-21-2013; 46 Ky.R. 1926; eff. 3-19-2020.)

201 KAR 2:030. License Transfer.

RELATES TO: KRS 315.191(1)(c), (d), 315.210

STATUTORY AUTHORITY: KRS 218A.205(8), 315.191(1)(a), (c), (d), 315.210

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.210 authorizes the board to establish conditions for licensure by reciprocity. KRS 218A.205(7) requires the board to establish requirements for background checks for licensees. This administrative regulation establishes conditions, forms, and examination requirements for licensure by reciprocity.

Section 1. Definitions.

- (1)"Board" is defined by KRS 315.010(4).
- (2)"License transfer" means a license to practice pharmacy in Kentucky issued by the board to a pharmacist licensed in another jurisdiction.
- (3)"NABP" means the National Association of Boards of Pharmacy.

Section 2. An applicant licensed in another jurisdiction shall be eligible for license transfer, if the:

- (1) Requirements for licensure of the jurisdiction that granted his or her license met or exceeded Kentucky requirements for licensure when the license in the other jurisdiction was granted;
- (2) Applicant holds in good standing, an active license to practice pharmacy;
- (3) Applicant has:
 - (a) Completed and certified the NABP Preliminary Application for Transfer of Pharmacist License form; and
 - (b) Received an NABP Official Application for Transfer of Pharmacist License;
- (4) Applicant is currently in good standing in the jurisdiction from which he or she has applied;
- (5) Applicant has successfully completed an examination in jurisprudence;
- (6) Applicant has submitted to a nation-wide criminal background investigation by means of fingerprint check by the Department of Kentucky State Police and the Federal Bureau of Investigation; and
- (7) Applicant has submitted to a query to the National Practitioner Data Bank of the United States Department of Health and Human Services.

Section 3. Required Information. An applicant shall provide the information required by the NABP Preliminary Application for Transfer of Pharmacist License form, including:

- (1) Name, maiden, and other names used currently or previously;
- (2) Address, telephone number;
- (3) Date of birth;
- (4) Social Security number;
- (5) Citizenship;
- (6) Sex ;
- (7) State of original license by examination, including:
 - (a) License number;
 - (b) Original date of issue;
 - (c) Current status of original licensure; and
 - (d) State for which license transfer is requested;
- (8) Pharmacy education, including:
 - (a) Name and location of pharmacy school;
 - (b) Name of pharmacy degree;
 - (c) Date degree was received; and
 - (d) Other professional degrees, including the information specified by paragraphs (a) to (c) of this subsection;
- (9) Whether the applicant has earned certification by the Foreign Pharmacy Graduate Examination Committee, and, if so, the examination equivalency number assigned;
- (10) Total hours of practical experience as an intern prior to licensure as a pharmacist;
- (11) States, dates, and results of pharmacist licensure examinations;
- (12) Pharmacist licenses currently held, including issue date, expiration date, status, and any board action taken against the licensee;
- (13) Practice and employment, including nonpharmacist employment, from the past three (3) years;

- (14) Record of charges or convictions of any felony or misdemeanor offense, other than traffic offenses, and whether or not a sentence was imposed or suspended;
- (15) Record of any surrender of a pharmacist license or registration issued by the federal government or any state controlled substance authority;
- (16) Record of any pharmacist license revocation, suspension, restriction, termination, or other disciplinary action by any board of pharmacy or other state authority;
- (17) Record of whether the pharmacist is currently under investigation or subject to disciplinary action by the licensing jurisdiction, federal Food and Drug Administration, federal Drug Enforcement Administration or any state drug enforcement authority for the violation of any state or federal pharmacy, liquor, or drug laws;
- (18) Record of any condition or impairment, such as substance or alcohol abuse or dependency that in any way affects the pharmacist's ability to practice pharmacy in a safe and competent manner; and
- (19) Record of any application for initial licensure, renewal licensure, or licensure by transfer that was denied by any licensing authority, whether in pharmacy or any other profession.

Section 4.

The board shall accept license transfer applications from jurisdictions that:

- (1) Are an active member of the NABP; and
- (2) Grant license transfers to pharmacists pursuant to conditions and requirements that are the equivalent of conditions and requirements established by the board.

Section 5. An applicant shall take and pass the Multistate Pharmacy Jurisprudence Examination administered by the NABP.

Section 6. Fee. An applicant shall include the fees specified by 201 KAR 2:050, Section 1(2) and (19).

Section 7.

- (1) "NABP Preliminary Application for Transfer of Pharmacist License", April 2018, is incorporated by reference.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. or on the Web site at <https://pharmacy.ky.gov/professionals/Pages/Reciprocal-Information.aspx>.

(Rx-3, 11; 1 Ky.R. 147; eff. 12-11-74; Am. 16 Ky.R. 794; 1943; eff. 3-8-90; 24 Ky.R. 1115; 1865; eff. 3-16-98; 25 Ky.R. 2185; 2832; eff. 6-16-99; 26 Ky.R. 1436; 1798; eff. 4-12-2000; 32 Ky.R. 1463; 1879; eff. 5-5-06; 39 Ky.R. 502; 1371; eff. 2-1-2013; 39 Ky.R. 2378; eff. 8-21-2013; 41 Ky.R. 298; 738; eff. 10-15-2014; Certified to be amended, filing deadline 12-23-2022; 48 Ky.R. 1235, 2025; eff. 1-13-2022.)

201 KAR 2:040. Registration of pharmacist interns.

RELATES TO: KRS 315.010(18), 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) 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) 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 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, 11/2012;
 - (b) "Pharmacist Preceptor's Affidavit", Form II, 11/2012
 - (c) "Internship Report", Form III, 11/2012; and
 - (d) "Academic Experience Affidavit", Form IV, 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.

(Rx-6; 1 Ky.R. 9; eff. 9-11-74; Am. 9 Ky.R. 247; eff. 9-8-82; 11 Ky.R. 1125; eff. 3-12-85; 16 Ky.R. 795; eff. 1-12-90; 25 Ky.R. 2187; 2832; eff. 6-16-99; 26 Ky.R. 1023; 1404; eff. 1-12-2000; 34 Ky.R. 1095; 1703; eff. 2-1-2008; 39 Ky.R. 1051; 1372; eff. 2-1-2013; 41 Ky.R. 300; 739; eff. 10-15-2014; 47 Ky.R. 2029; 48 Ky.R. 22; eff. 7-21-2021.)

201 KAR 2:045. Technicians.

RELATES TO: KRS 315.010(12), (20), (26), 315.020(4)(b), 315.191(1)(a), (g), (l)

STATUTORY AUTHORITY: KRS 315.010(20), 315.020(4)(b), 315.191(1)(a), (g), (l)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations governing pharmacy technicians. KRS 315.020(4)(b) authorizes the board to establish the scope of practice for pharmacy technicians. KRS 315.010(20) and 315.191(1)(l) authorize the board to promulgate administrative regulations establishing when a pharmacy technician can practice under the general, rather than immediate, supervision of a pharmacist. This administrative regulation establishes the qualifications required for a pharmacy technician to practice under the general supervision of a pharmacist, and establishes the scope of practice for a pharmacy technician.

Section 1. A person shall be recognized by the board as a certified pharmacy technician, if:

- (1) (a) The person has successfully completed the Pharmacy Technician Certification Exam (PTCE) administered by the Pharmacy Technician Certification Board (PTCB) or the Examination for the Certification of Pharmacy Technicians (ExCPT) by the National Healthcareer Association (NHA); and
- (b) The certificate issued by the PTCB or NHA is current; or
- (2) The person has successfully completed the Nuclear Pharmacy Technician Training Program at the University of Tennessee.

Section 2. A certified pharmacy technician may perform the following functions under the general supervision of a pharmacist:

- (1) Certify for delivery unit dose mobile transport systems that have been refilled by another technician;
- (2) Within a nuclear pharmacy, receive diagnostic orders; and
- (3) (a) Initiate or receive a telephonic communication from a practitioner or practitioner's agent concerning refill authorization, after the certified pharmacy technician clearly identifies himself or herself as a certified pharmacy technician; and
(b) If a practitioner or practitioner's agent communicates information that does not relate to the refill authorization:
 1. A technician shall immediately inform the pharmacist; and
 2. The pharmacist shall receive the communication.

Section 3. (1) A technician who has not been certified by PTCB or NHA may perform the functions specified by Section 2 of this administrative regulation under the immediate supervision of a pharmacist.

(2) A function performed by a certified pharmacy technician or pharmacy technician shall be performed subject to the review of the pharmacist who directed the technician to perform the function.

(3) A pharmacist who directs a certified pharmacy technician or pharmacy technician to perform a function shall be responsible for the technician and the performance of the function.

(23 Ky.R. 3124; Am. 3806; 4108; eff. 6-16-97; 26 Ky.R. 1687; 2238; eff. 6-12-2000; 35 Ky.R. 2484; 36 Ky.R. 321; eff. 8-12-2009; 43 Ky.R. 606, 952; eff. 12-14-2016.)

201 KAR 2:050. Licenses and permits; fees.

RELATES TO: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.0351(1), 315.036(1), 315.050(5), 315.060, 315.110, 315.120, 315.191, 315.402

STATUTORY AUTHORITY: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.036(1), 315.050(5), 315.060, 315.110(1), 315.120(4), 315.191(1)(i), 315.402(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(i) authorizes the board to assess reasonable fees for services rendered to perform its duties and responsibilities. This administrative regulation establishes reasonable fees for the board to perform all the functions for which it is responsible.

Section 1. The following fees shall be paid in connection with pharmacist examinations and licenses, pharmacy permits, intern certificates, and the issuance and renewal of licenses and permits:

- (1) Application for a licensee for pharmacist examination - \$150;
- (2) Application and initial license for a pharmacist license by license transfer - \$250;
- (3) Annual renewal of a pharmacist license - seventy (70) dollars;
- (4) Delinquent renewal penalty for a pharmacist license - seventy (70) dollars;
- (5) Annual renewal of an inactive pharmacist license - ten (10) dollars;
- (6) Pharmacy intern certificate valid six (6) years - twenty-five (25) dollars;
- (7) Duplicate of original pharmacist license wall certificate - seventy-five (75) dollars;
- (8) Application for a permit to operate a pharmacy - \$125;
- (9) Renewal of a permit to operate a pharmacy - \$125;

- (10) Delinquent renewal penalty for a permit to operate a pharmacy – \$100 dollars;
- (11) Change of location or change of ownership of a pharmacy or manufacturer permit - seventy-five (75) dollars;
- (12) Application for a permit to operate as a manufacturer - \$125;
- (13) Renewal of a permit to operate as a manufacturer - \$125;
- (14) Delinquent renewal penalty for a permit to operate as a manufacturer - \$125;
- (15) Change of location or change of ownership of a wholesale distributor license - seventy-five (75) dollars;
- (16) Application for a license to operate as a wholesale distributor - \$125;
- (17) Renewal of a license to operate as a wholesale distributor - \$125;
- (18) Delinquent renewal penalty for a license to operate as a wholesale distributor - \$125; and
- (19) Query to the National Practitioner Data Bank of the United States Department of Health and Human Services – twenty-five (25) dollars.

(Rx-1; 1 Ky.R. 10; eff. 9-11-1974; Am. 4 Ky.R. 122; eff. 11-2-1977; 8 Ky.R. 254; eff. 10-7-1981; 9 Ky.R. 12; eff. 8-11-1982; 1027; eff. 4-6-1983; 19 Ky.R. 444; eff. 11-9-1992; 25 Ky.R. 2188; 2834; eff. 6-16-1999; 32 Ky.R. 1465; 1890; eff. 5-5-2006; 35 Ky.R. 1833; eff. 6-5-2009; 39 Ky.R. 504; eff. 2-1-2013; 43 Ky.R. 607, 953; eff. 12-14-2016; 46 Ky.R. 2682; eff. 2-4-2021.)

201 KAR 2:061. Procedures followed by the Kentucky Board of Pharmacy in the investigation and hearing of complaints.

RELATES TO: KRS 218A.205, 315.121, 315.131, 315.191, 21 C.F.R. 310.305(b)

STATUTORY AUTHORITY: KRS 218A.205(3)(e), (f), (5), 315.191(1), (2), (3), (4)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations relating to the practice of pharmacy, including a process for complaints and hearings. KRS 315.191(2) authorizes the board to enforce pharmacy laws and administrative regulations. KRS 218A.205(3)(e), (f) and (5) require the board to promulgate administrative regulations relating to complaints, licensure standards, and disciplinary actions. The administrative regulation establishes board procedure for investigations, the administrative hearings process, and the penalties for violations.

Section 1. Definitions.

(1) "Adverse drug experience" means any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following:

- (a) An adverse event occurring in the course of the use of a drug product in professional practice;
- (b) An adverse event occurring from drug overdose, whether accidental or intentional;
- (c) An adverse event occurring from drug abuse;
- (d) An adverse event occurring from drug withdrawal; and
- (e) Any failure of expected pharmacological action.

(2) "Agreed order" means a formal written agreement between the board and the licensee, permit holder, or registrant that stipulates that a violation of pharmacy law may have occurred and specifies the disciplinary terms and conditions imposed on the licensee, permit holder, or registrant.

(3) "Board" is defined by KRS 315.010(4).

(4) "Charge" means a specific allegation alleging a violation of a specified provision of KRS Chapter 315, the provisions of KRS Chapters 217 and 218A pertaining to prescription drugs, or 201 KAR Chapter 2.

(5) "Complaint" means a formal administrative pleading that sets forth charges against a licensee, permit holder, or registrant and commences a formal disciplinary proceeding pursuant to KRS Chapter 13B.

(6) "Diversion agreement" means an interim agreement between the board and the licensee, permit holder, or registrant that is utilized as a method of ensuring patient safety during a time mutually agreed upon.

(7) "Executive director" means the executive director of the Kentucky Board of Pharmacy.

(8) "FDA" is defined by KRS 315.400(10).

(9) "General counsel" means the general counsel of the Kentucky Board of Pharmacy or any attorney hired or contracted with the Kentucky Board of Pharmacy to provide legal services.

(10) "Grievance" means any allegation alleging misconduct by a licensee, permit holder, or registrant.

(11) "Inordinate amount of compounded human drug products" means when a pharmacy has distributed interstate during any calendar year more than fifty (50) percent of the sum of the number of prescription orders for compounded human drug products that the pharmacy sent out of the facility in which the drug products were compounded during that same calendar year plus the number of prescription orders for compounded human drug products that were dispensed at the facility in which they were compounded during that same calendar year.

(12) "Letter of concern" means an advisory letter to notify a licensee, permit holder, or registrant that, although there is insufficient evidence to support disciplinary action, the board believes the licensee, permit holder, or registrant needs to modify or eliminate certain practices and that the continuation of those practices may result in action against the license, permit, or registration.

(13) "Letter of reprimand" means a letter admonishing a licensee, permit holder, or registrant for violating pharmacy law, but notifying the licensee, permit holder, or registrant that in consideration of mitigating evidence, the board has determined that disciplinary action is not appropriate.

(14) "Pharmacy Law" means any law in KRS Chapter 315 and 201 KAR Chapter 2 or any law in KRS Chapter 217 or 218A relating to prescription drugs.

(15) "Product quality issue" means any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article, any contamination, any significant chemical, physical, or other change or deterioration in the distributed drug product, or any failure of one (1) or more distributed batches of the drug product to meet the applicable specifications.

(16) "Serious adverse drug experience" means:

(a) Any adverse drug experience occurring at any dose that results in death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect; or

(b) Important medical events that do not result in death, are not life-threatening, or do not require hospitalization that are considered as a serious adverse drug experience if, based upon appropriate medical judgment, these events may jeopardize the patient or subject and may require medical or surgical intervention to prevent results of a serious adverse drug experience.

(17) "Serious product quality issue" means any product quality issue that may have the potential to cause a serious adverse drug experience.

Section 2. Grievances.

- (1) A grievance against a licensee may:
 - (a) Be submitted orally or in writing; and
 - (b) Originate from a consumer, competitor, health professional, government or provider agency, or other interested party.
- (2) A grievance may be submitted anonymously, and if the grievance is accompanied by sufficient corroborating evidence that there is a reasonable probability of a violation of pharmacy law, the grievance shall be accepted by the executive director or the general counsel.
- (3) A grievance shall not be required to be sworn to or notarized.
- (4) A grievance that alleges an adverse drug experience or a product quality issue from human drug products compounded in Kentucky and distributed outside the state shall be reviewed, and if the grievance is accepted and involves an alleged serious adverse drug experience or serious product quality issue, the grievance shall be reported to the FDA within five (5) business days from receipt of the grievance.
- (5) A grievance that alleges an adverse drug experience or a product quality issue from a compounded human drug product that was compounded in Kentucky by a physician and distributed outside the state shall be reported to the Kentucky Board of Medical Licensure and the FDA within five (5) business days from receipt of the grievance.

Section 3. Investigations.

- (1) Except as established in subsection (2) of this section, upon acceptance of a grievance, the executive director shall instruct its staff or a special investigator to:
 - (a) Conduct an investigation;
 - (b) Except as established in paragraph (d) of this subsection, notify the licensee, permit holder, or registrant via written letter sent through the United States Postal Service that a grievance has been filed, and that the board is investigating the merits of the grievance. If during the investigation, it is alleged that another licensee, permit holder, or registrant may have violated pharmacy law, that licensee, permit holder, or registrant shall also be notified via written letter sent through the United States Postal Service that a grievance has been filed and the board is investigating the grievance. Any licensee, permit holder, or registrant under investigation shall be given the opportunity to provide a written statement to the executive director;
 - (c) Report the case to the case review panel within 120 days of the receipt of the grievance. If an extension of time is requested, the case shall be brought before the case review panel to approve or deny the extension of time. If an extension of time is approved, the licensee, permit holder, or registrant that is the subject of the investigation shall be notified via written letter sent through the United States Postal Service of the extension of time. An extension shall not be granted for a period exceeding 120 days. Multiple extensions shall be permitted; and
 - (d) The executive director may hold an investigation in abeyance for a reasonable period of time or approve of a delay in notice to the licensee,

- permit holder, or registrant in order to permit law enforcement or a government agency to perform or complete essential investigative tasks, following a request by law enforcement or a government agency.
- (2) If the grievance pertains to the improper, inappropriate, or illegal dispensing of controlled substances, the board shall:
- (a) File a report with the Attorney General's office, the Office of Inspector General's office, and the Department of the Kentucky State Police within three (3) business days;
 - (b) Commence an investigation within seven (7) days of the grievance; and
 - (c) Produce a charging decision within 120 days of the receipt of the grievance, unless an extension for a definite time period is requested in writing by a law enforcement agency due to an ongoing criminal investigation.
- (3) If the grievance pertains to human drug products compounded in Kentucky and distributed outside of Kentucky, the investigation shall include assessing if there is a public health risk associated with the compounded drug product and if any public health risk associated with the product is adequately contained.
- (4) A special investigator shall only be utilized if a conflict of interest exists that prevents any board inspector from being assigned to investigate the grievance.

Section 4. Case Review Panel

- (1) A panel consisting of three (3) assigned board members, shall review the findings relating to an investigation.
- (2) Board staff or a special investigator shall provide the written findings and evidence from each investigation to the case review panel, executive director, and general counsel at least seven (7) days prior to the meeting of the case review panel.
- (3) The case review panel may request the attendance of any person, including the assigned inspector, at any meeting of the case review panel for the investigation of any grievance or consideration of any disciplinary matter.
- (4) The executive director and general counsel shall attend case review panel meetings in a non-voting, ex-officio capacity.
- (5) The panel shall determine if a preponderance of the evidence exists or does not exist that the licensee, permit holder, or registrant violated pharmacy law. If the panel determines that the preponderance of the evidence indicates that the licensee, permit holder, or registrant did not violate the law, the case review panel shall dismiss the case with or without prejudice or issue a letter of concern.
- (6) After reviewing the evidence, if the case review panel determines that a preponderance of the evidence indicates that the licensee, permit holder, or registrant violated pharmacy law, the case review panel, shall adopt one (1) of the following dispositions:
- (a) Non-adverse action against the licensee, permit holder, or registrant.
Non-adverse action includes:
 - 1. Issuance of a letter of reprimand; or
 - 2. Entry into a diversion agreement;
 - (b) Attempting resolution of the case through an agreed order;
 - (c) The issuance of a formal complaint, order, and notice of hearing; or
 - (d) Returning the case to the inspector or special investigator for further investigation.

(7) Documentation of a letter of reprimand, letter of concern, or diversion agreement shall be maintained in board records for three (3) years.

(8) Within thirty (30) days of the case review panel decision, the licensee, permit holder, or registrant shall be informed via letter sent through the United States Postal Service of the decision of the case review panel.

(9) In the case of recusal by a member of the case review panel, the executive director shall replace the recused board member as a voting member of the case review panel.

(10) If the case review panel determines by a preponderance of the evidence that a grievance involving human drug products compounded in Kentucky and distributed to another state did violate pharmacy law, the board shall take action to ensure that the relevant pharmacy investigates the root cause of the problem that is the subject of the grievance and undertakes sufficient corrective action to address any identified public health risk related to the problem, including the risk that future similar problems may occur. A sufficient corrective action plan may include tasks such as locating expired components, finding record-keeping errors, and ensuring proper temperature and sterility controls.

Section 5. Settlement.

(1) At any time after notice of a grievance or the filing of a complaint, a settlement conference may be requested by the licensee, permit holder, registrant, or their attorney to resolve a grievance or a complaint.

(2) If a settlement conference is requested, it shall be scheduled. The settlement conference shall include the general counsel, the licensee, permit holder, registrant, the attorney for the licensee, permit holder, or registrant, and anyone else at the request of the licensee, permit holder, or registrant.

(3) Except as established in subsection (4) of this section, if the parties to a settlement conference reach an agreement, general counsel, with the consent of the executive director, may resolve the case with a settlement agreement.

(4) If the case involves harm to any member of the public, diversion of controlled substances, proposed probation, suspension or revocation, the proposed settlement agreement shall be reviewed by the case review panel. If the settlement agreement is approved by the case review panel, the grievance or complaint shall be considered resolved.

Section 6. Hearings. All hearings shall be conducted in accordance with the provisions of KRS 315.131(1) and KRS Chapter 13B.

Section 7. Final Order.

(1) The board shall deliberate on issuance of a final order in closed session. Board members that voted on the disposition of the case for the case review panel shall recuse themselves. If board member recusal and the need for a tie-breaking vote, the executive director shall be available to deliberate and vote on issuance of the final order.

(2) Board counsel shall not attend, or be involved in any manner with, the closed session.

(3) The specific findings of the board shall be made in open session following the board's deliberation.

Section 8. Required Penalties for Violations of KRS Chapter 218A.

(1) Pursuant to KRS 218A.205(3)(f)1., a licensee convicted of a felony offense related to dispensing a controlled substance shall, at a minimum, be permanently banned from dispensing any controlled substance.

(2) Pursuant to KRS 218A.205(3)(f)2., the board shall impose restrictions short of a permanent ban from dispensing controlled substances on a licensee convicted of a misdemeanor offense relating to the dispensing of a controlled substance.

(3) Pursuant to KRS 218A.205(3)(f)3., a licensee disciplined by the licensing board of another state relating to the improper, inappropriate, or illegal dispensing of a controlled substance shall, at a minimum, have the same disciplinary action imposed in Kentucky as the disciplinary action imposed by the licensing board of the other state.

(4) Pursuant to KRS 218A.205(3)(g), the board shall submit all disciplinary actions to the National Practitioner Data Bank of the United States Department of Health and Human Services either directly or through a reporting agent.

Section 9. Required Reporting of Investigative Findings to the FDA.

(1) At the conclusion of an investigation of a grievance involving a serious adverse drug experience or a serious product quality issue relating to a drug product compounded at a pharmacy in Kentucky, but distributed outside the state, the board shall share, as permitted by state law, the findings of the investigation with the FDA.

(2) The board shall maintain records of grievances involving adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy, the investigations of the grievances, and any response to or action taken as a result of the grievance beginning when the board receives notice of the grievance. The board shall maintain these records for at least three (3) years. The three (3) year period begins on the date of final action on a grievance, or the date of a decision that the grievance requires no action.

Section 10. Information Sharing with the FDA.

(1) On an annual basis, the board shall identify pharmacies that distribute inordinate amounts of compounded human drug products interstate and within thirty (30) days of identifying the pharmacy, notify FDA of the pharmacy.

(2) For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the board shall identify during the same calendar year:

(a) The total number of prescription orders for sterile compounded human drugs distributed interstate;

(b) The names of states in which the pharmacy is licensed;

(c) The names of states into which the pharmacy distributed compounded human drug products; and

(d) If the state inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

(3) If the board becomes aware of a physician who is distributing any amount of compounded human drug products interstate, the board shall notify the Kentucky

Board of Medical Licensure and within thirty (30) business days of identifying the physician, notify the FDA.

(18 Ky.R. 2449; Am. 2773; eff. 3-4-92; 39 Ky.R. 506; 1374; eff. 2-1-2013; 47 Ky.R. 2421; 48 Ky.R. 310; eff. 8-26-2021.)

201 KAR 2:070. Prescription intermediary services restricted.

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.020(2), 315.121(1), 315.191(2), (8)

NECESSITY, FUNCTION, AND CONFORMITY: By the authority of KRS 315.191(2) the Board of Pharmacy is responsible to control all matters relating to pharmacies and pharmacists with respect to drugs sold by prescriptions only. This administrative regulation assures the public that a registered pharmacist is present and that prescription drugs distribution is curtailed.

Section 1. No pharmacist shall fill and dispense prescriptions obtained from an establishment or place which offers to the public, in any manner, its services as a "pickup station" or "intermediary" for the purpose of having prescriptions filled or delivered unless such establishment or place has a registered pharmacist in full charge of such services.

(Rx-7; 1 Ky.R. 10; eff. 9-11-1974; Crt eff. 4-17-2019.)

201 KAR 2:074. Pharmacy services in hospitals or other organized health care facilities.

RELATES TO: KRS 315.010, 315.020, 315.030, 315.121

STATUTORY AUTHORITY: 315.002, 315.005, KRS 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the Kentucky Board of Pharmacy to establish requirements to regulate and control pharmacies. KRS 315.002 and 315.005 require standards of practice in all settings where drugs are handled and requires the board to ensure the safety of all drug products provided to the citizens of Kentucky. This administrative regulation establishes requirements for pharmacy services in hospitals.

Section 1. Definitions.

(1) "Automated pharmacy system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information and shall be either:

(a) A decentralized automated pharmacy system that is located outside the pharmacy department, but within the same institution, and under the supervision of a pharmacist; or

(b) A centralized automated pharmacy system from which medications are prepared for final distribution that require the approval of a pharmacist.

(2) "Institutional pharmacy" means:

(a) A pharmacy in an acute care hospital licensed pursuant to 902 KAR 20:016; or

(b) An onsite pharmacy serving an infusion center where medication is administered.

(3) "Investigational drug" means a drug that has not been approved for use in the United States, but for which an investigational drug application has been approved by the FDA.

(4) "Unit dose distribution" means a system in which drug therapy profiles are maintained in the pharmacy and doses are scheduled, prepared, and delivered in a ready-to-administer form to the patient care area as the doses are needed.

(5) "Within the same institution" means a location that is not separated from the primary hospital facility by other commercial or residential property.

Section 2. Pharmacy Administration.

(1) General.

(a) The pharmacy, organized as a separate department or service, shall be directed by a pharmacist, who shall be thoroughly knowledgeable about institutional pharmacy practice and management.

(b) The director of pharmacy services shall be responsible for departmental management and the development and implementation of goals and objectives to meet the needs of the institution and shall be responsible to the chief executive officer of the institution or the chief executive officer's designee.

(c) If the director of pharmacy services is not employed full time, the institution shall establish an ongoing arrangement in writing with a pharmacist to provide services required by this administrative regulation and KRS 315.020(1).

(d) If a hospital pharmacy is decentralized, each decentralized section or separate organizational element shall be under the immediate supervision of a pharmacist responsible to the director of pharmacy services.

(2) Pharmacy personnel.

(a) The institutional pharmacy shall maintain additional pharmacists in cooperation with the institution's administration, either full time or part time, as required to operate safely and effectively to meet the needs of the patients.

(b) If nonpharmacist personnel are employed, nonpharmacist personnel shall perform all duties under the supervision of a pharmacist and shall not be assigned and shall not perform duties that are to be performed only by a pharmacist.

(3) Responsibilities.

(a)

1. Lines of authority and areas of responsibility within the pharmacy shall be clearly defined.

2. Written job descriptions for all categories of pharmacy personnel shall be prepared and revised as necessary.

(b)

1. There shall be policies and procedures to provide for selection of drugs as well as a distribution system to serve the needs of the patient.

2. Provision for procurement of drugs in an emergency situation shall be provided for.

(4) Supportive personnel.

(a) Sufficient supportive personnel (technical, clerical, and other) shall be available in order to optimize the participation of pharmacists in activities requiring professional judgment.

(b) The training and supervision of supportive personnel shall be the responsibility of the pharmacist.

(5) Availability.

(a) The services of a pharmacist shall be available continuously. If around-the-clock operation of the pharmacy is not feasible, the pharmacist shall be available on an on-call basis, and an adequate night drug cabinet shall be established. The pharmacy itself shall not be designated as the night drug cabinet.

(b) A hospital not having a full-time pharmacist, but in which drugs are prepackaged or relabeled or transferred from one (1) container to another, shall obtain a pharmacy permit and have at least a part-time pharmacist designated to perform those functions or to provide personal supervision of those functions.

Section 3. Physical Facility.

(1) The institutional pharmacy shall have adequate space, equipment, and supplies sufficient to provide for safe and efficient drug storage, preparation, and distribution, patient education and consultation, drug information services, and proper management of the department.

(2) Legal requirements. The physical facility shall meet state and federal regulations and shall be accessible by authorized pharmacy personnel only.

(3)

(a) A currently licensed hospital shall be exempt from the provisions of subsection (2) of this section if it:

1. Is authorized by the Department for Health and Human Services to provide pharmacy services; and
2. Does not currently possess a pharmacy permit.

(b) A currently licensed hospital exempt from the provisions of subsection (2) of this section shall permit access by authorized personnel only.

(4) Location. Locked storage or locked medication carts shall be provided for use in each nursing unit or service area.

(5) Reference materials. The pharmacy shall have current pharmaceutical reference materials in accordance with 201 KAR 2:090. References related to the following subjects shall also be available:

- (a) Drug identification;
- (b) Toxicology;
- (c) Drug interactions;
- (d) Parenteral drug compatibility; and
- (e) Microbiology.

Section 4. Drug Distribution and Control.

(1) General. The institutional pharmacy shall be responsible for the procurement, distribution, and control of all drugs and parenteral solutions used within the institution. Policies and procedures governing these functions shall be developed by the pharmacist with input from other involved hospital, or infusion center, staff (for example, nurses) and committees (for example, pharmacy and therapeutics committee and patient care committee).

(2) Dispensing. The pharmacist shall dispense medications only on the order of a licensed medical practitioner.

(3) Prescriber's order. The pharmacist shall review the medication order.

- (4) Recordkeeping. The pharmacist shall maintain appropriate records of each medication order. The records shall be retained for the time and in the manner prescribed by state and federal law.
- (5) Patient medication profile. A medication profile shall be maintained for all inpatients and for those ambulatory patients routinely receiving care at the institution. The pharmacist shall utilize this profile to properly review, schedule, prepare, and distribute medications except in an emergency situation.
- (6) Labeling and packaging.
- (a) Each licensee shall comply with U.S.P. Standards established pursuant to federal law and all state and federal laws and regulations regarding labeling and packaging.
 - (b) Labeling and packaging of medications used for outpatients shall meet the requirements of state and federal law.
- (7) Dispensing. The pharmacist shall dispense medications by the unit dose distribution system if feasible. If the unit dose distribution system is not utilized, adequate safeguards shall be in place to protect patients.
- (8) Stop orders. There shall be established written stop order policies or other methods of assuring that drug orders are not continued inappropriately in accordance with the status of the patient.
- (9) Administration.
- (a) Drugs shall be administered only upon order of a licensed medical practitioner.
 - (b) The institutional pharmacy shall participate in the establishment of policies and procedures regarding the administration of medications. Specific procedures shall be developed in cooperation with appropriate hospital, infusion center, or other health care facility personnel and shall include personnel authorized to schedule, prepare, and administer medications.
- (10)
- (a) Unused medication. The institutional pharmacy shall establish policies and procedures for the disposition of patients' unused medications.
 - (b) Medication in unit dose form may be reissued if package integrity has been maintained and the product has not expired.
- (11) Hospital floor stocks.
- (a) Floor stocks of drugs shall be kept as small as possible. The pharmacist in charge shall be responsible for authenticating the need for floor stock.
 - (b) A pharmacist shall review all orders distributed through floor stock.
 - (c) The pharmacist in charge shall be responsible for defining those areas of the hospital requiring floor stock (for example, emergency room, surgery, critical care, or medical or surgical wards).
 - (d) All drug storage areas within the hospital shall be routinely inspected by pharmacy personnel at least monthly, and documentation shall be maintained to ensure that:
 - 1. Unusable items shall not be present; and
 - 2. All stock items shall be properly labeled and stored.
 - (e) This subsection shall apply to infusion centers where medications are administered with an onsite pharmacy.

(12) Drug recall. There shall be a system for removing from use a drug that has been recalled.

(13) Sample medications. The institutional pharmacy shall establish policies and procedures regarding medical representatives and the obtaining, storage, and dispensing of complimentary packages of medications.

(14) Emergency drugs.

(a) The institutional pharmacy shall establish policies and procedures for supplying emergency drugs.

(b) For expediency and efficiency, emergency drugs shall be limited in number to include only those whose prompt use and immediate availability are generally regarded by physicians as essential in the proper treatment of sudden and unforeseen patient emergencies.

(c) Emergency stocks shall be routinely inspected by pharmacy personnel on a monthly basis and documentation maintained to determine if contents have become outdated and if the stocks are being maintained at adequate levels.

(15) Investigational drugs.

(a) Policies and procedures controlling the use of investigational drugs (if used in the institution) shall be developed and followed.

(b) The pharmacy shall be responsible for storing, packaging, labeling, distributing, maintaining inventory records (including lot numbers and expiration date), and providing information about investigational drugs (including proper disposal).

(16) Controlled substances. All permit holders shall comply with state and federal laws regarding controlled substances.

(17) Compounding. Compounding at a location that is not within the same institution shall require a separate pharmacy permit.

Section 5. Assuring Rational Drug Therapy.

(1) Appropriate clinical information about patients shall be available and accessible to the pharmacist for use in daily practice activities.

(2) The pharmacist shall be a member of the pharmacy and therapeutics committee and any other committees where input concerning the use of drugs is required.

(3) The pharmacist shall provide a means to ensure that patients receive adequate information about the drugs they receive. Patient education activities shall be in coordination with the nursing and medical staffs and patient education department, if any.

Section 6. Responsibility. The pharmacist-in-charge of a pharmacy utilizing an automated pharmacy system shall be responsible for:

(1) An initial validation of system accuracy prior to use for distribution to patients;

(2) Ensuring the system:

(a) Is properly maintained;

(b) Is in good working order;

(c) Accurately dispenses the correct strength, dosage form, and quantity of drug prescribed; and

(d) Complies with the recordkeeping, access, and security safeguards pursuant to all applicable state and federal laws;

- (3) Assuring medications are reviewed prior to loading into an automated pharmacy system and distribution;
- (4) Implementing an ongoing quality assurance program that monitors performance of the pharmacy compounding robotics, which is evidenced by written policies and procedures and requires a continued documented validation of doses distributed on a routine basis and annual review of the quality assurance program;
- (5) Establishing policies and procedures if there is a system failure of an automated pharmacy system;
- (6) Providing the board with prior written notice of installation or removal of an automated pharmacy system. This notification shall include the:
 - (a) Name and address of the pharmacy; and
 - (b) Initial location of the automated pharmacy system;
- (7) Oversight for assigning, discontinuing, or changing personnel access to the system, including establishment of written policies and procedures for security and control;
- (8) Reviewing personnel access on at least an annual basis;
- (9) Assuring that the decentralized automated pharmacy system stock is checked at least monthly in accordance with established policies and procedures, including checking for:
 - (a) Accuracy;
 - (b) Integrity of packaging; and
 - (c) Expiration dates;
- (10) Maintaining in the pharmacy the following documentation relating to an automated pharmacy system:
 - (a) The name and address of the pharmacy or inpatient health care facility where the system is being used;
 - (b) The automated pharmacy system manufacturer's name, model, serial number, and software version;
 - (c) A description of how the system is used;
 - (d) Written quality assurance procedures and accompanying documentation of use to determine continued appropriate use of the system as established in subsections (7) and (8) of this section; and
 - (e) Written policies and procedures for system operation, safety, security, accuracy, emergency medication access, access, and malfunction which includes clearly defined down time and procedures;
- (11) Maintaining adequate security systems and procedures, evidenced by written policies and procedures to:
 - (a) Prevent unauthorized access;
 - (b) Maintain patient confidentiality;
 - (c) Allow user access modification; and
 - (d) Comply with federal and state laws; and
- (12) Maintaining in the pharmacy a current list of all locations where automated pharmacy systems are located and providing the list to the board upon request.

Section 7. Standards.

- (1)
 - (a) All events involving the contents of the automated pharmacy system shall be recorded electronically.

- (b) Records shall be maintained by the pharmacy and be available to the board and shall include the following:
1. The date, time, and location of the system accessed;
 2. Identification of the individual accessing the system;
 3. Type of transaction;
 4. Name, strength, dosage form, and quantity of drug accessed; and
 5. Name of the patient for whom the drug was ordered, if applicable.

(2)

(a) All medications to be stocked into the centralized automated pharmacy system shall:

1. Have been previously validated by a machine readable identifier that meets established industry standards as approved by the board to ensure quality, performance, and safety; and
2. Be utilized by a pharmacist, pharmacist intern, or certified pharmacy technician.

(b) Integrity and accuracy shall be validated by a pharmacist.

(3) The stocking of medications in a decentralized automated pharmacy system utilizing a machine readable identifier that meets established industry standards as approved by the board to ensure quality, performance, and safety shall be done by a pharmacist, pharmacist intern, or a certified pharmacy technician.

(4) The stocking of medications in a decentralized automated pharmacy system without a machine readable identifier that meets established industry standards as approved by the board to ensure quality, performance, and safety shall be done by a pharmacist, pharmacist intern, or a certified pharmacy technician. Integrity and accuracy shall be validated by a pharmacist.

(5) If a hospital licensed pursuant to 902 KAR 20:016 utilizes technology that validates appropriate drug, dose, dosage form, route of administration, time of administration, and patient at the exact time of medication administration, the stocking of the decentralized automated pharmacy system shall be done by a pharmacist, pharmacist intern, or certified pharmacy technician.

(6) A record of medications stocked in an automated pharmacy system shall be maintained for at least five (5) years and shall include:

- (a) The name of the person repacking the medications; and
- (b) Documentation of the pharmacist checking the medications.

(7) All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws.

(8) The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, in accordance with federal and state laws.

(9) All medications initially received in the pharmacy for use in an automated pharmacy system shall be quarantined until validation by a machine readable identifier that meets established industry standards as approved by the board to ensure quality, performance, safety, accuracy, and existence of the item in the database powering automated pharmacy system by a certified pharmacy technician, pharmacist intern, or pharmacist.

(10) If a medication needs to be repackaged:

- (a) A pharmacist, pharmacist intern, or certified pharmacy technician shall:

1. Perform the repackaging and validate the presence of an accurate machine readable identifier that meets established industry standards as approved by the board to ensure quality, performance, and safety on the unit dose packaging; and

2. Document the repackaging process including:

- a. Manufacturer;
- b. Date and time of repackaging;
- c. The person repackaging;
- d. The lot number or batch number;
- e. The expiration date; and
- f. The quantity repackaged; and

(b) A pharmacist shall:

1. Validate for accuracy and integrity prior to the addition to the automated pharmacy system; and

2. Document the validation including:

- a. The date and time of the validation;
- b. The name of the pharmacist validating;
- c. The lot number or batch number;
- d. The expiration date; and
- e. The quantity validated.

(11) A medication returned to the pharmacy from a patient care area shall follow the processes established pursuant to Section 4(10) of this administrative regulation.

(12) A medication distributed by the centralized automated pharmacy system shall be distributed in the delivery device utilized by that system.

(13) A medication distributed by an automated pharmacy system shall be accessed and administered by a professional licensed to administer medications.

(14) A medication distributed by an automated pharmacy system shall not be dispensed.

(15) Board inspectors may inspect and investigate complaints regarding an automated pharmacy system on all premises owned by the hospital where an automated pharmacy system is located and supplied with medications purchased under the hospital's pharmacy permit.

(16) All transfers of medications to automated pharmacy systems shall be in accordance with federal and state laws.

(16 Ky.R. 1713; Am. 2150; 17 Ky.R. 2175; eff. 12-13-1990; 30 Ky.R. 75; 577; eff. 8-20-2003; 39 Ky.R. 1753; 2175; 2312; eff. 6-19-2013; 44 Ky.R. 15, 447; eff. 7-17-2017; 48 Ky.R. 1237, 2026; eff. 1-13-2022.)

201 KAR 2:076. Compounding.

RELATES TO: KRS 217.055(2), 217.065(7), 315.020(1), 315.035(6), 315.0351, 315.121, 315.191(1)(a), (g)

STATUTORY AUTHORITY: KRS 315.020(1), 315.035(6), 315.0351, 315.191(1)(a), (g)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.020(1) requires the owner of a pharmacy who is not a pharmacist to place a pharmacist in charge of the owner's pharmacy. KRS 315.035(6) authorizes the board to promulgate administrative regulations to assure that proper equipment and reference material is on hand considering the nature of the pharmacy practice conducted at the particular pharmacy and to assure reasonable health and safety standards for areas within the pharmacies, which are not subject to these standards under CHFS. KRS 315.191(1) authorizes the board to promulgate administrative

regulations necessary to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers. This administrative regulation establishes the requirements for compounding non-sterile and sterile preparations.

Section 1.

- (1) A policy and procedure manual for non-sterile and sterile compounding shall be readily available at a pharmacy for inspection purposes. (2) A copy of the manual shall be made available to the board upon request.
- (3) The manual shall be reviewed and revised on an annual basis.

Section 2.

- (1) All non-sterile compounded preparations shall be compounded pursuant to United States Pharmacopeia (USP) 795, unless specified portions submitted by a pharmacist have been waived by the board. Notwithstanding any USP guidance to the contrary, the addition of flavoring to a drug shall not be considered non-sterile compounding, if the additive:
 - (a) Is inert, nonallergenic, and produces no effect other than the instillation or modification of flavor; and
 - (b) Is not greater than five (5) percent of the drug product's total volume.
- (2) All sterile compounded preparations shall be compounded pursuant to USP 797, unless specified portions submitted by a pharmacist have been waived by the board.
- (3) All preparation, compounding, dispensing and repackaging of radiopharmaceuticals shall be pursuant to United States Pharmacopeia (USP) 825, unless specified portions submitted by a pharmacist have been waived by the board.
- (4) All written waiver requests submitted by a pharmacist shall be considered by the Board at its next regularly scheduled meeting.
- (5) The board, upon a showing of good cause and in balancing the best interest of the public health, safety, and welfare, may waive the requirement of any specified portion of USP 795, 797 or 825.

Section 3.

- (1) A facility that compounds non-sterile or sterile preparations shall be managed by a pharmacist-in-charge (PIC) licensed to practice pharmacy in the Commonwealth and who is knowledgeable in the specialized functions of preparing and dispensing compounded non-sterile and sterile preparations, including the principles of aseptic technique and quality assurance.
- (2) The PIC shall be responsible for the: purchasing, storage, compounding, repackaging, dispensing, distribution of all drugs and preparations, development and continuing review of all policies and procedures, training manuals, quality assurance programs, and participation in those aspects of the facility's patient care evaluation program relating to pharmaceutical material utilization and effectiveness.
- (3) The PIC may be assisted by additional pharmacy personnel adequately trained, to the satisfaction of the PIC, in this area of practice and for each product they will be compounding.

Section 4.

(1) The pharmacist shall receive a written, electronic, facsimile, or verbal prescription, or medical order from a prescriber before dispensing any compounded, non-sterile or sterile preparation. These prescriptions or medical orders shall contain the following:

- (a) Patient's name and species, if not human;
- (b) Patient's address on controlled substances prescriptions or location (room number);
- (c) Drug name and strength;
- (d) Directions for use;
- (e) Date;
- (f) Authorized prescriber's name;
- (g) Prescriber's address and DEA number, if applicable;
- (h) Refill or end date instructions, if applicable; and
- (i) Dispensing quantity, if applicable.

(2) A pharmacy generated patient profile shall be maintained separate from the prescription file. The patient profile shall be maintained under the control of the PIC for a period of two (2) years following the last dispensing activity. In addition, a medication administration record (MAR) as part of the institutional record shall be retained for a period of five (5) years from date of the patient's discharge from the facility, or in the case of a minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longer. Supplemental records may also be employed as necessary. The patient profile shall contain:

- (a) Patient's name;
- (b) Name of compounded preparation dispensed;
- (c) Date dispensed;
- (d) Drug content and quantity; and
- (e) Patient's directions.

(3) Each compounded preparation dispensed to patients shall be labeled with the following information:

- (a) Name, address, and telephone number of the licensed pharmacy, if product will leave the premises;
- (b) Date;
- (c) Identifying number;
- (d) Patient's full name;
- (e) Name of each drug, strength, and amount;
- (f) Directions for use, including infusion rate;
- (g) Required controlled substances transfer warnings, if applicable;
- (h) Beyond use date;
- (i) Identity of dispensing pharmacist;
- (j) Storage requirements, if applicable; and
- (k) Auxiliary labels, if applicable.

(4) The PIC shall maintain access to and submit, as appropriate, these records and reports as are required to ensure the patient's health, safety, and welfare. Records shall be readily available, maintained for two (2) years at a facility not computerized, but for five (5) years at a facility utilizing computerized recordkeeping, and subject to inspection by the Board of Pharmacy or its agents. These shall include the following:

- (a) Patient profile;

- (b) Purchase records;
- (c) Biennial controlled substances inventories;
- (d) Policy and procedures manual;
- (e) Policies and procedures for hazardous wastes, if applicable;
- (f) Quality assurance records; and
- (g) Other records and reports as may be required by KRS 217 or 315 and 201 KAR Chapter 2.

(5) Information regarding individual patients shall be maintained in a manner to assure confidentiality of the patient's records. Release of this information shall be in accordance with federal and state laws.

(6) The PIC shall be responsible for the environmental control of all products shipped. Any compounded product that is frozen or requires refrigeration shall be shipped or delivered to a patient in appropriate temperature controlled delivery containers, if the product leaves the premises.

(7) The PIC shall be responsible for assuring that there is a system for the disposal of hazardous waste in a manner that does not endanger the public health.

Section 5. Hazardous Drugs.

(1) All non-sterile preparations that contain hazardous substances shall be compounded pursuant to USP 795.

(2) All sterile compounded preparations that contain hazardous substances shall be compounded pursuant to USP 797.

Section 6. Violation of any provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121.

Section 7. Incorporation by Reference.

(1) The following material is incorporated by reference:

- (a) "USP 795, Revision Bulletin, Official" January 1, 2014;
- (b) "USP 797, Revision Bulletin, Official" June 1, 2008; and
- (c) "USP 825, Revision Bulletin, Official, Official" December 1, 2020.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. through 4:30 p.m. This material is also available on the board's Web site at <https://pharmacy.ky.gov/statutesandregulations/Pages/default.aspx>.

(16 Ky.R. 1716; Am. 2152; 2652; eff. 6-10-1990; 43 Ky.R. 2184; 44 Ky.R. 510; eff. 9-20-2017; 48 Ky.R. 879; 1726; eff. 12-15-2021.)

201 KAR 2:090. Reference material and prescription equipment.

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.035(6), 315.19(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.035(6) authorizes the Board of Pharmacy to promulgate administrative regulations regarding reference material and equipment suitable for pharmaceutical practice. This administrative regulation establishes the minimum reference material and equipment required for pharmaceutical practice.

Section 1.

(1) The pharmacy shall have appropriate reference material and equipment as dictated by experience to meet the needs of the particular pharmacy, and necessary to practice pharmacy in a safe manner.

(a) Appropriate reference material includes references such as those from the following categories:

- (1) Category I - Pharmacology;
- (2) Category II - Drug Interactions;
- (3) Category III - Drug Product Composition; and
- (4) Category IV - State and Federal Laws and Regulations.

(b) Appropriate equipment as determined by the pharmacist in charge includes items such as the following:

- (1) A prescription balance with a sensitivity not less than that of a Class 3 balance;
- (2) Weights - metric or apothecary - complete set;
- (3) Graduates capable of accurately measuring from 1 ml to 250 ml;
- (4) Mortars and pestles - glass, porcelain, or wedgewood;
- (5) Spatulas - steel and nonmetallic;
- (6) Filtration funnel with filter papers;
- (7) A heating unit;
- (8) Suitable refrigeration unit for proper storage of drugs; and
- (9) Ointment slab or ointment papers.

(2) Electronic references shall be acceptable.

(Rx-10; 1 Ky.R. 147; eff. 12-11-74; 10 Ky.R. 890; eff. 4-13-84; 1444; 1792; eff. 2-7-2002; 45 Ky.R. 410; eff. 8/19/2019.)

201 KAR 2:095. Pharmacist interns.

RELATES TO: KRS 315.010(12), (18), (27), 315.020, 315.050

STATUTORY AUTHORITY: KRS 315.020(4), 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters set forth in KRS Chapter 315 relating to the practice of pharmacists and pharmacist interns. This administrative regulation establishes the professional responsibilities of a pharmacist and a pharmacist intern under supervision.

Section 1. A pharmacist intern, under the supervision and direction of a licensed pharmacist, shall practice pharmacy pursuant to KRS 315.010(22) with the exception that prior to dispensing, a pharmacist shall verify the accuracy and appropriateness to include drug utilization review (DUR) and final product verification of the prescription or product dispensed.

Section 2. A pharmacist shall be responsible for all the actions of a pharmacist intern.

(Rx-12; 1 Ky.R. 718; 2 Ky.R. 172; eff. 9-10-1975; 11 Ky.R. 1615; eff. 6-4-1985; 26 Ky.R. 1118; eff. 12-15-1999; Ky.R.2881; eff. 7-3-2020.)

201 KAR 2:100. Security and control of drugs and prescriptions.

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.035, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191 (1) authorizes The Kentucky Board of Pharmacy to promulgate administrative regulations necessary to regulate and control pharmacists and pharmacies. This administrative regulation establishes requirements for adequate security and control of drugs and prescriptions.

Section 1. (1) A pharmacy shall:

- (a) Provide adequate security and control of its controlled substances and prescription legend drugs; and
 - (b) Be closed in absence of a pharmacist.
- (2) If a pharmacy is located within a larger establishment, which is open to the public for business at times when a pharmacist is not present, then the pharmacy shall be enclosed by partitions which shall be either solid, solid transparent, or chain linked secured by lock from other departments of the store. In the absence of a pharmacist, pharmacies shall be locked and secured. A person shall not enter the closed pharmacy during those hours when a pharmacist is not present.

Section 2. All prescription files, all legend drugs and other items which are restricted to sale either by or under the supervision of a pharmacist shall be kept in the pharmacy area.

Section 3. Written prescription orders and refill requests can be delivered to a pharmacy at any time. But if no pharmacist is present, then the prescription order(s) shall be deposited, by the patient or the patient's agent delivering the prescription order or refill request to the establishment, into a "mail slot" or "drug box" such that the prescription order is stored in the pharmacy area.

Section 4. Prepared prescription medications shall be stored in the pharmacy and shall not be removed from the pharmacy unless the pharmacist is present and the removal is for the immediate delivery to the patient, person picking up the prescription for the patient, or person delivering the prescription to the patient at his residence or similar place.

(Rx-13; 1 Ky.R. 718; 2 Ky.R. 173; eff. 9-10-75; 11 Ky.R. 1615; eff. 6-4-85; 45 Ky.R. 3451; 46 Ky.R. 411; eff. 8/19/2019.)

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

RELATES TO: KRS 315.010, 315.121, 315.350, 315.400, 315.402, 315.404, 315.406, 315.408, 315.410, 315.412

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

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

Section 1. Definitions.

- (1) "Component" means any raw material, ingredient, or article intended for use in the manufacture of a drug and drug-related device.
- (2) "Distribution" or "distribute" is defined by KRS 315.400(5).
- (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.
- (4) "Illegitimate Product" is defined by KRS 315.400(11).

- (5) "Medical gas wholesaler" is defined by KRS 315.400(13).
- (6) "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, such as capsules, tablets, and lyophilized products before reconstitution.
- (7) "Suspect product" means a component, prescription drug, or drug-related device for which there is reason to believe that such component, prescription drug, or drug-related device:
- (a) Is potentially counterfeit, diverted, or stolen;
 - (b) Is potentially intentionally adulterated such that the component, prescription drug, or drug-related device would result in serious adverse health consequences or death to humans or animals;
 - (c) Is potentially the subject of a fraudulent transaction; or
 - (d) Appears otherwise unfit for distribution such that the component, prescription drug, or drug-related device would result in serious adverse health consequences or death to humans or animals.
- (8) "Wholesale distribution" is defined by KRS 315.400(20).
- (9) "Wholesale distributor" is defined by KRS 315.400(21).
- (10) "Wholesaler" is defined by KRS 315.010(28), and includes medical gas wholesalers, wholesale distributors, and virtual wholesale distributors.
- (11) "Virtual wholesale distributor" has the same meaning given in KRS 315.400(21).

Section 2. Requirements.

- (1) A wholesaler engaged in wholesale distribution in the Commonwealth shall apply for a license from the Board of Pharmacy in accordance with KRS 315.350, 315.402, 315.406, and this administrative regulation.
- (2) A surety bond is required of not less than \$25,000, or other equivalent means of security acceptable to the Board of Pharmacy or a third party recognized by the Board of Pharmacy such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution. This shall be used to secure payment of any administrative penalties imposed by the Board of Pharmacy and any fees or costs incurred by the Board of Pharmacy regarding that licensee if those penalties, fees, or costs are authorized under state law, and the licensee fails to pay thirty (30) days after the penalty, fee, or costs becomes final. A separate surety bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies or groups if separate locations or affiliated companies or groups are required to apply for or renew their wholesaler license with the Board of Pharmacy. The Board of Pharmacy may make a claim against the bond or other equivalent means of security until one (1) year after the wholesaler's license closes, lapses or expires, or until sixty (60) days after any administrative or legal proceeding before or on behalf of the Board of Pharmacy that involves the wholesaler is concluded, including any appeal, whichever occurs later. The Board of Pharmacy may waive the bond requirement, if the wholesaler:
- (a) Has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the wholesaler possesses a valid license in good standing;
 - (b) Is a publicly held company;
 - (c) Is a medical gas wholesaler; or

- (d) Has a license for the sole purpose of distribution within a health care entity under com-mon ownership.
- (3) A separate license shall be required for each wholesaler’s facility that engages in wholesale distribution within the Commonwealth regardless of whether joint ownership or control exists.
- (4) An agent or employee of a licensee shall not be required to obtain a license under this section if the agent or employee is acting in the usual course of business or employment.
- (5) A license shall not be issued or renewed unless the applicant demonstrates or continues to demonstrate acceptable operational procedures, including:
 - (a) Adequate operational, maintenance, and storage conditions to ensure proper lighting, ventilation, temperature and humidity control, sanitation, space, and security as per label requirements or official United States Pharmacopoeia (USP) compendium requirements, USP Chapter 659, Packaging and Storage Requirements. Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs and drug-related devices;
 - (b) Separation and quarantine of deteriorated, damaged, outdated, misbranded, adulterated or otherwise recalled prescription drugs and drug-related devices until they are destroyed or returned;
 - (c) Providing accurate and precise records of all prescription drugs and drug-related devices sold, purchased, traded, delivered, handled, stored, or received and any other information pertinent to the distribution or disposition; and
 - (d) Providing proof of registration with the U.S. Drug Enforcement Administration (DEA) and shall comply with all DEA regulations, if applicable.
- (6) Wholesale distributors and virtual wholesale distributors shall comply with all requirements outlined in the Drug Supply Chain Security Act (DSCSA), 21 U.S.C. 360eee-360eee-4.
- (7) Wholesalers shall establish a system to:
 - (a) Quarantine and investigate suspect product to determine if it is illegitimate; and
 - (b) Notify U.S. Food and Drug Administration (FDA), if applicable, the Board of Pharmacy and recipient(s) of illegitimate product, if illegitimate product is found.
- (8) A virtual wholesale distributor shall be exempt from the following, subsection 2(5)(a) and (b) of this Section, and Section 5(1)(a) and (b), and (2)(a) and (b) of this administrative regulation.

Section 3. Qualifications for License. (1) The Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs and drug-related devices within the Commonwealth:

- (a) Any convictions of the applicant under any federal, state, or local laws relating to drugs, including drug samples and controlled substances;
- (b) Any felony convictions of the applicant under federal, state, or local laws;
- (c) The applicant's past experience in the distribution of prescription drugs and drug-related devices, including drug samples and controlled substances;

- (d) The furnishing by the applicant of false or fraudulent material in any application made in connection with the distribution of prescription drugs and drug-related devices;
 - (e) Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant for distribution of any prescription drugs and drug-related devices, including drug samples and controlled substances;
 - (f) Compliance with the requirements under any previously granted license or permit, if any; and
 - (g) Compliance with requirements to maintain or make available to the Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this administrative regulation.
- (2) The Board of Pharmacy shall have the right to deny a license to an applicant if it determines that the granting of that license would not be in the public interest based on health and safety considerations.
- (3) 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 drugs; and
 - (b) That the applicant is equipped as to land, buildings, and security to properly carry on the business described in the application.
- (4) A license issued pursuant to this administrative regulation failing to comply with the provisions of KRS 315.350, 315.400, 315.402, 315.404, 315.406, 315.408, 315.410, 315.412, or this administrative regulation may result in action under KRS 315.121.

Section 4. Application, Fees, Renewals.

- (1) An application for a license shall be submitted to the Board of Pharmacy on the Application for a License to Operate as a Wholesaler.
- (2) An application shall be accompanied by the annual fee set forth in 201 KAR 2:050.
- (3) An application shall include:
- (a) The name, full business address, and telephone number of the licensee;
 - (b) All trade or business names used by the licensee;
 - (c) Addresses, telephone numbers, and the names of contract persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs and drug-related devices;
 - (d) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship);
 - (e) The name(s) of the owner and operator of the licensee, including:
 - 1. If a person, the name and Social Security number of the person;
 - 2. If a partnership, the name and Social Security number of each partner, and the name of the partnership;
 - 3. If a corporation, the name, Social Security number and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and
 - 4. If a sole proprietorship, the full name and Social Security number of the sole proprietor and the name of the business entity;

- (f) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs and drug-related devices; and
 - (g) Proof of surety bond or equivalent.
- (4) All licenses shall:
- (a) Expire on September 30 following date of issuance; and
 - (b) Be renewable annually thereafter upon submission of the Renewal Application to Operate as a Wholesaler accompanied by the renewal fee set forth in 201 KAR 2:050 and shall be nontransferable.

Section 5. Standards.

(1) Facilities.

- (a) All facilities in which prescription drugs and drug-related devices are held for wholesale distribution, stored, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.
- (b) All facilities shall meet all applicable federal, state, and local standards. The facility shall quarantine prescription drugs and drug-related devices that are outdated, damaged, deteriorated, misbranded, recalled, or adulterated, or that are in immediate or sealed secondary containers that have been opened.
- (c) A facility shall not be located in a residence.
- (d) A facility shall be located apart and separate from a pharmacy permitted by the Board of Pharmacy, with the exception of a medical gas wholesaler.

(2) Security.

- (a) A wholesaler shall be equipped with an alarm system to detect entry after hours.
- (b) A wholesaler shall ensure that access from outside their premises is well controlled and reduced to a minimum. This includes the installation of adequate lighting at the outside perimeter of the premises.
- (c) Internal security policies shall be developed to provide reasonable protection against theft and diversion by limiting access to areas where prescription drugs and drug-related devices are held to authorized personnel. These policies shall provide protection against tampering with computers or electronic records.
- (d) A licensee shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of prescription drugs and drug-related devices.

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

- (a) Inventories and other records regarding the receipt and distribution or disposition of prescription drugs and drug-related devices shall be maintained and readily available for inspection or photocopying by the Board of Pharmacy and authorized law enforcement officials for a period of six (6) years). These records shall include:
 1. The proprietary and established name of the prescription drug and related device, if applicable;
 2. The dosage, if applicable;
 3. The size of the container, if applicable;
 4. The number of containers;

5. The lot number or control number of the prescription drug and related device, if applicable;
6. The business name and address of all parties involved in each receipt and distribution or disposition of the prescription drug and related device, starting with the manufacturer; and
7. The date of each receipt and distribution or disposition of the prescription drug and related device.

(b) Records described in this section that are kept at the inspection site or that can be readily retrievable within forty-eight (48) hours by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by the Board of Pharmacy or an authorized official of a federal, state, or local law enforcement agency.

(c) Wholesalers shall maintain an ongoing list of verified persons or businesses with whom they do business.

(d) A wholesaler may sell or distribute prescription drugs and drug-related devices only to the following, except as provided in KRS 315.0351(2) and 315.404:

1. A currently licensed wholesaler;
2. A currently licensed third party logistics provider;
3. A currently permitted pharmacy;
4. A currently licensed outsourcing facility;
5. A currently licensed practitioner;
6. A currently permitted repackager;
7. A currently licensed hospital, but only for use by or in that hospital pursuant to KRS 217.182(1);
8. A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes pursuant to KRS 217.182(1); or
9. Any other appropriately licensed or permitted facility in the jurisdiction in which it is located.

(e) A wholesaler may acquire prescription drugs and drug-related devices only from the following, except as provided in KRS 315.404:

1. A currently permitted manufacturer;
2. A currently permitted repackager;
3. A currently licensed wholesaler; or
4. A currently licensed third-party logistics provider.

(f) Wholesalers shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion, or other significant loss of any prescription drug and related device to the Board of Pharmacy, and if applicable, the FDA and DEA.

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

(a) A wholesaler shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, distribution, and disposition of prescription drugs and drug-related devices

(b) There shall be written policies and procedures for identifying, recording, and reporting losses or thefts.

- (c) There shall be written policies and procedures to assure that the wholesaler prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.
 - (d) 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 to assure that any outdated stock or any stock with an expiration date that, in the wholesaler's view, does not allow sufficient time for repacking or resale shall be segregated from other stock and shall be prepared for return to the manufacturer or otherwise destroyed, and this shall be documented.
 - (f) There shall be written policies and procedures by which the wholesaler exercises control over the shipping and receiving of all stock within the operation.
 - (g) There shall be written policies and procedures for investigating suspect product and re-reporting illegitimate product to the Board of Pharmacy and the FDA pursuant to the DSCSA, if applicable.
- (5) Returned, damaged, and outdated prescription drugs and drug-related devices. A wholesaler shall maintain and follow a written policy and procedure to assure the proper handling and disposal of returned goods. If conditions under which a prescription drug or related device has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug or related device shall be destroyed, or returned, unless examination, testing, or other investigation proves that the drug or drug-related device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a prescription drug or related device has been returned cast doubt on the drug's or related device's safety, identity, strength, quality, or purity, the wholesaler shall consider, among other things, the conditions under which the drug or related device has been held, stored, or shipped before or during its return and the condition of the drug or related device and its container, carton, or labeling, as a result of storage or shipping.
- (6) Handling recalls. A wholesaler shall establish, maintain, and adhere to a written policy and procedure for handling recalls and withdrawals of prescription drugs and drug-related devices. The policy and procedure shall cover all recalls and withdrawals of drugs and drug-related devices due to:
- (a) Any voluntary action on the part of the manufacturer;
 - (b) The direction of the FDA, or any other federal, state, or local government agency; and
 - (c) Replacement of existing.
- (7) Procedures
- (a) A visual examination of all materials received or shipped shall be made to guarantee product identity and to reasonably guard against acceptance or delivery of damaged, contaminated, tampered, or otherwise unfit stock.
 - (b) Procedures for distribution of approved stock shall provide for a rotation whereby the expiration date is taken into consideration when distributing inventory.
 - (c) A wholesaler shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug and related device salvaging or reprocessing.

Section 6. Violations.

- (1) A wholesaler shall not distribute prescription drugs and drug-related devices directly to a consumer or a patient, except as provided in KRS 315.0351(2).
- (2) A wholesaler 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 for a License to Operate as a Wholesaler", May 2020;
- (b) "Renewal Application to Operate as a Wholesaler", May 2020; and
- (c) "USP Chapter 659 Packaging and Storage Requirements", November 1, 2020.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601-8024. Monday through Friday, 8 a.m. to 4:30 p.m.

(9 Ky.R.77; eff. 8-11-1982; 11 Ky.R. 1616; eff. 6-4-1985; 16 Ky.R. 1597; eff. 4-12-1990; 18 Ky.R. 2348; 2832; 2917; eff. 3-25-1992; 19 Ky.R. 445; eff. 10-8-1992; 28 Ky.R. 2406; 29 Ky.R. 98; eff. 7-15-2002; 35 Ky.R. 982; 1826; 1740; eff. 2-18-2009; 47 Ky.R. 119, 985, 1361; eff. 2-4-2021.)

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

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

STATUTORY AUTHORITY:KRS 315.191(1)(a)

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

Section 1. Definitions.

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

- (a)Acute illness or incapacitation;
- (b)Death;
- (c)Fire, flood, or other natural disaster;
- (d)Bankruptcy proceedings; or
- (e)Court, government, or Board of Pharmacy action.

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

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

- (a)Ceases to do business and permanently closes; and
- (b)Does not file application for a license or permit for the same location.

(4)"Temporary closure" means a pharmacy whose hours of operation have deviated over a period of two (2) consecutive days, five (5) aggregate working days within a fourteen (14) day period or nine (9) aggregate working days within a thirty (30) day period from those of record at the Board of Pharmacy office for a reason other than a federal holiday, permanent voluntary closure or involuntary closure.

Section 2. Procedures for Closure Applicable to All Licensees and Permit Holders.

(1) Permanent voluntary closure.

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

1. Date of business termination;
2. Name, address, and DEA number of registrant to whom the prescription drugs and drug-related devices including controlled substances are to be transferred; and
3. Name, address, and DEA number of registrant to whom the records including inventories, acquisition records, purchase records, and disposition records are to be transferred.

(b) In the absence of directives to the contrary from the DEA, the Board of Pharmacy, or the Cabinet for Health and Family Services, the transfer shall be effected on the assigned date.

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

1. U.S. Official Order Forms, DEA-222 Schedule II;
2. Schedules III, IV, and V Invoices; and
3. Controlled substances inventory.

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

1. Inventories;
2. Acquisition records;
3. Purchase records; and
4. Disposition records.

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

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

1. Remove all signs pertinent to pharmacy or drugs from the building and premises; and
2. Return the voided permits, the DEA registration, and unused Schedule II Order Forms to their respective office of issue.

(2) Involuntary closure.

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

1. Notify the Board of Pharmacy in writing; and
2. Guarantee the security and control of the licensed or permitted premises in a manner that will allow continued storage of prescription drugs and drug-related devices, including controlled substances, and records, including patient records, if applicable, for sixty (60) days after the effective date of the involuntary closure.

(b) Within sixty (60) days after the effective date of the involuntary closure, a licensee or permit holder shall make arrangements for the lawful transfer or

other disposition of prescription drugs and drug-related devices, including controlled substances, and records.

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

- 1.A lawful transfer or other disposition has not been made; or
- 2.An agreement between the Board of Pharmacy and the licensee or permit holder or person authorized to act on behalf of the licensee or permit holder, has not been reached.

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

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

- 1.Termination date of business; and
- 2.Name and address of the licensee or permit holder to which prescription files or other patient records will be transferred.

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

- 1.The sign shall remain in place for a period of thirty (30) days after the closure; and
- 2.All efforts shall be undertaken to assure a smooth transition of uninterrupted service to those affected by the closure.

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

- 1.An application for a pharmacy permit or outsourcing facility license for the same location is filed; or
- 2.During a sale of a pharmacy or outsourcing facility, prescription records are transferred to another permitted pharmacy or licensed outsourcing facility that is within five (5) miles of the location of the pharmacy or outsourcing facility that is sold and owned by the purchasing entity.

(4)Deviation of Hours for Non-Pharmacy Licensees and Permit Holders.

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

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

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

- 1.License or permit shall be closed; and
- 2.Procedures for involuntary closure shall be followed.

(5)Temporary Closure of a Pharmacy.

(a) A pharmacy permit holder that is temporarily closed shall immediately notify the Board of Pharmacy in writing of the temporary closure, reason for the closure, the anticipated date of reopening, and the plan to provide emergency patient assistance and access to medication throughout the period of closure.

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

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

1. Pharmacy shall be closed; and

2. Procedures for involuntary closure shall be followed.

(d) At the time the pharmacy permit holder notifies the Board of Pharmacy of the temporary closure, the pharmacy shall place patient-facing signage on all pharmacy entrances and drive through windows providing up to date notification of the closure. The signage shall include notification of the closest, open pharmacy, regardless of ownership, that can assist patients immediately as well as anticipated date and time of reopening.

(e) The pharmacy permit holder shall update their phone message to include notice of the closure, and if the pharmacy has a Web site, the website shall also indicate the closure. The phone message and the website shall include a method to speak with an on-call pharmacist during regular operating hours on file with the Board of Pharmacy.

(f) The pharmacy permit holder shall have a pharmacist onsite or remotely if a common database is utilized and readily available during the posted pharmacy hours for the purpose of transferring prescription record(s) or reversing adjudicated claim(s) to a third party payer during the time of the temporary closure.

(g) The pharmacy permit holder shall make a reasonable effort to notify prescribers of the temporary closure and time and date of anticipated reopening.

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

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

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

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

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

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

(a) Be in writing;

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

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

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

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

- (1) Fully cooperate with the Board of Pharmacy to promote the efficient administration of action required by the provisions of this administrative regulation; and
- (2) Be financially liable to the Board of Pharmacy for expenses incurred by the Board of Pharmacy in its implementation of the provisions of this administrative regulation.

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

201 KAR 2:116. Substitution of drugs, biologics and biosimilar products.

RELATES TO: KRS 217.819

STATUTORY AUTHORITY: KRS 217.814(5), (6), (7), (8), 217.819(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.819(1) requires the Kentucky Board of Pharmacy to prepare by administrative regulation a drug product formulary of drugs which should not be interchanged by pharmacists. This administrative regulation references drug products with active ingredients or dosage forms that are interchangeable. All other products not referenced as interchangeable non-interchangeable.

Section 1. The following have been determined by the board to be:

- (1) Drugs, drug products, or dosage formulations considered by the United States Food and Drug Administration to be therapeutically equivalent as published in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book); and
- (2) Biologics drugs, biologics drug products, or biologics dosage formulations considered by the United States Food and Drug Administration to be therapeutically equivalent as published in the Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book).

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

- (a) "Approved Drug Products with Therapeutic Equivalence Evaluations," (Orange Book), U.S. Food and Drug Administration, 39th Edition, 2019; and
- (b) "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" (Purple Book), United States Food and Drug Administrations, June 2019.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601-8204, Monday through Friday, 8 a.m. to 4:30 p.m. and is available online at <http://www.fda.gov>.

(16 Ky.R. 1720; 2154; eff. 5-13-90; 17 Ky.R. 2212; 2725; eff. 4-5-91; 45 Ky.R. 3453, 46 Ky.R. 412; eff. 8-19-2019.)

201 KAR 2:160. Licensees; inactive status.

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.065, 315.110, 315.120, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: Senate Bill 241 of the General Assembly, Commonwealth of Kentucky, Regular Session 1982, provided for changes in KRS Chapter 315. This necessitated requirements for licensees to be issued inactive status and for those who desire to apply for renewal of a license to return to active practice.

Section 1. A pharmacist may apply for inactive status by:

- (1) Completing annual renewal application; and
- (2) Paying annual fee for inactive status.

Section 2. Pharmacists maintaining an active license to practice in another state or jurisdiction are ineligible for inactive status in Kentucky.

Section 3. Pharmacists seeking relicensure from inactive to active status must fulfill the following requirements:

- (1) If the pharmacist has been inactive for no more than five (5) consecutive years, he must:
 - (a) Provide written notice to the board requesting their consideration to active status. The board shall act upon such request within sixty (60) days.
 - (b) Satisfy the board's continuing education requirements for each year of inactive status.
 - (c) Successfully complete a jurisprudence examination given by the board.
 - (d) Pay all cumulative annual renewal fees required for active licensees.
- (2) If a pharmacist has had inactive status for more than five (5) consecutive years, he must:
 - (a) Provide written notice to the board requesting their consideration to active status. The board shall act upon such request within sixty (60) days.
 - (b) Successfully complete a satisfactory examination before the board.
 - (c) Pay all cumulative annual renewal fees required of active licensees.

(9 Ky.R. 633; 778; eff. 12-1-1982; Crt eff. 4-17-2019.)

201 KAR 2:165. Transfer of prescription information.

RELATES TO: KRS 217.215(2), 315.191(1)(f)

STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1)(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(f) authorizes the Board of Pharmacy to promulgate administrative regulations to control the transfer of prescription drug orders between pharmacists and pharmacies. This administrative regulation establishes the procedures by which a prescription may be transferred between pharmacies in the Commonwealth or between a pharmacy and an establishment located in a state or United States Territory or District outside the Commonwealth and similarly credentialed as a pharmacy by that state or U.S. Territory or District for the purpose of dispensing.

Section 1.

- (1) The transfer of prescription information for any noncontrolled substance prescription for the purpose of refill dispensing may occur if:

- (a) It is orally communicated directly between two (2) pharmacists or pharmacist interns in the Commonwealth or between a pharmacist and an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District;
 - (b) It is made through an on-line real-time computer system that provides documentation of the presence of a pharmacist or an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District when the information is transferred;
 - (c) It is made through the use of a facsimile machine and all the information required by this administrative regulation is provided to the sending and receiving pharmacist or an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District; or
 - (d) It is made through the use of voice recording technology and all information required by this administrative regulation is provided to the sending and receiving pharmacist or an individual located in a state or U.S. Territory or District outside the Commonwealth and similarly credentialed as a pharmacist by that state or U.S. Territory or District.
- (2) If in the Commonwealth the transferring pharmacist shall record the following information:
- (a) That the prescription is void;
 - (b) The name and address of the pharmacy or the establishment located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacy by that state or U.S. Territory or District to which it was transferred and the name of the pharmacist or the individual located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacist by that state or U.S. Territory or District receiving the prescription information; and
 - (c) The date of the transfer and the name of the pharmacist transferring the information.
- (3) If in the Commonwealth the pharmacist receiving the transferred prescription shall record the following information:
- (a) That the prescription is a transfer;
 - (b) The date of issuance of the original prescription;
 - (c) The refill authorization on the original prescription;
 - (d) The date of original dispensing, if applicable;
 - (e) The refill authorization remaining and the date of the last refill, if applicable;
 - (f) The name and address of the pharmacy or the establishment located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacy by that state or U.S. Territory or District and the original prescription number from which the prescription was transferred; and
 - (g) The name of the transferor pharmacist or the individual located in a state or U.S. Territory or District outside the Commonwealth that is similarly credentialed as a pharmacist by that state or U.S. Territory or District.
- (4) Both the original prescription and the transferred prescription shall be maintained for a period of five (5) years from the date of the last refill.

(5) Pharmacies electronically accessing the same prescription record shall satisfy all information of a manual mode for a prescription transfer.

Section 2. The transfer of prescription information for a controlled substance prescription, except a Schedule II controlled substance, for the purpose of refill dispensing may occur if the transfer complies with the requirements of 21 C.F.R. 1306.25.

Section 3. Violation of a provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121(2)(d), (f), and (g).

(9 Ky.R. 1264; eff. 6-1-83; 16 Ky.R. 797; eff. 1-12-90; 25 Ky.R. 1944; 2545; eff. 5-19-99; 1445; 1793; eff. 2-7-2002; 37 Ky.R. 1328; eff. 2-4-2011; 45 Ky.R. 3454; eff. 11-01-2019.)

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 the board to establish administrative regulations relating to the storage and retrieval of prescription records in licensed pharmacies, including administrative regulations regarding computerized recordkeeping. This administrative regulation provides standards for licensed pharmacies 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 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;
- (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 the prescription is first filled and upon 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 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. 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 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 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 assure continuity in the maintenance of records throughout any transition in computerized record systems utilized.

Section 2. A computer malfunction or data processing service 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.

(47 Ky.R.2179, 48 Ky.R. 23; eff. 7-21-2021.)

201 KAR 2:175. Emergency prescription refills of up to a seventy-two (72) hour supply or greater than a seventy-two (72) hour supply.

RELATES TO: KRS Chapters 217, 315

STATUTORY AUTHORITY: KRS 217.215(3), 315.191

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.215(3) requires the Board of Pharmacy to promulgate administrative regulations to carry out the provisions for emergency refills by a pharmacist in emergency situations when authorization may not be readily or easily obtained from the prescribing practitioner. KRS 315.191 authorizes the board to promulgate administrative regulations necessary to regulate and control all matters set forth in KRS Chapter 315 relating to pharmacists. This administrative regulation establishes the conditions for when a prescription may be refilled in an emergency situation and the prescriber is unavailable.

Section 1. If a pharmacist receives a request for a prescription refill with no refill authorized and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may:

(1) Dispense a one (1) time emergency refill of up to a seventy-two (72) hour supply of the maintenance medication when:

- (a) The prescription refill is not for a controlled substance;
- (b) The medication is essential to the maintenance of life or to the continuation of therapy in chronic conditions;
- (c) In the pharmacist's professional judgment, the interruption of therapy may reasonably produce undesirable health consequences or may be detrimental to the patient's welfare and cause physical or mental discomfort;
- (d) The pharmacist notes on the prescription record the date, the quantity dispensed, and the pharmacist's name or initials; and
- (e) In all situations an emergency refill shall be followed by authorization from the prescriber for continued therapy.

(2) Dispense greater than a seventy-two (72) hour supply of maintenance medication if in addition to the requirements in subsection (1) of this section:

- (a) The standard unit of dispensing for the drug exceeds a seventy-two (72) hour supply;
- (b) The pharmacist dispenses a supply of the drug that is equal to the standard unit of dispensing for the drug; and
- (c) The drug is used for insulin therapy or the treatment of chronic respiratory diseases.

Section 2. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

(9 Ky.R. 1265; 10 Ky.R. 5; eff. 6-1-1983; 16 Ky.R. 798; eff. 1-12-1990; 46 Ky.R. 2683; 47 Ky.R. 41; eff. 7-29-2020.)

201 KAR 2:180. Pharmacies sanitation.

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.035(6), 315.191(1), (5)

NECESSITY, FUNCTION, AND CONFORMITY: There is no existing uniform administrative regulation for which the Kentucky Board of Pharmacy can monitor a pharmacy for cleanliness. Existing administrative regulations pertain only to food handling facilities. The purpose of this administrative regulation is to provide the board with the authority to require standards for compliance.

Section 1. The designated pharmacy area(s) shall be used exclusively for the compounding and dispensing of drugs and other usual procedures incidental to compounding and dispensing of drugs. This area shall be maintained in a clean and sanitary condition, adequately lighted and ventilated.

Section 2. No compounding or dispensing of drugs shall be carried on in any room used as a dwelling or for usual household purposes.

Section 3. Hot and cold water shall be readily accessible. Adequate facilities, separate and distinct from toilets and washrooms, shall be provided for maintaining clean and sanitary conditions.

Section 4. All equipment used in the storage, compounding, and dispensing of drugs or medicines shall be kept in a clean and sanitary manner.

Section 5. Proper temperatures shall be maintained for compounding and dispensing of drugs and medicines. Controlled room temperatures shall be fifteen (15) to thirty (30) degrees Centigrade, fifty-nine (59) to eighty-six (86) degrees Fahrenheit. Refrigeration temperatures shall be two (2) to eight (8) degrees Centigrade, thirty-six (36) to forty-six (46) degrees Fahrenheit. Freezer temperatures shall be minus twenty (-20) to minus ten (-10) degrees Centigrade, minus four (-4) to fourteen (14) degrees Fahrenheit. Under nonspecific conditions, it is to be understood that the storage conditions include protection from moisture, freezing, and excessive heat.

Section 6. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

(10 Ky.R. 951; eff. 2-1-84; Crt eff. 4-17-19.)

201 KAR 2:185. Noncontrolled substance prescription drug refills.

RELATES TO: KRS 215.191(f), (g), 315.191(1)(f)

STATUTORY AUTHORITY: KRS 217.215, 315.191(1)(f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.010, 315.191 and 217.215(2) require the Board of Pharmacy to promulgate administrative regulations necessary to regulate the practice of pharmacists and the recordkeeping systems associated with prescriptions. This administrative regulation establishes the responsibilities of pharmacists and practitioners relating to prescription drug refills.

Section 1.

(1) A pharmacist shall not refill a prescription for a noncontrolled substance prescription drug unless authorized by the prescribing practitioner.

(2) A pharmacist shall record all refills by writing the date of the refill together with his name or initials on the original prescription.

(3) If an alternate approved automated data processing system is used, refills and records shall be maintained in compliance with 201 KAR 2:170.

Section 2.

- (1) The use of the terms "prn" and "ad lib" in relation to authorization for refilling prescriptions shall mean the prescription may be refilled for a maximum period of one (1) year from the date prescribed.
- (2) After one (1) year from the date prescribed, the prescribing practitioner shall issue a new prescription.

Section 3. If the authorized refills are expressed solely as a number, the prescription shall be refilled for the authorized limit of refills within one (1) year of the date prescribed.

Section 4. Violation of a provision of this administrative regulation shall constitute unethical or unprofessional conduct in accordance with KRS 315.121(2)(d), (f), (g).

(10 Ky.R. 951; eff. 2-1-84; Am. 25 Ky.R. 11945; 2546; eff. 5-19-99; Crt eff. 4-17-2019)

201 KAR 2:190. Return of prescription drugs prohibited.

RELATES TO: KRS Chapters 217 and 315

STATUTORY AUTHORITY: KRS 315.010(5), 315.191(1), (5)

NECESSITY, FUNCTION, AND CONFORMITY: To prevent the dispensing of drugs that have been adulterated, contaminated or misbranded.

Section 1. No pharmacy, pharmacist, or agent thereof shall accept for reuse or resale a prescription drug. This administrative regulation shall not apply to sealed/unopened unit dose, unit of use or tamper resistant drug packaging.

Section 2. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

(10 Ky.R. 952; eff. 2-1-84; 11 Ky.R. 1126; eff. 3-12-85; 16 Ky.R. 799; eff. 1-12-90; Crt eff. 4-17-2019.)

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) 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, 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 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;
 - (b) "Application for Non-Resident Pharmacy Permit", Form 3, 5/2020;
 - (c) "Application for Resident Pharmacy Renewal", Form 2, 5/2020; and
 - (d) "Application for Non-Resident Pharmacy Permit Renewal", Form 4, 5/2020.
- (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>.

(19 Ky.R. 1018; Am. 1340; eff. 11-30-92; 27 Ky.R. 194; 738; eff. 9-11-2000; 39 Ky.R. 508; eff. 2-1-2013; 47 Ky.R. 2031; 48 Ky.R. 23; eff. 7-21-2021.)

201 KAR 2:210. Patient records and patient counseling.

RELATES TO: KRS 315.191(1), (5), (6), 42 C.F.R. Part 456

STATUTORY AUTHORITY: KRS 217.215(2), 315.191(1), (5), 42 C.F.R. Part 456

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1), (56), 42 CFR Part 456 mandates that pharmacists implement drug utilization reviews and provide patient counseling to those recipients of health-care benefits for which federal funds are allocated. This administrative regulation provides for this mechanism and broadens its magnitude by rendering this valuable service available to all Kentucky's citizenry, equitably.

Section 1. Patient Records.

- (1) (a) A patient record system shall, with the exercise of professional judgment, be maintained by a pharmacy for patients for whom prescriptive drug orders are dispensed at that pharmacy location.
- (b) A pharmacist, with the exercise of professional judgment, shall establish a procedure for obtaining, recording, and maintaining information required for a patient record.
- (c) A pharmacist, or his designee, shall obtain, record, and maintain the information for a patient record.
- (d) A patient record shall:
 1. Be readily retrievable by manual or electronic means;
 2. Enable the pharmacist to identify previously dispensed drugs and known disease conditions;
 3. Enable the pharmacist to determine the impact of previously dispensed drugs and known disease conditions upon the newly submitted prescriptive drug order; and
 4. Be maintained for not less than 180 days from the date of the last entry.
- (2) A patient record shall include:
 - (a) Full name of patient for whom the drug is intended;
 - (b) Address and telephone number of the patient;
 - (c) Patient's age or date of birth;
 - (d) Patient's gender;
 - (e) A list of all prescriptions obtained by the patient at that pharmacy location for the past twelve (12) months by:
 1. Prescription number;
 2. Name and strength of medication;
 3. Quantity;
 4. Date received;
 5. Identity of prescriber; and
 6. Comments or other information as may be relevant to the specific patient or drug; and
 - (f) Individual medical history if significant, including known disease states, known allergies, idiosyncrasies, reactions or conditions relating to prospective drug use and drug regimen reviews.

Section 2. Patient Counseling.

- (1) The pharmacist shall offer to counsel a patient on matters which he believes will optimize drug therapy with each patient or caregiver:

- (a) Upon the presentation of an original prescription order; and
 - (b) On refill prescriptions, as professional discretion dictates.
- (2) (a) The offer shall be made by the pharmacist in a face-to-face communication with the patient or caregiver, unless, in the professional judgment of the pharmacist, it is deemed impractical or inappropriate.
- (b) If deemed impractical or inappropriate, the offer to counsel may be made:
- 1. By the pharmacist designee;
 - 2. In written communication;
 - 3. By telephone through access to a telephone service that is toll-free for long distance calls, unless the primary patient population is accessible through a local, measured, or toll-free exchange; or
 - 4. In another manner determined by the pharmacist to be appropriate.
- (3) Patient counseling shall be:
- (a) In person when practical; or
 - (b) With reasonable effort, by telephone.
- (4) The pharmacist shall include the following elements of patient counseling that he has determined are appropriate:
- (a) The name and description of the drug;
 - (b) The dosage form, dose, route of administration, and duration of therapy;
 - (c) Special directions and precautions;
 - (d) Common and clinically significant adverse effects, interactions, or contraindications that may be encountered, including their avoidance and the action required should they occur;
 - (e) Techniques for self-monitoring of drug therapy;
 - (f) Proper storage;
 - (g) Refill information;
 - (h) Action to be taken in event of a missed dose;
 - (i) His comments relevant to the individual's therapy; and
 - (j) Any other information peculiar to the specific patient or drug.
- (5) If a pharmacist determines that it is appropriate, he may supplement patient counseling with additional forms of patient information, such as:
- (a) Written or printed information leaflets;
 - (b) Pictogram labels; and
 - (c) Video programs.
- (6) Mail-order pharmacies shall be subject to the same counseling requirements as any other pharmacy.

Section 3. Confidentiality.

- (1) A patient record shall be held in confidence.
- (2) It shall be communicated or released:
 - (a) To the patient;
 - (b) As the patient directs; or
 - (c) As prudent, professional discretion dictates.

Section 4. Prospective Drug Use Review.

- (1) A prospective drug use review shall be conducted by a pharmacist prior to dispensing.

(2) It shall include an assessment of a patient's drug therapy and the prescription order.

(3) A prospective drug use review shall include a review by the pharmacist of the following:

- (a) Known allergies;
- (b) Rationale for use;
- (c) Proper dose, route of administration, and directions;
- (d) Synergism with currently employed modalities;
- (e) Interaction or adverse reaction with applicable:
 - 1. Drugs;
 - 2. Foods; or
 - 3. Known disease states;
- (f) Proper utilization for optimum therapeutic outcomes; and
- (g) Clinical misuse or abuse.

Section 5. Documentation of Counseling.

(1) A record that the patient refused the pharmacist's offer to counsel shall be maintained for one (1) year.

(2) If there is no record that the patient refused the pharmacist's offer to counsel, there shall be a presumption that:

- (a) The offer to counsel, as required in Section 2 of this administrative regulation, was made and accepted; and
- (b) The counseling was provided.

Section 6. The provisions of this administrative regulation shall not apply:

(1) To inpatients of a hospital or institution, if other licensed health-care professionals are authorized to administer the drugs; or

(2) If there is documentation that the patient or caregiver refused consultation.

(19 Ky.R. 1694; eff. 2-17-93; Crt eff. 4-17-2019.)

201 KAR 2:215. Nuclear pharmacy services.

RELATES TO: KRS Chapter 315

STATUTORY AUTHORITY: KRS 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: The Kentucky Board of Pharmacy shall be responsible for imposing minimum standards in all settings where drug products are dispensed and to ensure the safety of all drug products provided to the citizens of the Commonwealth. This administrative regulation applies to pharmacies as defined in KRS 315.010. The requirement of these administrative regulations are in addition to, and not in substitution of, other applicable administrative regulations promulgated by the Cabinet for Human Resources for radioactive materials and applicable administrative regulations promulgated by the Kentucky Board of Pharmacy.

Section 1. Definitions.

(1) "Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

(2) "Radiopharmaceutical services" means those acts, services, operations and transactions necessary in the conduct, operation, management and control of a nuclear pharmacy, including, for example:

- (a) The compounding, dispensing, labeling and delivery of radiopharmaceuticals;

- (b) The participation in radiopharmaceutical utilization reviews; and
- (c) The proper and safe storage and distribution of radiopharmaceuticals.
- (3) "Radiopharmaceutical" means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any of those drugs intended to be made radioactive. This includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance, but does not include drugs which are carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.
- (4) "Radiopharmaceutical quality assurance" means the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, and it shall include, for example, internal test assessment, authentication of product history and the keeping of proper records.
- (5) "Internal test assessment" means conducting those tests necessary to insure the integrity of the test.
- (6) "Authentication of product history" means identifying the purchase source, the ultimate use or disposition and any intermediate handling of any components of a radiopharmaceutical.
- (7) "Authorized practitioner" means a practitioner duly authorized by applicable federal and state law to possess, use and administer radiopharmaceuticals. This person shall be named on a radioactive materials license issued by the Radiation Control Branch of the Cabinet for Human Resources.
- (8) "Designated agent" means an individual who shall be under the direct supervision of an authorized practitioner and who shall be authorized to communicate that practitioner's instructions to a nuclear pharmacy.
- (9) "Nuclear pharmacist" means a pharmacist licensed to practice in the Commonwealth of Kentucky and who meets minimal standards of training and experience in the handling of radioactive materials in accordance with the requirements of the Radiation Control Branch of the Cabinet for Human Resources.
- (10) "Direct supervision" means that the supervising nuclear pharmacist shall be physically present in the general area or location where the supportive personnel are performing supportive duties and shall conduct in-process and final checks.

Section 2. General Requirements for Pharmacies Providing Radiopharmaceutical Services.

- (1) A license to operate a pharmacy providing radiopharmaceutical services shall only be issued to a pharmacy operating under the direct supervision of a nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radioactive drugs shall be under the direct supervision of a nuclear pharmacist. A nuclear pharmacist shall be responsible for all operations of the licensed area and in personal attendance at all times that the pharmacy is open for business.
- (2) Nuclear pharmacies may be exempted from the general space requirements for pharmacies, but shall:
 - (a) Have adequate space, commensurate with the scope of services required and meeting Radiation Control Branch, Cabinet for Human Resources, requirements established for all radioactive material licensees in the Commonwealth;
 - (b) Be separate from the pharmacy areas for nonradioactive drugs;

- (c) Be inaccessible to all unauthorized personnel; and
 - (d) Have a radioactive storage and decay area.
- (3) The process used for handling radioactive materials by any license holder shall involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution and disposal of radioactive materials as approved in a Kentucky radioactive materials license. In order to ensure the public health and safety in this respect, a nuclear pharmacy shall first meet the following general environmental requirements where the handling of radiopharmaceutical materials takes place:
- (a) Proper ventilation so that radioactive materials cannot be airborne from that environment to other nonoccupationally unrestricted areas;
 - (b) Proper location so that the receipt and dispersal of radioactive materials do not result in inadvertent and undesired contamination of other nonoccupationally labeled areas; and
 - (c) Proper design to allow radioactive materials to be contained in given areas to ensure adequate safety and protection to personnel working in or near them and to ensure proper operation of the corresponding assay equipment.
- (4) Nuclear pharmacies shall maintain records of acquisition and disposition of all radioactive drugs in accordance with administrative regulations of the Radiation Control Branch of the Cabinet for Human Resources.
- (5) A nuclear pharmacy, upon receiving an oral prescription for a radiopharmaceutical, shall immediately have the prescription reduced to writing or recorded in a data processing system, which writing or record shall contain at least the following:
- (a) The name of the authorized user or his agent;
 - (b) The date of distribution and the time of administration of the radiopharmaceutical;
 - (c) The name of the procedure;
 - (d) The name of the radiopharmaceutical;
 - (e) The dose or quantity of the radiopharmaceutical;
 - (f) The serial number assigned to the order for the radiopharmaceutical;
 - (g) Any specific instructions; and
 - (h) The patient's name, whenever an order is for a therapeutic or blood-product radiopharmaceutical.
- (6) The immediate outer container (shield) of a radioactive drug to be dispensed shall be labeled with the:
- (a) Standard radiation symbol;
 - (b) Words, "Caution-Radioactive Material";
 - (c) Radionuclide;
 - (d) Chemical form;
 - (e) Amount of radioactive material contained in millicuries or microcuries;
 - (f) Volume in cubic centimeters, if a liquid;
 - (g) Requested calibration time for the radioactivity contained;
 - (h) Name, address, and telephone number of the nuclear pharmacy;
 - (i) Prescription number;
 - (j) Date; and
 - (k) Space for patient's name.
- (7) The immediate container shall be labeled with the:
- (a) Standard radiation symbol;

- (b) Words, "Caution-Radioactive Material";
 - (c) Prescription number; and
 - (d) Name of the radiopharmaceutical.
- (8) Nuclear pharmacies shall only dispense radiopharmaceuticals which comply with acceptable professional standards of radiopharmaceutical quality assurance.
- (9) A nuclear pharmacist may transfer to authorized persons, in accordance with the provisions of a Kentucky radioactive materials license, radioactive materials not intended for drug use and radiopharmaceuticals intended for individual patient use.
- (10) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies including those laws and regulations governing nonradioactive drugs. For nuclear pharmacies handling radiopharmaceuticals exclusively, the Kentucky Board of Pharmacy may waive regulations pertaining to pharmacy licenses for nonradiopharmaceuticals which requirements do not pertain to the practice of nuclear pharmacy.
- (11) Radioactive drugs are to be dispensed only upon a nonrefillable prescription order from a Radiation Control Branch, Cabinet for Human Resources, licensed medical practitioner (or the designated agent) authorized to possess, use and administer radiopharmaceuticals.
- (12) Prescription orders for delivery of radioactive drugs for use in the medical practice of a Radiation Control Branch, Cabinet for Human Resources, licensed medical practitioner may be placed on a telephone answering and recording device, only if the practitioner (or the designated agent) is identified in such a manner that is clearly recognized by the nuclear pharmacist dispensing the radioactive drug.
- (13)(a) A nuclear pharmacist in charge of a nuclear pharmacy shall have the authority to delegate to any qualified and properly trained person or persons, acting under his direct supervision, any nuclear pharmacy act which a reasonable and prudent nuclear pharmacist would find is within the scope of sound pharmaceutical judgment to delegate.
- (b) The delegation shall only occur if, in the professional opinion of the delegating nuclear pharmacist-in-charge, the act may be properly and safely performed by the person to whom the act is delegated.
 - (c) The delegated act shall only be performed in its customary manner and not in violation of other statutes.
 - (d) Persons to whom nuclear pharmacy acts are delegated shall not hold themselves out to the public as being authorized to practice pharmacy.

Section 3. Minimum Requirements for Space, Equipment, Supplies, and Library.

- (1) Each nuclear pharmacy must meet the following requirements for space:
- (a) The area for the storage, compounding, and dispensing of radioactive drugs shall be completely separate from pharmacy areas for nonradioactive drugs;
 - (b) Hot lab and storage area shall be a minimum of 120 square feet; and
 - (c) The compounding and dispensing area shall be a minimum of 300 square feet.
- (2) Each nuclear pharmacy shall be equipped with at least the following items of equipment:
- (a) Dose calibrator;
 - (b) Refrigerator;
 - (c) Drawing station;
 - (d) Well scintillation counter;

- (e) Microscope;
 - (f) Chromatographic apparatus or comparable means of effectively assuring tagging efficiency;
 - (g) Portable radiation survey meter; and
 - (h) Other equipment deemed necessary for radiopharmaceutical quality assurance for products compounded or dispensed as shall be determined by the Radiation Control Branch, Cabinet for Human Resources, and the Kentucky Board of Pharmacy.
- (3) Each nuclear pharmacy shall have on the premises current editions or revisions of the following reference materials:
- (a) United States Pharmacopedia-National Formulary with supplements;
 - (b) State statutes and administrative regulations relating to pharmacy;
 - (c) State and federal regulations governing the use of applicable radioactive materials; and
 - (d) Text relating to the practice of nuclear pharmacy and radiation safety.

Section 4. Radiopharmaceutical Quality Assurance. The holder of a nuclear pharmacy license shall be responsible for the radiopharmaceutical quality assurance of all radiopharmaceuticals, including biologicals, dispensed or manufactured.

(19 Ky.R. 1462; 1742; eff. 1-27-93; Crt eff. 4-17-2019.)

201 KAR 2:220. Collaborative care agreements.

RELATES TO: KRS 315.010(4), 315.121, 315.040(4), 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations to regulate and control matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers. This administrative regulation establishes minimum requirements for the development and maintenance of collaborative care agreements between pharmacist and practitioner.

Section 1. A collaborative care agreement shall:

- (1) Be in writing;
- (2) Be signed and dated by:
 - (a) Each practitioner; and
 - (b) Each pharmacist who is a party to the agreement;
- (3) Provide the method for referral of patients to be managed under the agreement; and
- (4) State the method for termination of the agreement.

Section 2. The following information relating to a patient managed under the collaborative care agreement shall be maintained by the pharmacist:

- (1) Name;
- (2) Address and phone number;
- (3) Emergency notification contact;
- (4) Date of birth, weight, height, and gender;
- (5) Medical history, including:
 - (a) Known diseases;

- (b) Known allergies;
- (c) Reactions and conditions relating to:
 - 1. Prescription medications; and
 - 2. Nonprescription medications;
- (d) Current prescription regimen; and
- (e) Current nonprescription regimen;
- (6) Lab tests ordered, including results of lab tests;
- (7) Assessment of patient outcomes;
- (8) Notes relating to the care and course of therapy of the patient; and
- (9) Documentation of patient consent to receive care under the collaborative care agreement.

Section 3. Documentation relating to the care and course of therapy of the patient pursuant to the agreement shall be documented in the patient's record maintained by the pharmacist, provided to the collaborating practitioner, and be readily available to other healthcare professionals providing care to the patient.

Section 4. A collaborative care agreement shall comply with KRS 315.010(4) and contain the following information:

- (1) Protocol, criteria, standing orders, or other method by which services are authorized;
- (2) The method established for the assessment of patient outcomes, if appropriate; and
- (3) Lab tests that may be ordered.

Section 5. A collaborative care agreement and information and records required by the provisions of this administrative regulation shall be maintained:

- (1) At the pharmacist's practice site; and
- (2) For at least five (5) years after termination.

(23 Ky.R. 3125; Am. 3807; 4109; eff. 6-16-97; 34 Ky.R. 2421; eff. 8-1-2008; 42 Ky.R.458; 1548; 1710; eff. 12-16-2015.)

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

RELATES TO: KRS 217.015(11), 315.010(9), 315.020, 315.035, 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.020, 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations to regulate and control all matters set forth in KRS Chapter 315 relating to pharmacists and pharmacies. This administrative regulation establishes, consistent with the requirements of KRS 315.191(1)(a), minimum requirements for the permitting of those entities that distribute medical gases.

Section 1. Definitions.

- (1) "Medical gases" means gases (including liquefied gases) classified by FDA as drugs or devices that are used for medical applications and which may be stored and administered through the use of medical gas related equipment, which may or may not be required under federal or state law for the immediate container to bear the label, "Rx only" or "Caution: Federal or State law prohibits dispensing without a prescription."

(2) "Special limited pharmacy permit" means a permit issued to a pharmacy that provides miscellaneous specialized pharmacy service and functions.

Section 2. General Requirements. (1)(a) An applicant for a special limited pharmacy permit for medical gases shall comply with the requirements of 201 KAR 2:180, except Section 5 and 201 KAR 2:205, except that the pharmacist-in-charge designated on the special permit shall be exempt from the requirements of 201 KAR 2:205, Section 2(2).

(b) The pharmacist-in-charge shall review the records and do an onsite visit of the special limited pharmacy permit applicant for medical gases not less than once each quarter.

(2) An applicant for a special limited pharmacy permit for medical gases shall prepare and adopt a policy and procedures manual that sets forth a detailed description of how the:

(a) Operation will comply with applicable federal, state, or local laws or administrative regulations; and

(b) Licensee will maintain the premises so that the medical gas remains secure and complies with applicable compendial monographs of official pharmacopoeias.

(3) An applicant for a special limited pharmacy permit for medical gases shall be inspected by the board prior to the issuance of the license.

Section 3. Qualifications for License. (1) The board shall consider the following in reviewing the qualifications of an applicant for a special limited pharmacy permit for medical gases:

(a) The applicant's experience in the sale or distribution of prescription drugs, including controlled substances;

(b) A felony conviction of the applicant under federal, state, or local laws;

(c) The furnishing by the applicant of false or fraudulent material in a previous application for:

1. A special limited pharmacy permit for medical gases; or

2. A federal or state medical assistance program;

(d) Suspension or revocation of an applicant's license or permit by federal, state, or local government; and

(e) Compliance with requirements under a previously granted license or permit.

(2) The board shall deny an application for a special limited pharmacy permit for medical gases, if an applicant has:

(a) Been convicted for a violation of federal, state, or local laws relating to:

1. The practice of pharmacy;

2. Drugs; or

3. Federal or state medical assistance programs.

(b) Furnished false or fraudulent material in the application for a special limited pharmacy permit for medical gases;

(c) Failed to maintain or make available required records to the:

1. Board; or

2. Federal, state, or local law enforcement officials;

(d) Failed to comply with applicable federal, state, and local laws and regulations relating to medical gas; or

(e) Failed to provide appropriate land, buildings, and security necessary to properly carry on the business described in his application.

Section 4. License Fees; Renewals. An applicant shall submit:

- (1) An initial or renewal application for a special limited pharmacy permit for medical gases on either the Application for Special Limited Pharmacy Permit- Medical Gas or the Application for Special Limited Pharmacy Permit – Medical Gas Renewal; and
- (2) As appropriate, the:
 - (a) Initial application fee established by 201 KAR 2:050, Section 1(8); or
 - (b) Renewal fee established by 201 KAR 2:050, Section 1(9).

Section 5. Incorporation by Reference. (1) The following material is incorporated by reference:

- (a) "Application for Special Limited Pharmacy Permit – Medical Gas", May 2020; and
- (b) "Application for Special Limited Pharmacy Permit – Medical Gas Renewal", May 2020.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601-8204, Monday through Friday, 8 a.m. to 4:30 p.m.

(23 Ky.R. 4021; 24 Ky.R. 329; eff. 7-16-1997; 45 Ky.R. 3456, 46 Ky.R. 412; eff. 8-19-2019; 47 Ky.R. 362, 1366; eff. 2-4-2021.)

201 KAR 2:230. Special limited pharmacy permit - Central Fill.

RELATES TO: KRS 315.010(9), 315.020, 315.035, 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.020, 315.035, 315.0351, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters set forth in KRS Chapter 315 relating to pharmacists and pharmacies. KRS 315.020 requires that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist. KRS 315.035 and 315.0351 require that all pharmacies hold a permit issued by the board. This administrative regulation establishes, consistent with the requirements of KRS 315.191(1)(a), minimum requirements for the permitting of those pharmacies that package, label, and distribute central fill prescriptions to pharmacies in the Commonwealth.

Section 1. Definition. "Central fill pharmacy" means a pharmacy that provides packaging, labeling, and delivery of a prescription product to another pharmacy for the purpose of the dispensing of a valid prescription.

Section 2. The central fill pharmacy shall:

- (1) Either:
 - (a) Have a written contract with the pharmacy which has custody of the original prescription authorization for dispensing; or
 - (b) Be under common ownership with that pharmacy;
- (2) Prepare the label for the prescription product which clearly identifies the name and address of the pharmacy preparing the product for dispensing and the name and address of the pharmacy that will receive the prepared product for dispensing to the patient;
- (3) In addition to its obligation to maintain complete and accurate records of drug products received and otherwise disposed of, maintain complete and accurate records of the preparation of the prescription product, including the name of the:

- (a) Pharmacist who verified the accuracy of the prescription product;
- (b) Pharmacy preparing the prescription product; and
- (c) Pharmacy to which the prepared prescription product is delivered;
- (4) Provide the originating pharmacy with written information that describes how a patient may contact the central fill pharmacy if the patient has any questions about the preparation of the prescription; and
- (5) Be responsible for ensuring that the order has been properly prepared and verified by a pharmacist.

Section 3. The pharmacy to which a prepared centrally filled prescription product is delivered shall:

- (1) In addition to its obligation to maintain complete and accurate records of drug products received and otherwise disposed of, maintain complete and accurate records of the receipt and dispensing of the centrally filled prescription product, including the name of the:
 - (a) Pharmacist who verified the accuracy of the prescription product prior to its dispensing; and
 - (b) Pharmacy preparing the prescription product;
- (2) Be responsible for ensuring that the centrally filled prescription product has been properly prepared, packaged, and labeled;
- (3) Provide the patient with written information that described how a patient may contact either:
 - (a) The central fill pharmacy if the patient has any questions about the preparation of the prescription; or
 - (b) The dispensing pharmacy if the patient has any questions about the use of the medication; and
- (4) Be responsible for adherence to the requirements of 201 KAR 2:210.

Section 4. Effective January 1, 2020, a pharmacist who provides a pharmacy service on a prescription dispensed in Kentucky shall be licensed in Kentucky.

(26 Ky.R. 1735; 2238; eff. 6-12-2000; 35 Ky.R. 1851; eff. 3-11-2009; 46 Ky.R. 2292; 47 Ky.R. 41; eff. 7-29-2020.)

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

RELATES TO: KRS 315.035

STATUTORY AUTHORITY: KRS 315.020, 315.030, 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations to prescribe the criteria for obtaining a pharmacy permit to dispense legend drugs and the procedures for the safe dispensing of legend drugs to citizens of the Commonwealth. This administrative regulation identifies the manner and procedure by which a charitable organization may obtain a pharmacy permit and dispense legend drugs in the Commonwealth.

- Section 1. Definitions. (1) "Charitable organization" means an organization qualified as a charitable organization pursuant to Section 501(c)(3) of the Internal Revenue Code. (2) "Legend drug sample" means an unopened package of a manufacturer's legend drug product that has been distributed to either a practitioner or the charitable pharmacy in accordance with the provisions of the Prescription Drug Marketing Act of 1987.

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

(4) "Special limited pharmacy permit" means a permit issued to a pharmacy that provides specialized pharmacy services, such as dispensing legend drugs, and counseling patients.

- Section 2. (1) A charitable pharmacy: (a) Shall comply with all pharmacy permit requirements except those specifically exempted by the board pursuant to paragraph (b) of this sub-section; and
(b) May petition the board in writing to be exempted from those pharmacy permit requirements that do not pertain to the operation of that charitable pharmacy.
- (2) The charitable pharmacy only shall dispense prescription legend drug samples or prescription legend drugs to qualified indigent patients of the pharmacy.
- (3) The charitable pharmacy shall not charge any fee for the dispensing of prescription legend drug samples or prescription legend drugs to qualified indigent patients of the pharmacy.
- (4) A charitable pharmacy may accept prescription legend drugs in their unbroken original packaging from pharmacies, wholesalers, or manufacturers, provided appropriate records of receipt and dispensing are maintained.
- (5) A charitable pharmacy shall not:
- (a) Accept controlled substances from pharmacies, wholesalers, or manufacturers;
 - or
 - (b) Dispense controlled substances.
- (6) A pharmacy that requests a special limited pharmacy permit - charitable shall submit to the board for prior approval, a plan describing the method by which the charitable pharmacy and the pharmacy shall maintain a separate and distinct prescription drug stock. The failure of either pharmacy to follow the plan shall result in revocation of the special limited pharmacy permit - charitable and the pharmacy permit.

Section 3. License Fees; Renewals. An applicant shall submit:

- (1) An initial or renewal application for a special limited pharmacy permit - charitable pharmacy on either the Application for Special Limited Pharmacy Permit – Charitable Pharmacy or the Application for Special Limited Pharmacy Permit – Charitable Pharmacy Renewal; and
- (2) As appropriate, the:
- (a) Initial application fee established by 201 KAR 2:050, Section 1(8); or
 - (b) Renewal fee established by 201 KAR 2:050, Section 1(9) and (10).

Section 4. Incorporation By Reference. (1) The following material is incorporated by reference:

- (a) "Application for Special Limited Pharmacy Permit – Charitable Pharmacy", May 2020; and
- (b) "Application for Special Limited Pharmacy Permit – Charitable Pharmacy Renewal", May 2020.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.
(27 Ky.R. 254; 739; eff. 9-11-2000; 45 Ky.R. 3458; 46 Ky.R. 413; eff. 8-19-2019; 47 Ky.R. 125, 1367; eff. 2-4-2021.)

201 KAR 2:250. Pharmacist Recovery Network Committee.

RELATES TO: KRS 315.121(1)(d), 315.126

STATUTORY AUTHORITY: KRS 315.126(3), 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.126(1) requires the Board of Pharmacy to establish a pharmacy recovery network committee (PRNC). This administrative regulation establishes minimum requirements for the establishment and operation of the PRNC. This administrative regulation specifies the manner by which the board's PRNC consultant works with the board in intervention, evaluating and treating a pharmacist or intern, and providing for continuing care and monitoring by the consultant through a treatment provider.

Section 1. The board's Pharmacist Recovery Network Committee (PRNC) consultant shall be a pharmacist licensee of the board. The consultant shall assist the Case Review Committee (CRC) and the PRNC in carrying out their respective responsibilities. This shall include working with the board's inspectors and investigators to determine whether a pharmacist or intern is in fact impaired.

Section 2. If a pharmacist or intern self-reports impairment as a result of the misuse or abuse of alcohol or drugs, or both; or if the board receives a legally sufficient complaint alleging that a pharmacist or intern is impaired as a result of the misuse or abuse of alcohol or drugs, or both, and no complaint against the pharmacist or intern other than impairment exists, the reporting of any impairment information to the board shall be forwarded to the consultant and shall not constitute grounds for discipline, if the PRNC finds the pharmacist or intern has:

- (1) Acknowledged the impairment problem;
- (2) Voluntarily enrolled in an appropriate, approved treatment program;
- (3) Voluntarily withdrawn from practice or limited the scope of practice as required by the consultant, in each case, until the PRNC is satisfied the licensee has successfully completed an approved treatment program; and
- (4) Executed releases for medical records, authorizing the release of all records of evaluations, diagnoses, and treatment of the licensee, including records of treatment for emotional or mental conditions, to the consultant. The consultant shall not make copies or reports of records that do not regard the issue of the licensee's impairment and his or her participation in a treatment program.

Section 3.

- (1) A treatment provider shall disclose to the consultant or board if applicable all information in its possession regarding the issue of a pharmacist's or intern's impairment and participation in the treatment program. Failure of the treatment provider to provide information to the consultant shall be a basis for the withdrawal of the use of the program or provider.
- (2) If in the opinion of the consultant or PRNC, an impaired pharmacist or intern has not progressed satisfactorily in a treatment or recovery program, all information regarding the issue of a pharmacist's or intern's impairment and participation in a

treatment or recovery program in the consultant's possession shall be disclosed to the board. That disclosure shall constitute a complaint.

Section 4. All information concerning a pharmacist or intern held by the consultant, PRNC, CRC, or board shall remain confidential.

Section 5.

- (1) The PRNC shall be comprised of eleven (11) members. The members shall include:
 - (a) The President of the Board of Pharmacy;
 - (b) The Chair of the PRNC;
 - (c) The Executive Director of the Board of Pharmacy; and
 - (d) Eight (8) other members, of which seven (7) shall be pharmacists and one (1) shall be a citizen member.
- (2)
 - (a) All members shall have the same rights, which include voting privileges.
 - (b) A member of the PRNC shall not be on the board, except the President of the Board.
 - (c) Any criminal conviction or disciplinary action by a licensure board against a proposed member shall be reported to the board prior to consideration for appointment.
 - (d) There may be no more than four (4) members in successful recovery on the PRNC.
 - (e) A pharmacist under a Pharmacist Recovery Network Agreement shall not serve on the PRNC.
- (3)
 - (a) A PRNC member may be appointed by the board a maximum of three (3), four (4) year terms.
 - (b) A PRNC member shall not serve more than (2) terms consecutively.
 - (c) After serving two (2) consecutive terms a PRNC member shall rotate off the PRNC for at least two (2) years.
 - (d) A committee member shall serve no more than twelve (12) years on the PRNC.
 - (e) The President of the Board, the PRNC Consultant, and the Executive Director of the Board membership on the PRNC shall not constitute a twelve (12) year term.
 - (f) Membership of the PRNC shall be selected by the board from a list of qualified candidates submitted by an interested individual or entity.
- (4) A member of the PRNC who becomes impaired, relapses, has any criminal conviction, or has any disciplinary action by a licensure board shall immediately resign from the PRNC.
- (5) The board by majority vote, with the recusal of the President of the Board, may remove a member of the PRNC for any of the following reasons:
 - (a) Refusal or inability of a committee member to perform duties as a member of the committee in an efficient, responsible, and professional manner;
 - (b) Misuse of the committee by a member to obtain personal, pecuniary, or material gain or advantage for the member or others; and
 - (c) Violation of any provision of KRS Chapter 315.

(28 Ky.R. 1517; 1793; eff. 2-7-2002; 33 Ky.R. 4201; 34 Ky.R. 229; eff. 8-16-07; Crt eff. 4-17-2019.)

201 KAR 2:260. Automated Pharmacy System in Residential Hospice Facilities.

RELATES TO KRS 315.010(9), 315.020, 315.035, 315.295, 315.300, 216B3195

STATUTORY AUTHORITY: KRS 315.035, 315.191(1)(a), 315.295

NECESSITY, FUNCTION, AND CONFORMITY: KRS 335.020(1) requires that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist. KRS 315.295 authorizes the board to regulate an automated pharmacy system in a residential hospice facility. This administrative regulation establishes the standards for the operation of this type of system.

Section 1. Definitions.

- (1) "Automated Pharmacy System" is defined by KRS 315.295(1)(a).
- (2) "Residential Hospice Facility" is defined by KRS 315.295(1)(b).

Section 2. Responsibility. The pharmacist-in-charge of a pharmacy utilizing an automated pharmacy system shall be responsible for all of the following:

- (1) Assuring that the automated pharmacy system is in good working order and accurately dispenses the correct strength, dosage form, and quantity of drug prescribed and complying with the recordkeeping and security safeguards pursuant to Section 3 of this administrative regulation;
- (2) Assuring medications are reviewed by a pharmacist prior to access;
- (3) Implementing an ongoing quality assurance program that monitors performance of the automated system, which is evidenced by written policies and procedures; and
- (4) Notifying the board with prior written notice of the installation or removal of an automated pharmacy system. This notification shall include the following:
 - (a) Name and address of pharmacy;
 - (b) Initial location of the automated pharmacy system. The automated pharmacy system may thereafter be relocated within the pharmacy or health care facility without providing subsequent notification to the board; and
 - (c) Pharmacist-in-charge.
- (5) Assigning, discontinuing or changing personnel access to the system;
- (6) Assuring that access to the medications comply with state and federal laws; and
- (7) Assuring that the automated pharmacy system is stocked accurately and that the automated pharmacy system stock is checked monthly in accordance with established written policies and procedures, including the following:
 - (a) Accuracy;
 - (b) Integrity; and
 - (c) Expiration date.

Section 3. Standards. An automated pharmacy system shall comply with the following provisions:

- (1) A pharmacy shall maintain on-site the following documentation relating to an automated pharmacy system:
 - (a) Name and address of the pharmacy or inpatient health care facility where the system is being used;
 - (b) The automated pharmacy system manufacturer's name, model, and serial number;
 - (c) Description of how the system is used;

- (d) Written quality assurance procedures to determine continued appropriate use of the system; and
 - (e) Written policies and procedures for system operation, safety, security, accuracy, access and malfunction.
- (2) All written policies and procedures shall be maintained in the pharmacy responsible for the automated pharmacy system.
- (3) An automated pharmacy system shall maintain adequate security systems and procedures, evidenced by written policies and procedures to prevent unauthorized access to maintain patient confidentiality and to comply with federal and state laws.
- (4) Records and data kept by the automated pharmacy system shall meet the following requirements:
- (a) All events involving the contents of the automated pharmacy system shall be recorded electronically; and
 - (b) Records shall be maintained by the pharmacy and be available to the Board and shall include the following:
 - 1. The time and location of the system accessed;
 - 2. Identification of the individual accessing the system;
 - 3. Type of transaction;
 - 4. Name, strength, dosage form and quantity of drug accessed;
 - 5. Name of the patient for whom the drug was ordered;
 - 6. The prescription number;
 - 7. The name of the prescriber; and
 - 8. All events involving user database modifications shall be recorded electronically and maintained.
- (5) The stocking of all medications in the automated pharmacy system shall be done by a pharmacist, pharmacist intern, or pharmacy technician, who shall be under the general supervision of a pharmacist on-site.
- (6) A record of medications stocked into an automated pharmacy system shall be maintained for five (5) years and shall include identification of the person stocking and pharmacist checking for accuracy.
- (7) All containers of medications stored in the automated pharmacy system shall be packaged and labeled in accordance with federal and state laws.
- (8) The automated pharmacy system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated pharmacy system, in accordance with federal and state laws.
- (9) The automated pharmacy system shall provide a mechanism for securing and accounting for medications returned to the system and accounting for wasted medications in accordance with federal and state laws.

(33 Ky. R. 3305; 3602; eff. 6-20-2007; Crt eff. 4-17-2019.)

201 KAR 2:270. Expungement.

RELATES TO: KRS 315.121(6), 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.121(6), 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations relating to subject matters governed by KRS Chapter 315. KRS 315.121(6) requires the board to promulgate administrative regulations to establish violations that are considered minor and subject to expungement. This

administrative regulation establishes the violations considered minor and the criteria and procedure for expungement.

Section 1. Definition. "Expungement" means:

- (1) The affected records shall be sealed;
- (2) The proceedings to which they refer shall be deemed not to have occurred; and
- (3) The affected party may properly represent that no record exists regarding the matter expunged.

Section 2. Minor Violations and Expungement Procedure.

- (1) The following violations shall be considered minor in nature:
 - (a) Any unlicensed or unpermitted practice occurring no more than seven (7) days after the expiration of the license or permit due to failure to timely renew a license or permit;
 - (b) Failure to timely obtain required continuing education; and
 - (c) Failure to comply with any provisions of 201 KAR 2:106 for licensed or permitted facility closures; or
 - (d) At the discretion of the board, any other offense:
 1. Not involving the diversion of controlled substances;
 2. Not demonstrating a serious inability to practice the profession or to assist in the practice of pharmacy;
 3. Not adversely affecting public health, safety, or welfare;
 4. Not resulting in economic or physical harm to a person; and
 5. Not creating a significant threat of economic or physical harm.
- (2) In accordance with KRS 315.121(6), a licensee, registrant, or permit holder seeking expungement of a record of a disciplinary action resulting from a violation designated in subsection (1) of this section shall:
 - (a) Not have been the subject of a subsequent violation of the same nature for a period of three (3) years after the date of completion of disciplinary sanctions imposed for the violation sought to be expunged; and
 - (b) Submit a written request to the board.
- (3) The board shall consider each request and shall, if the conditions of subsection (2) of this section are satisfied, expunge every record under its custody relating to the subject disciplinary order.
- (4) The expungement of a record under this administrative regulation is limited to the removal of records in the board's custody and shall not guarantee expungement of a record previously reported to the National Practitioner's Data Bank.

(29 Ky.R. 2196; 2447; eff. 4-11-2003; 45 Ky.R. 3460, 46 Ky.R. 414; eff. 8-19-2019; 48 Ky.R. 100, 1112; eff. 10-20-2021.)

201 KAR 2:280. Prescription dispensing for formulary Compliance.

RELATES TO: KRS 217.814, 315.191

STATUTORY AUTHORITY: KRS 315.191(1)(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters set forth in KRS Chapter 315 relating to pharmacists. KRS 315.191(1)(f) authorizes the board to promulgate administrative regulations to control the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders within and between qualifying pharmacists and pharmacies. This administrative regulation establishes procedural and substantive

requirements for dispensing an equivalent drug product pursuant to a practitioner declaration of formulary compliance approval.

Section 1. Dispensing.

(1) A pharmacist may dispense a therapeutic equivalent drug product under the following conditions:

(a) The ordering practitioner has indicated "formulary compliance approval" on the prescription, in one of the following ways:

1. In the practitioner's own handwriting; or
2. By checking a "formulary compliance approval" box on a preprinted form;

(b) The pharmacist receives a formulary change as a consequence of the patient's third-party plan; and

(c) The product designated as "preferred" by the third-party formulary is in the same therapeutic class as the prescribed drug.

(2) The pharmacist, within twenty-four (24) hours of the formulary compliance substitution, shall notify the ordering practitioner, in an original writing or by facsimile:

- (a) That the pharmacist engaged in formulary compliance; and
- (b) The therapeutic equivalent drug product that was dispensed.

Section 2. The pharmacist may make adjustments in the quantity and directions to provide for an equivalent dose of the preferred formulary therapeutic alternative.

(29 Ky.R. 2197; 2447; eff. 4-11-03; Crt eff. 4-17-2019)

201 KAR 2:300. Common database.

RELATES TO: KRS 315.020, 315.035, 315.0351

STATUTORY AUTHORITY: KRS 315.035, 315.0351, 315.191(1)(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.035 and 315.0351 require that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist. KRS 315.191(1)(a) and (f) authorize the Kentucky Board of Pharmacy to promulgate administrative regulations pertaining to pharmacies; pharmacists; and the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders. This administrative regulation establishes minimum requirements for prescription drug orders within and between pharmacists and pharmacies.

Section 1. Definition. "Common Database" means information shared among pharmacists and pharmacies for the purpose of dispensing medications or providing other forms of pharmacist care to a patient.

Section 2. The use of a common database shall not constitute a transfer as established in 201 KAR 2:165, provided that the following conditions are met:

- (1) All pharmacies involved in the transactions pursuant to which the prescription is dispensed shall be under common ownership and utilize a common database;
- (2) All pharmacies involved in the transactions pursuant to which the prescription is dispensed and all pharmacies engaging in dispensing functions shall be properly permitted in Kentucky pursuant to KRS 315.035 or 315.0351.
- (3) A pharmacist who provides a pharmacy service on a prescription dispensed in Kentucky shall be licensed in Kentucky;

- (4) The common database shall maintain a record of all pharmacists, pharmacist interns, and pharmacy technicians involved in the process of dispensing a prescription;
- (5) The owner of the common database shall maintain a policy and procedure manual that governs its participating pharmacies, pharmacists, and pharmacy employees and that is available to the board or its agents upon request within five (5) business days and which shall include:
- (a) A procedure detailing how each pharmacy and each pharmacist accessing the common database shall comply with applicable federal and state laws, rules, and regulations;
 - (b) The procedure for maintaining appropriate records for regulatory oversight for tracking a prescription during each stage of the filling and dispensing process, identifying the pharmacists involved in filling and dispensing the prescription and counseling the patient, and responding to any requests for information made by the board;
 - (c) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information; and
 - (d) A quality assurance program designed to objectively and systemically monitor, evaluate, and improve the quality and appropriateness of patient care through the use of a common database; and
- (6) A pharmacist dispensing a prescription shall at all times exercise independent professional judgment and shall be responsible for his or her actions and the professional actions of those individuals the pharmacist is required to supervise.

(34 Ky.R. 2252; 2390; eff. 6-6-2008; Crt. eff. 4-17-2019)

201 KAR 2:311. Compounding drugs for veterinary use.

RELATES TO: KRS 315.191(1)(a), 321.441

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, and pharmacies. This administrative regulation establishes requirements for compounding for veterinary use.

Section 1. The pharmacist shall receive a written, verbal, facsimile, or electronic request for a compounded drug from a practitioner, indicating the formulation, strength, and quantity ordered.

Section 2. A compounded drug containing a controlled substance shall only be compounded for patient specific dispensation from the pharmacy to the ultimate user.

Section 3. (1) A pharmacist, pharmacist intern, or pharmacy technician may prepare a non-controlled compounded drug to be dispensed for veterinary use or administration that is either institutional or ambulatory, and which does not designate a specific patient for the purpose of direct administration to patients for:

- (a) Emergency treatment;
 - (b) Situations when a time delay would negatively affect a patient outcome; or
 - (c) Diagnostic purposes.
- (2) The compounded drug shall have a beyond use date.

(3) The veterinary institution or ambulatory unit shall maintain only an emergency stock supply.

(4) A veterinarian or licensed veterinary technician, as defined in KRS 321.441, may administer a compounded drug for veterinary use.

Section 4. Label Requirements. Except as provided for in Section 5, a label shall be generated for the compounded drug and shall include:

- (1) The name of the requesting veterinarian;
- (2) The designated name and strength of the compounded drug;
- (3) The quantity dispensed;
- (4) If for a specific patient and the patient is a food producing animal, the withdrawal time;
- (5) A lot or batch number of the compounded drug;
- (6) The beyond use date for the compounded drug;
- (7) The date the compounded drug is dispensed;
- (8) The pharmacy's name, address, and telephone number;
- (9) Any special storage requirements;
- (10) A notation stating "For veterinary use"; and
- (11) Any auxiliary label required for the compounded drug.

Section 5. (1) A non-controlled substance compounded drug shall be dispensed by a veterinarian for emergency take home use when in his or her professional judgment, failure to provide the drug would result in potential harm to the patient.

(2) If dispensed from the veterinary institution or ambulatory unit, a compounded drug prescription for a veterinary patient shall be for up to a 14-day supply in accordance with the veterinarian prescription and dispensation labeling requirements as established in 201 KAR 16:600.

Section 6. The prescription for the compounded drug shall be kept pursuant to 201 KAR 2:170.

(46 Ky.R. 3063; 47 Ky.R. 941; eff. 11-19-2020)

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

RELATES TO: KRS 315.010, 315.020(2), 315.036, 315.191(1)(a), 315.400, 315.404

STATUTORY AUTHORITY: KRS 315.020(2), 315.036, 315.191(1), 315.400

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.020, 315.036 and 315.191(1)(a)

authorizes the board to promulgate administrative regulations to regulate the manufacturers and virtual manufacturers of drugs and drug-related devices. This administrative regulation establishes the requirements for the regulation of manufacturers and virtual manufacturers.

Section 1. Definitions.

- (1) "Component" means any raw material, ingredient, or article intended for use in the manufacture of a drug and drug-related device.
- (2) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.
- (3) "Illegitimate Product" is defined by KRS 315.400(11).
- (4) "Manufacturer or virtual manufacturer" is defined by KRS 315.010(13).

- (5) "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, such as capsules, tablets, and lyophilized products before reconstitution.
- (6) "Relabeler" means:
- (a) Any person who owns or operates an establishment that changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name; and
 - (b) Does not include establishments that do not change the original labeling, but merely add their own name.
- (7) "Repackager" is defined by KRS 315.400(16).
- (8) "Suspect product" means a component, prescription drug, or drug-related device for which there is reason to believe that such component, prescription drug, or drug-related device:
- (a) Is potentially counterfeit, diverted, or stolen;
 - (b) Is potentially intentionally adulterated such that the component, prescription drug, or drug-related device would result in serious adverse health consequences or death to humans or animals;
 - (c) Is potentially the subject of a fraudulent transaction; or
 - (d) Appears otherwise unfit for distribution such that the component, prescription drug, or drug-related device would result in serious adverse health consequences or death to humans or animals.

Section 2. Requirements.

- (1) A manufacturer or virtual manufacturer engaging in manufacturing in the Commonwealth shall apply for a permit from the Board of Pharmacy in accordance with KRS 315.036 and this administrative regulation.
- (2) A separate permit shall be required for each facility within the Commonwealth regardless of whether joint ownership or control exists.
- (3) An agent or employee of a permit holder shall not be required to obtain a permit under this section when the agent or employee is acting in the usual course of business or employment.
- (4) A permit shall not be issued or renewed unless the applicant 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 and drugs and drug-related devices;
 - (b) Separation and quarantine of deteriorated, damaged, outdated, misbranded, adulterated, or otherwise recalled components and drugs and drug-related devices until they are destroyed or returned;
 - (c) Providing accurate and precise records of all components and drugs and drug-related devices shipped or received including source or and recipient, date, quantity, itemized description, and any other information pertinent to the receipt and distribution or disposition; and

- (d) Providing proof of registration with the U.S. Food and Drug Administration (FDA), the U.S. Drug Enforcement Administration (DEA), and compliance with all federal, state, and local laws and regulations.
- (5) Manufacturers and virtual manufacturers shall comply with all requirements as outlined in the Drug Supply Chain Security Act (DSCSA), 21 U.S.C. 360eee-360eee-4., if applicable.
- (6) Manufacturers and virtual manufacturers shall establish a system to:
 - (a) Quarantine and investigate suspect product to determine if it is illegitimate; and
 - (b) Notify FDA, the Board of Pharmacy, and recipient(s) of illegitimate product, if illegitimate product is found.
- (7) All virtual manufacturers shall be exempt from the requirements of subsection 2(4)(a) and (b) of this Section, and Section 5(1)(a) and (b) and (2)(a) and (b) of this administrative regulation.

Section 3. Qualifications for Permit.

- (1) The Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in manufacture or virtual manufacture of drugs and drug-related devices within the Commonwealth:
 - (a) Any convictions of the officers of the applicant under any federal, state, or local laws relating to drugs, including drug samples and controlled substances;
 - (b) Any felony convictions of the applicant or its officers under federal, state, or local laws;
 - (c) The applicant's and its officers' past experience in the manufacture or virtual manufacture of drugs and drug-related devices, including drug samples and controlled substances;
 - (d) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or virtual drug manufacturing;
 - (e) Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant or its officers for the manufacture or virtual manufacture of any drugs and drug-related devices, including drug samples and controlled sub-stances;
 - (f) Compliance with the requirements under any previously granted license or permit, if any; and
 - (g) Compliance with requirements to maintain or make available to the Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this administrative regulation.
- (2) The Board of Pharmacy shall have the right to deny a permit to an applicant if it determines that the granting of that permit would not be in the public interest based on health and safety considerations.
- (3) A permit 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 drugs and drug-related devices; and
 - (b) That the applicant is equipped as to land, buildings, and security to properly carry on the business described in the application.

- (4) A permit issued pursuant to this administrative regulation may be disciplined, suspended, or revoked for failure to comply with the provisions of KRS 315.020, 315.036, 315.400, or this administrative regulation.
- (5) No permit shall fail to designate a pharmacist-in-charge.

Section 4. Application, Fees, Renewals.

- (1) An application for a permit shall be submitted to the Board of Pharmacy on the Application for a Permit to Operate as a Manufacturer or Virtual Manufacturer.
- (2) An application shall be accompanied by the annual fee set forth in 201 KAR 2:050.
- (3) An application shall include:
 - (a) The name, full business address, and telephone number of the applicant;
 - (b) All trade or business names used by the applicant;
 - (c) Addresses, telephone numbers, and the names of the persons for the facility used by the permit holder for the storage, handling, and manufacturing or virtual manufacturing of drugs and drug-related devices;
 - (d) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship);
 - (e) The name(s) of the owner and operator of the permit holder, including:
 - 1. If a person, the name and Social Security number of the person;
 - 2. If a partnership, the name and Social Security number of each partner, and the name of the partnership;
 - 3. If a corporation, the name, Social Security number and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and
 - 4. If a sole proprietorship, the full name and social security number of the sole proprietor and the name of the business entity; and
 - (f) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to manufacture, virtual manufacture or possess drugs and drug-related devices.
- (4) All permits shall:
 - (a) Expire on September 30 following the date of issuance; and
 - (b) Be:
 - 1. Renewable annually thereafter upon completion of the Renewal Application to Operate as a Manufacturer or Virtual Manufacturer that is accompanied by the renewal fee set forth in 201 KAR 2:050; and
 - 2. Nontransferable.

Section 5. Standards.

- (1) Facilities.
 - (a) All facilities in which components and drugs and drug-related devices are labeled, relabeled, packaged, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.
 - (b) All facilities shall meet all applicable federal, state, and local standards. The facility shall quarantine components and drugs and drug-related devices that are outdated, damaged, deteriorated, misbranded, recalled, or adulterated,
 - (c) A facility shall not be located in a residence.

(2) Security.

(a) A manufacturer shall be equipped with an alarm system to detect entry after hours.

(b) A manufacturer shall ensure that access from outside their premises is well-controlled and reduced to a minimum. This includes the installation of adequate lighting at the outside perimeter of the premises.

(c) Internal security policies shall be developed to provide reasonable protection against theft and diversion by limiting access to areas where components and drugs and drug-related devices are held to authorized personnel. These policies shall provide protection against tampering with computers or electronic records.

(d) A permit holder shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the manufacture or virtual manufacture of drugs and drug-related devices.

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

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

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

These records shall include:

1. The business name and address of the source of the components and drugs and drug-related devices including the seller or transferor and the address of the location from which the components and drugs and drug-related devices were shipped;
2. The business name and address to whom components and drugs and drug-related devices were shipped including the purchaser and the address of the location where the components and drugs and drug-related devices were shipped;
3. The identity and quantity of the components and drugs and drug-related devices received and distributed or disposed of; and
4. The dates of receipt and distribution or disposition of the components and drugs and drug-related devices.

(b) The manufacturer or virtual manufacturer shall keep production and process control records for a period of six (6) years following completion of manufacturing.

(c) Records described in this section that are kept at the inspection site or that can be readily retrievable within forty-eight (48) hours by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by the Board of Pharmacy or an authorized official of a federal, state, or local law enforcement agency.

(d) Manufacturers and virtual manufacturers shall maintain an ongoing list of verified persons and businesses with whom they do business.

(e) A permitted manufacturer and virtual manufacturer may sell or distribute drugs and drug-related devices only to the following:

1. A currently permitted manufacturer or virtual manufacturer;
2. A currently licensed third-party logistics provider;
3. A currently licensed wholesaler;
4. A currently permitted pharmacy;
5. A currently licensed outsourcing facility;
6. A currently licensed practitioner;
7. A currently permitted repackager or relabeler;
8. A currently licensed hospital, but only for use by or in that hospital pursuant to KRS 217.182(1);
9. A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes pursuant to KRS 217.182(1); or
10. Any other appropriately licensed or permitted facility in the jurisdiction in which it is located.

(f) Manufacturers and virtual manufacturers shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion, or other significant loss of any component or drug or drug-related device to the Board of Pharmacy and if applicable the FDA and DEA.

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

(a) A manufacturer or virtual manufacturer shall establish, maintain, and adhere to written policies and procedures for all operations including production, process controls, receipt, security, storage, inventory, and distribution or disposition of components and drugs and drug-related devices.

(b) There shall be written policies and procedures for identifying, recording, and reporting losses or thefts.

(c) There shall be written policies and procedures to assure that the manufacturer and virtual manufacturer prepares for, protects against, and handles crisis situations that affect the security, or operation, and records of the permit holder. 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 to assure that any outdated components or drugs or drug-related devices or any components or drugs or drug-related devices with an expiration date that, in the manufacturer's or virtual manufacturer's view, does not allow sufficient time for repacking or resale shall be segregated and shall be prepared for return or otherwise destroyed, and this shall be documented.

(f) There shall be written policies and procedures by which the manufacturer or virtual manufacturer exercises control over the shipping and receiving of all components and drugs and drug-related devices within the operation.

(g) There shall be written policies and procedures for investigating suspect product and reporting illegitimate product to the Board of Pharmacy, FDA, and recipient(s) of illegitimate product.

(5) Returned, damaged, and outdated drugs and drug-related devices. A manufacturer or virtual manufacturer shall maintain and follow a written procedure to assure the proper handling and disposal of returned components or drugs or drug-related devices. If conditions under which a drug or drug-related device has been returned cast doubt on the drug's or drug-related device's safety, identity, strength, quality, or purity, then the drug or drug-related device shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug or drug-related device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug or drug-related device has been returned cast doubt on the drug or drug-related device's safety, identity, strength, quality, or purity, the manufacturer or virtual manufacturer shall consider, among other things, the conditions under which the drug or drug-related device has been held, stored, or shipped before or during its return and the condition of the drug or drug-related device and its container, carton, or labeling, as a result of storage or shipping.

(6) Handling recalls. A manufacturer or virtual manufacturer shall adopt, maintain, and follow a written policy and procedure for handling recalls and withdrawals of components or drugs or drug-related devices. The policy shall cover all recalls and withdrawals due to:

- (a) Any voluntary action on the part of the manufacturer or virtual manufacturer;
- (b) The direction of the FDA, or any other federal, state, or local government agency; and
- (c) Replacement, relabeling, or repackaging of existing component or drug or drug-related devices.

(7) Procedures.

- (a) A visual examination of all materials received or shipped shall be made to guarantee product identity and to reasonably guard against acceptance or delivery of damaged, contaminated, tampered, or otherwise unfit stock.
- (b) A manufacturer or virtual manufacturer shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to drug product and drug-related devices salvaging or reprocessing.

Section 6. Pharmacist-in-charge. A manufacturer or virtual manufacturer shall designate a pharmacist-in-charge of the facility. The pharmacist-in-charge shall review security and records by conducting and documenting an on-site inspection not less than quarterly.

Section 7. Violations.

- (1) A drug manufacturer or virtual manufacturer shall not distribute prescription drugs and drug-related devices directly to a consumer or a patient.
- (2) A manufacturer or virtual manufacturer shall not operate in a manner that endangers the public health.
- (3) Violation of any of these provisions shall be grounds for the discipline, suspension, or revocation of the permit.

Section 8. Incorporation by Reference. (1) The following material is incorporated by reference:

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

(b) "Renewal Application to Operate as a Manufacturer or Virtual Manufacturer", May 2020.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601-8024, Monday through Friday, 8 a.m. through 4:30 p.m.

(36 Ky.R. 618; 778; eff. 10-21-2009; 47 Ky.R. 127, 1367; eff. 2-4-2021.)

201 KAR 2:330. Emergency pharmacy powers.

RELATES TO KRS 39A.100, 315.500

STATUTORY AUTHORITY: KRS 315.191, 315.505

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.500 establishes the conditions under which a pharmacy may operate temporarily in an area not designated on the pharmacy permit pursuant to an executive order issued by the Governor pursuant to KRS 39A.100. 315.191 authorizes the Board of Pharmacy to promulgate administrative regulations governing pharmacists and pharmacies. This administrative regulation sets out the conditions whereby a prescription may be refilled pursuant to an executive order issued by the Governor as authorized by KRS 315.500 when the prescriber is unavailable. This administrative regulation sets out the conditions whereby a pharmacy may operate temporarily in an area not designated on the pharmacy permit pursuant to an executive order issued by the Governor as authorized by KRS 315.500.

Section 1. If a pharmacist receives a request for a prescription refill with no refill authorized and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense an emergency refill of up to a thirty (30) day supply of the medication if:

- (1) The Governor has issued an executive order as authorized by KRS 315.500 for the county where the pharmacy is located;
- (2) The pharmacist obtains prescription information from:
 - (a) A prescription label;
 - (b) A prescription record within the pharmacy;
 - (c) A prescription record from another pharmacy;
 - (d) A common database;
 - (e) The patient; or
 - (f) Any other healthcare record;
- (3) The prescription refill is not for a controlled substance;
- (4) The prescription is for a maintenance medication;
- (5) In the pharmacist's professional judgment, the interruption of therapy may produce undesirable consequences or may be detrimental to the patient's welfare and cause physical or mental discomfort; and
- (6) The pharmacist notes on the prescription record the date, the quantity dispensed, and the pharmacist's name or initials.

Section 2.

- (1) A pharmacy may temporarily relocate to and operate at a new location if:

- (a) It is not safe or practicable to operate a pharmacy at the address listed on the permit; and
 - (b) The Governor has issued an executive order as authorized by KRS 315.500 for the county where the pharmacy is located.
- (2) The pharmacy owner shall:
- (a) Maintain confidentiality of patient records;
 - (b) Secure all drugs; and
 - (c) Notify the board of the temporary address as soon as practicable.
- (3) The following regulatory requirements shall not apply for this temporary location:
- (a) The requirement to maintain references as listed in 201 KAR 2:090, Section 1;
 - (b) The requirement to maintain equipment as listed in 201 KAR 2:090, Section 2; and
 - (c) The requirement that the pharmacy be enclosed by a floor to ceiling partition if it is located within a larger establishment which is open to the public for business when a pharmacist is not present.

(37 Ky.R. 951; eff. 10-20-2010; Crt eff. 4-17-2019.)

201 KAR 2:340. Special limited pharmacy permit - clinical practice.

RELATES TO KRS 315.010(9), 315.020, 315.035, 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.035 authorizes the Board of Pharmacy issue a permit to a pharmacy. KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations with minimum requirements for the permitting of those entities that provide non-dispensing pharmacy services. This administrative regulation establishes the requirements for the Special limited pharmacy permit - Clinical practice.

Section 1. Definitions. (1) "Special limited pharmacy permit" means a permit issued to a pharmacy that provides miscellaneous specialized pharmacy service and functions. (2) "Special limited pharmacy permit - clinical practice" means a permit issued to a pharmacy that maintains patient records and other information for the purpose of engaging in the practice of pharmacy and does not dispense prescription drug orders.

Section 2. General Requirements. (1) An applicant for a special limited pharmacy permit - clinical practice shall:

- (a) Prepare and adopt a policy and procedure manual that is updated annually;
- (b) Maintain pharmacy references as outlined in 201 KAR 2:090;
- (c) Maintain a physical pharmacy address;
- (d) Designate a Pharmacist-in-Charge (PIC) without a required minimum number of hours of physical presence;
- (e) Maintain patient records for five (5) years in a manner that shall provide adequate safeguard against improper manipulation or alteration of the records; a computer malfunction or data processing services' negligence is not a defense against the charges of improper recordkeeping; and
- (f) Maintain patient records by establishing:
 - 1. A patient record system to be maintained for patients for whom non-dispensing pharmacy services and functions are being performed;

2. A procedure for obtaining, recording, and maintaining information required for a patient record by a pharmacist, pharmacist intern, or pharmacy technician; and
3. A procedure for a patient record to be readily retrievable by manual or electronic means.

(2) An applicant for a special limited pharmacy permit - clinical practice shall be exempt from the following:

- (a) Prescription equipment requirements of 201 KAR 2:090, Section 1;
- (b) Pharmacy sanitation requirements of 201 KAR 2:180; and
- (c) Security and control of drugs and prescriptions requirements of 201 KAR 2:100, Sections 1, 2, 3, and 4.

Section 3. Pharmacy Closure. The permit holder shall provide notification to the board fifteen (15) days prior to permanent pharmacy closure.

Section 4. License Fees; Renewals. An applicant shall submit:

- (1) An initial or renewal application for a special limited pharmacy permit - clinical practice on either the Application for Special Limited Pharmacy Permit - Clinical Practice or the Application for Special Limited Pharmacy Permit - Clinical Practice Renewal; and
- (2) As appropriate, the:
 - (a) Initial application fee established by 201 KAR 2:050, Section 1(9); or
 - (b) Renewal application fee established by 201 KAR 2:050, Section 1(10).

Section 5. Incorporation by Reference. (1) The following material is incorporated by reference:

- (a) "Application for Special Limited Pharmacy Permit - Clinical Practice", May 2019; and
- (b) "Application for Special Limited Pharmacy Permit - Clinical Practice Renewal", May 2019.

(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, 8:00 a.m. to 4:30 p.m.

(39 Ky.R. 172; 458; eff. 9-19-2012; 45 Ky.R. 3462, 46 Ky.R. 414; eff. 8-19-2019.)

201 KAR 2:360. Naloxone dispensing.

RELATES TO: KRS 217.186

STATUTORY AUTHORITY: KRS 217.186, KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.186 requires the Board of Pharmacy to promulgate administrative regulations governing dispensing of naloxone by a pharmacist pursuant to a physician-approved protocol. This administrative regulation establishes the minimum requirements for the pharmacist to be able to dispense naloxone pursuant to a physician-approval protocol.

Section 1. Certification.

(1) A pharmacist desiring to achieve certification to initiate the dispensing of naloxone shall complete and submit an Application for Pharmacist Certification for Naloxone Dispensing, Form 1, with the board and provide the following:

- (a) Name;
- (b) Address;
- (c) Phone number; and
- (d) Pharmacist license number.

(2) The board shall issue the certification to a pharmacist within thirty (30) days of the receipt of the application.

Section 2. Procedures for Dispensing of Naloxone. A pharmacist may initiate the dispensing of naloxone under the following conditions:

(1) The pharmacist has met the requirements of Section 1 of this administrative regulation;

(2) The pharmacist has received his or her certification;

(3) The pharmacist has a physician-approved protocol that meets the minimum requirements of Section 3 of this administrative regulation; and

(4) The pharmacist documents the dispensing event in the pharmacy management system including:

(a) Documentation as required in 201 KAR 2:171 for the dispensing of prescription medication; and

(b) Documentation that the individual receiving naloxone was provided with the required training and education pursuant to Section 4 of this administrative regulation, unless the recipient of the Naloxone is a person or agency operating a harm reduction program.

(5) A pharmacist may dispense naloxone to any person or agency who provides training on the mechanism and circumstances for the administration of naloxone to the public as part of a harm reduction program, regardless of whom the ultimate user of the naloxone may be. The documentation of the dispensing of naloxone to any person or agency operating a harm reduction program shall satisfy any general documentation or recording requirements.

Section 3. Protocol Minimum Requirements. A physician-approved protocol authorizing a pharmacist to initiate the dispensing of naloxone shall contain:

(1) Criteria for identifying persons or agencies eligible to receive naloxone under the protocol;

(2) Naloxone products authorized to be dispensed, including:

(a) Name of product;

(b) Dose; and

(c) Route of administration;

(3) Specific education to be provided to the person whom the naloxone is dispensed;

(4) Procedures for documentation of naloxone dispensation, including procedures for notification of the physician authorizing the protocol, if desired by the physician in accordance with KRS 217.186(5)(b)3;

(5) The length of time the protocol is in effect;

(6) The date and signature of the physician approving the protocol; and

(7) The names and work addresses of pharmacists authorized to initiate dispensing of naloxone under the protocol.

Section 4. Education to be Provided to Person Receiving Naloxone Prescription Under Protocol. A pharmacist dispensing naloxone to a person or agency not operating a harm reduction program shall provide verbal counseling and written educational materials appropriate to the dosage form of naloxone dispensed.

Section 5. Incorporation by Reference.

(1) "Application for Pharmacist Certification for Naloxone Dispensing", Form 1, 6/2021, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. or on the Web site at:

<https://pharmacy.ky.gov/Documents/APPLICATION%20FOR%20PHARMACIST%20CERTIFICATION%20FOR%20NALOXONE%20DISPENSING.pdf>.

(41 Ky.R. 2691; Am. 42 Ky.R. 273 eff. 9-4-2015; 48 Ky.R. 101, 1112; eff. 10-20-2021.)

201 KAR 2:370. Pharmacy services in long-term care facility (LTCF).

RELATES TO: KRS 315.010, 315.020, 315.030, 315.121

STATUTORY AUTHORITY: KRS 315.002, 315.005, 315.191

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the Kentucky Board of Pharmacy to establish requirements to regulate and control pharmacies. KRS 315.002 and 315.005 require standards of practice in all settings where drugs are handled and require the board to ensure safety of all drug products provided to the citizens of Kentucky. This administrative regulation establishes requirements for pharmacy services in long-term care facilities.

Section 1. Definitions.

(1) "Automated Dispensing System" or "ADS" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transaction information.

(2) "Emergency Drug" means drugs required to meet the immediate therapeutic needs of patients that are not available from any other authorized source in sufficient time to prevent risk of harm to patients because of delay.

(3) "Emergency Medication Kit" or "EMK" means an onsite manual or automated mechanism for delivering emergency medications.

(4) "Immediate supervision" is defined by KRS 315.010(12).

(5) "Individual dose" means smallest unit that is commercially available.

(6) "Long-term care facility" or "LTCF" is defined by KRS 216.510(1), excluding family-care homes

(7) "Long Term Care Facility Drug Stock" or "LTCF drug stock" means a dose or doses generated from a prescription order sufficient until the next pharmacy business day or IV fluids that are used for replenishment, which contain no additive drugs, or irrigation solutions.

(8) "Pharmacist-in-charge" or "PIC" means a pharmacist mandated as in charge under KRS 315.020 and who meets the requirements of 201 KAR 2:205.

(9) "Supervision" is defined by KRS 315.010(27).

Section 2. General Requirements.

- (1) The pharmacist-in-charge of the dispensing pharmacy shall:
 - (a) Be responsible for policies and procedures governing the procurement, distribution, storage, security, access, administration, and control of all drugs that are provided to a LTCF;
 - (b) Review all policies and procedures at least once every twelve (12) months;
 - (c) Provide LTCF drug stock or an EMK only to facilities that authorize entry by a board agent for the purposes of inspection or investigation of the LTCF drug stock or EMK at the facility;
 - (d)
 1. Maintain written authorization for entry; and
 2. Immediately provide written authorization for entry to the board upon request of a board agent; and
 - (e) Maintain a current list of all locations where LTCF drug stock or an EMK are stored, which shall be made immediately available upon request by a board agent.
- (2) Dispensing.
 - (a) Controlled substance medications shall be dispensed only by prescription drug order of a licensed practitioner.
 - (b) Non-controlled substance medications shall be dispensed only on a medical order or prescription drug order of a licensed practitioner.
 - (c) A medical order entered on the medical record of a patient at a LTCF shall contain:
 1. Name of patient;
 2. Date of issuance;
 3. Name, strength, and dosage form of drug prescribed;
 4. Directions for use; and
 5. Practitioner's name.
 - (d) Each licensee shall comply with United States Pharmacopeia (USP) Chapter 7 Labeling regarding labeling and packaging.
- (3) The services of a pharmacist shall be readily available at all times.
- (4) Emergency drugs.
 - (a) Emergency drugs for controlled substances in a LTCF EMK shall be stocked pursuant to 902 KAR 55:070.
 - (b) Emergency drugs for non-controlled substances in an EMK shall not exceed six (6) individual doses of thirty (30) different non-controlled substances, per LTCF.
 - (c) The pharmacist-in-charge may request a waiver from the board to increase the number of doses or numbers of non-controlled substances in the EMK based on evidence of use.
 - (d) An EMK shall be assessed for outdated, damaged or adulterated drugs, and stock adequacy by:
 1. A pharmacist or any lawful person as stated in 902 KAR 55:070 on a monthly basis for controlled substances; or
 2. A pharmacist, a PIC authorized pharmacist intern, or certified pharmacy technician on a monthly basis for non-controlled substances.
 - (e) EMK drugs shall be supplied in unit dose packaging unless precluded by manufacturer packaging.

- (f) An EMK shall be conspicuously labeled.
 - (g) An EMK drug shall be accessed only upon a lawful prescription order.
 - (h) All prescription orders shall be reviewed by a pharmacist within one (1) pharmacy business day.
 - (i) An EMK shall not be stocked in a personal care home without personnel lawfully licensed to administer medications.
- (5) Initial dose of LTCF drug stock in a LTCF.
- (a) Excluding personal care homes, LTCF drug stock of drugs shall not exceed fifteen (15) individual doses each of 150 non-controlled substances.
 - (b) LTCF drug stock in a personal care home shall not exceed five (5) individual doses each of thirty (30) non-controlled substances.
 - (c) The pharmacist-in-charge may request from the board a waiver to increase the number of non-controlled substance items to be placed in LTCF drug stock based upon evidence of use.
 - (d) The pharmacist-in-charge shall be responsible for authenticating the need for LTCF drug stock.
 - (e) A pharmacist shall review the prescription drug or medical order before the release of medication.
 - (f) LTCF drug stock shall be inspected by pharmacy personnel at least monthly and documentation shall be maintained to determine if:
 1. Medications are outdated; and
 2. Stocks are maintained at adequate levels.
 - (g) Except for LTCF drug stock of intravenous fluids with no additive drugs or irrigation solutions, the LTCF drug stock shall be replenished by:
 1. A tamper-resistant secure container delivered from the pharmacy;
 2. A tamper-resistant secure container for the stocking of an ADS;
 3. A pharmacist, pharmacist intern, or a certified pharmacy technician who shall be under the immediate supervision of a pharmacist on-site, if there is no pharmacy on-site; or
 4. A pharmacist, pharmacist intern, or a certified pharmacy technician who shall be under the supervision of a pharmacist, if there is a pharmacy on-site.

Section 3. The pharmacist-in-charge of an ADS in a LTCF shall be responsible for the following:

- (1) Initial validation of the ADS accuracy prior to use for distribution to patients assuring that the ADS:
 - (a) Is in good order and accurately dispenses the correct strength, dosage form, and quantity of drug prescribed; and
 - (b) Complies with the recordkeeping and security safeguards pursuant to Section 4 of this administrative regulation.
- (2) Assuring that non-controlled substance prescription drug orders and medical orders are reviewed and approved by a pharmacist prior to access, except for emergency drugs;
- (3) Assuring that controlled substance prescription drug orders are reviewed and approved by a pharmacist prior to accessing the controlled substance emergency drugs;

- (4) Implementing an ongoing quality assurance program that monitors performance of the ADS, pursuant to the written policies and procedures;
- (5) Assigning, discontinuing, or changing personnel access to the system; and
- (6) Assuring appropriate access to medications.

Section 4. Standards.

- (1) A permit holder utilizing an ADS shall comply with the following provisions:
 - (a) A pharmacy shall maintain the following documentation:
 1. Name and address of the LTCF where the system is being used;
 2. The ADS manufacturer's name, model, and serial number;
 3. An operations manual;
 4. Description of how the system is used;
 5. Written quality assurance procedures to determine continued appropriate use of the system; and
 6. Written policies and procedures for system operation, safety, security, accuracy, access, and malfunction.
 - (2) All written policies and procedures shall be maintained in the pharmacy responsible for the ADS.
 - (3) An ADS shall maintain adequate security systems and procedures, pursuant to written policies and procedures that prevent unauthorized access to patient records and maintain patient confidentiality.
 - (4) ADS records and data shall meet the following requirements:
 - (a) All events involving the contents of the ADS shall be recorded electronically; and
 - (b) Records shall be maintained by the pharmacy for five (5) years, be available to the board, and shall include the following:
 1. The time and location of each system access;
 2. Identification of the individual accessing the system;
 3. Name of the patient for whom the drug was ordered;
 4. Name, strength, dosage form, and quantity of drug accessed;
 5. Type of transaction;
 6. The prescription or transaction number if assigned; and
 7. The name of the prescriber.
 - (c) All events involving user database modifications shall be recorded electronically and maintained.
 - (d) A twenty-four (24) hour emergency call center shall be available for any ADS malfunction.
- (5) The stocking of all medications in an ADS shall be performed by a:
 - (a) Pharmacist;
 - (b) Pharmacist intern; or
 - (c) Certified pharmacy technician who shall be under the supervision of a pharmacist on-site.
- (6) If the pharmacy utilizes a tamper resistant barcoding technology, microchip, or other equivalent tamper-resistant ADS, a pharmacist-verified drug may then be loaded by a pharmacist-in-charge trained pharmacist, pharmacist intern, or certified pharmacy technician.

(7) A record of medications stocked in an ADS shall be maintained for five (5) years and shall include identification of the person stocking the ADS and the pharmacist checking for accuracy.

(8) The pharmacist-in-charge shall provide a policy for accounting for medications removed from an ADS and subsequently wasted.

(9) The pharmacist-in-charge shall provide a policy for accounting for medications returned to an ADS.

Section 5. Incorporation by Reference.

(1) "USP Chapter 7 Labeling", (December 1, 2017), is incorporated by reference.

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

(42 Ky.R. 630; 1131; eff. 11-6-2015; TAm eff. 2-15-2016; 42 Ky.R. 273, 630, 1131, 2414; eff. 5-6-2016; 45 Ky.R. 740, 1684, 2575; eff. 3-13-2019.)

201 KAR 2:380. Board authorized protocols.

RELATES TO: KRS 315.010(25), 315.191(1)(a), (f)

STATUTORY AUTHORITY: KRS 315.010(25), 315.191(1)(a), (f)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.010(25) defines a prescription drug order, which includes orders issued through protocols authorized by the board. KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters pertaining to pharmacists, pharmacist interns, pharmacy technicians, and pharmacies. KRS 315.191(1)(f) authorizes the board to promulgate administrative regulations that are necessary to control the dispensing of prescription drug orders. This administrative regulation establishes procedures for board authorized protocols by which pharmacists may initiate the dispensing of noncontrolled medications or other professional services.

Section 1. Definition. "Prescriber" means any individual authorized to prescribe a legend drug.

Section 2. Procedures. A pharmacist may initiate the dispensing of noncontrolled medications, over-the-counter medications, or other professional services under the following conditions:

(1) A prescriber-approved protocol that meets the minimum requirements in Section 3 of this administrative regulation is in place, and is dated and signed by the prescriber and pharmacist authorized to initiate the dispensing of noncontrolled medications, over-the-counter medications, or other professional services;

(2) The protocol directs the care, based on current clinical guidelines, for conditions listed in Section 5 of this administrative regulation;

(3) The protocol has been approved by the board, who provides notice to the prescriber's licensure board within ten (10) business days of approval by the board;

(4) The pharmacist documents the dispensing event in the pharmacy management system, including:

(a) Documentation as required by 201 KAR 2:170 for the dispensing of prescription medication; and

- (b) Documentation that the individual receiving the medication or other professional service was provided with education pursuant to Section 4 of this administrative regulation; and
- (5) A pharmacist shall request the individual's primary care provider's information, provided one exists, and shall provide notification to the primary care provider within two (2) business days.

Section 3. Minimum Requirements of Protocol. Protocols shall contain the following elements:

- (1) Criteria for identifying persons eligible to receive medication therapies or other professional services under the protocol, and referral to an appropriate prescriber if the patient is high-risk or treatment is contraindicated;
- (2) A list of the medications, including name, dose, route, frequency of administration, and refills authorized to be dispensed under the protocol;
- (3) Procedures for how the medications are to be initiated and monitored, including a care plan implemented in accordance with clinical guidelines;
- (4) Education to be provided to the person receiving the dispensed medications, including aftercare instructions, if appropriate;
- (5) Procedures for documenting in the pharmacy management system all medications dispensed, including notification of the prescriber signing the protocol, if requested;
- (6) Length of time protocol is in effect;
- (7) Date and signature of prescriber approving the protocol;
- (8) Dates and signatures of pharmacists authorized to initiate dispensing of medications or other professional services under the protocol; and
- (9) The date, and education or training of the pharmacist as referenced in Section 4 of this administrative regulation.

Section 4. Pharmacist Education and Training Required. A pharmacist who dispenses medication pursuant to a prescriber-approved protocol shall first receive education and training in the subject matter of the protocol from a provider accredited by the Accreditation Council for Pharmacy Education or by a comparable provider approved by the board. Documentation of education shall be provided to the board upon request. Education shall be obtained prior to initiating care under the protocol.

Section 5. Authorized Conditions. Board-authorized protocols may be established for the following conditions:

- (1) Acute influenza infection pursuant to recommendations by the Centers for Disease Control and Prevention (CDC);
- (2) Acute streptococcal pharyngitis infection;
- (3) Acute, uncomplicated urinary tract infection;
- (4) Acute cutaneous or mucocutaneous fungal infection;
- (5) Alcohol use disorder utilizing naltrexone-based therapy pursuant to recommendations from the American Psychiatric Association;
- (6) Allergic rhinitis;
- (7) Anaphylaxis;
- (8) Colorectal cancer prevention and screening;
- (9) HCV infection screening;

- (10) HIV infection prophylaxis, pre-exposure and post-exposure pursuant to recommendations by the CDC;
- (11) HIV infection screening pursuant to recommendations by the CDC;
- (12) Nutritional supplementation with vitamins and minerals;
- (13) Opioid use disorder pursuant to recommendations by the American Society of Addiction Medicine;
- (14) Tobacco use disorder;
- (15) Traveler's health pursuant to recommendations by the CDC;
- (16) Tuberculosis prevention and control through skin testing, and referral as necessary, pursuant to recommendations by the CDC; and
- (17) Self-care conditions appropriately treated with over-the-counter medications and products.

(44 Ky.R. 447; 961; 1215; 1813 eff. 12-13-2017; 47 Ky.R. 1422, 2404, 2577; eff. 6-16-2021.)

201 KAR 2:390. Requirements for third-party logistics provider.

RELATES TO: KRS 315.0351, 315.121, 315.191(1)(a), 315.400, 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. This administrative regulation establishes requirements for the regulation of third-party logistics providers.

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) "Distribution" or "distribute" is defined by KRS 315.400(5).
- (4) "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) "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) "Suspect product" means a component, prescription drug, or drug-related device for which there is a reason to believe that the component, prescription drug, or drug-related device:
 - (a) Is potentially counterfeit, diverted, or stolen;
 - (b) Is potentially intentionally adulterated so that the component, prescription drug, or drug-related device may 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 that the component, prescription drug, or drug-related device may result in serious adverse health consequences or death to humans or animals.
- (8) "Third-party logistics provider" is defined by KRS 315.400(18).

Section 2. Requirements.

- (1) A third-party logistics provider providing services in the Commonwealth, including distributing into the Commonwealth, shall apply for a license from the board 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 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, upon written request of the board or its agents, and maintain for board inspection, a list of all manufacturers, wholesale distributors, repackagers, and dispensers for whom the third-party logistics provider provides services;
- (8) A third-party logistics provider shall have readily retrievable within forty-eight (48) hours, upon written request of the board or its agents, and maintain for board inspection, a list of each partner, limited liability company member, corporate officer or director, and facility manager, including a description of the duties and qualifications of each; and
- (9) A third-party logistics provider shall have readily retrievable within forty-eight (48) hours, upon written request of the board or its agents, and maintain for board 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.

Section 3. Qualifications for Licensure.

- (1) The board 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 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 deny a license to an applicant if it finds 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:
 - (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 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.

(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 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 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 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 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 in KRS 315.0351(2) and 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, 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 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 Provider", May 2020;
and

(b) "Application for Third-Party Logistics Provider License Renewal", May 2020.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite

300, 125 Holmes Street, Frankfort, Kentucky 40601-8024, 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>.

(44 Ky.R. 699, 1363, 1501; eff. 1-18-2018; 47 Ky.R. 2032; 48 Ky.R. 24; eff. 7-21-2021.)

201 KAR 2:400. Outsourcing facility.

RELATES TO: KRS 315.002, 315.005, 315.010(16), 315.191(1)(a), 315.340, 315.342

STATUTORY AUTHORITY: KRS 315.010(16), 315.340, 315.342

NECESSITY, FUNCTION AND CONFORMITY: KRS 315.340 establishes requirements for in-state outsourcing facilities doing business in Kentucky, requires the board to set fees, and requires the board to promulgate administrative regulations relating to in-state permit applicants for licensure and renewal. KRS 315.342 establishes requirements for out-of-state out-sourcing facilities doing business in Kentucky, requires the board to set fees, and requires the board to promulgate administrative regulations relating to in-state permit applicants for licensure and renewal. This administrative regulation establishes further licensure, renewal, and general requirements for in-state and out-of-state outsourcing facilities.

Section 1. Application Requirements for Initial Licensure and Renewal.

(1) An applicant for initial licensure or renewal as an outsourcing facility shall submit:

- (a) A nonrefundable initial licensure or renewal fee of \$250 by check or money order made payable to the Kentucky State Treasurer;
- (b) A complete, sworn, and notarized Application to Operate as an Outsourcer Facility;
- (c) Unless previously provided, proof of registration as an outsourcing facility with the secretary of the U. S. Department of Health and Human Services, Food and Drug Administration;
- (d)1. Unless previously provided, a copy of the current inspection report conducted by the United States Food and Drug Administration pursuant to KRS 315.340(2)(a)2. and (b)1. or KRS 315.342(2)(a)2. and (b)1., if applicable; or
2. If a current inspection report is not available from the United States Food and Drug Administration, the applicant shall submit an inspection report by:
 - a. The National Association of Boards of Pharmacy (NABP); or
 - b. 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, owner, officer, or pharmacist-in-charge has ever been convicted of a felony or had a professional license or permit disciplined under federal, state, or local law; and
- (h) Ownership information for each owner or officer, including:
 - 1. Name and title;
 - 2. Address;
 - 3. Phone number;
 - 4. Social security number; and
 - 5. Date of birth.

- (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) A license shall expire on June 30 following date of issuance, unless earlier suspended or revoked. There shall be a delinquent renewal fee of \$250 for failure to renew by June 30 of each year.

Section 2. Qualifications for License. (1) The board shall consider the following in determining whether to grant a license:

- (a) A felony conviction related to:
 - 1. The practice of pharmacy;
 - 2. Drugs; or
 - 3. Federal or state medical assistance programs;
 - (b) The furnishing of false or fraudulent information in any application;
 - (c) Suspension or revocation of a license or permit by federal, state, or local government;
 - (d) Compliance with a previously granted license or permit; and
 - (e) Failure to maintain and make readily available those records required to be maintained by an outsourcing facility.
- (2) The board shall have the right to deny a license to an applicant if, in considering the factors listed in subsection 1 of this Section, it determines that granting such a license would not be consistent with public health and safety.
- (3) If the board considers denying or resolves to deny an application based solely on an applicant's prior conviction of a crime, the board shall follow the notification and procedure requirements in KRS 335B.030(2).

Section 3. General Requirements. An outsourcing facility shall:

- (1) Permit, to the extent authorized by laws or rules, board agents to enter and inspect its premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records; and
- (2) Follow closure procedures established in 201 KAR 2:106 Section 2.

Section 4. Incorporation by Reference. (1) "Application to Operate as an Outsourcer Facility", July 2017, is incorporated by reference.

- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601-8024, Monday through Friday, 8:00 a.m. to 4:30 p.m.

(44 Ky.R. 701, 1502; eff. 1-18-2018.)

201 KAR 002:412E. Ordering and administering vaccinations.

RELATES TO:KRS 39A.180, 315.010, 315.020, 315.050, 315.065, 315.135, 315.205, 315.500, 42 U.S.C. 247d-6d, 85 Fed. Reg. 15198, 52136, 79190, 86 Fed. Reg. 7872, 9516, 10588, 14462 and 41977.

STATUTORY AUTHORITY: KRS 315.500, 315.505

NECESSITY, FUNCTION, AND CONFORMITY: 85 Fed. Reg. 15198, 85 Fed. Reg. 52136 and 86 Fed. Reg. 9516, 10588 and 41977 require the Board of Pharmacy to promulgate an administrative regulation to conform state law to federal law during the period of this public health emergency resulting from the coronavirus (COVID-19) pandemic. KRS

315.010(22) does not authorize pharmacists to order vaccinations nor does KRS 315.010(22) authorize the use of prescriber-approved protocols for pharmacists or pharmacist interns to administer vaccinations to children under the age of nine (9). 85 Fed. Reg. 52136, requires that state-licensed pharmacists be authorized to order and to administer vaccinations to children between the ages of three (3) and seventeen (17) and that state-registered pharmacist interns and pharmacy technicians be authorized to administer vaccinations to children between the ages of three (3) and seventeen (17). 85 Fed. Reg. 79190, published on December 3, 2020 and effective on February 4, 2021, requires that technicians be authorized to administer childhood vaccinations and COVID-19 vaccinations and requires that state law establish a training requirement for all pharmacists, technicians, and interns that will be ordering or administering vaccinations pursuant to the declaration. Moreover, on August 4, 2021, 86 FR 41977 was released requiring that pharmacists be authorized to order the seasonal flu vaccine for individuals aged nineteen and over and that interns and technicians be authorized to administer the seasonal flu vaccine. The Prep Act (42 U.S.C. 247d-6d(8)) preempts any state law that would prohibit or effectively prohibit activities authorized by the secretary in a PREP Act Declaration. This administrative regulation establishes requirements for Kentucky to comply with 85 Fed. Reg. 15198, 52136, 79190 and 86 Fed. Reg. 7872, 9516, 10588, 14462 and 41977 and ensure a robust pool of pharmacist for ordering and administering vaccines.

Section 1. Definitions.

- (1) "Administer" is defined by KRS 315.010(1).
- (2) "Pharmacist" is defined by KRS 315.010(17).
- (3) "Pharmacist intern" is defined by KRS 315.010(18).
- (4) "Pharmacy technician" is defined by KRS 315.010(21).
- (5) "Prescribe" means to issue an original or new order from a pharmacist for an FDA-approved or authorized vaccination or medication, including but not limited to, epinephrine, diphenhydramine and corticosteroids, to treat emergency reactions to vaccines.

Section 2.

Pharmacist Requirements.

- (1) A pharmacist may administer a vaccine to an individual pursuant to the Advisory Committee on Immunization Practices (ACIP) standard immunization schedule in accordance with KRS 315.010(22).
- (2) A pharmacist may administer a vaccine to a child, age three (3) through eight (8), pursuant to a prescriber-approved protocol.
- (3) A pharmacist may prescribe and administer a vaccine to an individual eighteen (18) and under, pursuant to the ACIP standard immunization schedule or a seasonal flu vaccine to any individual aged nineteen and over or a COVID-19 vaccine to any individual, if the pharmacist:
 - (a) Completes, or has completed practical training on administering vaccinations. This may include:
 1. Completion of a practical training program accredited by the Accreditation Council for Pharmacy Education (ACPE) that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines;

2. Graduation from an ACPE-approved pharmacy school in which hands-on immunization training was part of the curriculum; or
 3. Training via hands-on experience immunizing in current or previous pharmacy practice; and
- (b) Possesses a current certificate in basic cardiopulmonary resuscitation.
4. No provision in this regulation affects the ability of a pharmacist to administer a vaccination pursuant to a prescription drug order.

Section 3. Pharmacist Intern Requirements. A pharmacist intern under the general supervision of a pharmacist may administer a vaccine to an individual if the pharmacist intern:

- (1) Completes, or has completed as part of pharmacy school curriculum, a practical training program accredited by the Accreditation Council for Pharmacy Education (ACPE) that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; and
- (2) Possesses a current certificate in basic cardiopulmonary resuscitation.

Section 4. Pharmacy Technician Requirements. A pharmacy technician may administer a vaccine under the general supervision of a pharmacist to an individual, if the pharmacy technician:

- (1) Completes a minimum of two (2) hours of immunization-related continuing education accredited by the Accreditation Council for Pharmacy Education (ACPE) per each state registration period;
- (2) Completes, or has completed, a practical training program accredited by the Accreditation Council for Pharmacy Education (ACPE) that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; and
- (3) Possesses a current certificate in basic cardiopulmonary resuscitation.

Section 5. Effective Date.

- (1) This administrative regulation shall become effective at 5 p.m. on the date it is filed.
- (2) In accordance with KRS 13A.190, this administrative regulation shall remain in effect until:
 - (a) Expiration of the time period established by KRS 13A.190; or
 - (b) Withdrawn in accordance with KRS 13A.190(12).
- (3) The Board of Pharmacy shall regularly consult with the Governor's Office, the Centers for Disease Control and Prevention, and other public health authorities to determine if this administrative regulation shall be withdrawn prior to its expiration under KRS 13A.190.

201 KAR 002:420. Administration of vaccines.

RELATES TO: KRS 315.010, 315.050, 315.136

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations relating to pharmacists, pharmacist interns, and pharmacy technicians. This administrative regulation authorizes pharmacist interns and pharmacy technicians to administer vaccinations pursuant to requirements. This administrative regulation shall not change the authorization for pharmacists to administer vaccinations pursuant to KRS 315.010(22).

Section 1. Definitions.

- (1) "Administer" is defined by KRS 315.010(1).
- (2) "Pharmacist" is defined by KRS 315.010(17).
- (3) "Pharmacist intern" is defined by KRS 315.010(18).
- (4) "Pharmacy technician" is defined by KRS 315.010(21).

Section 2. Pharmacist Requirements. A pharmacist may administer a vaccine to an individual pursuant to the Advisory Committee on Immunization Practices (ACIP) standard immunization schedule in accordance with KRS 315.010(22).

Section 3. Pharmacist Intern Requirements. A pharmacist intern under the general supervision of a pharmacist may administer a vaccine to an individual if the pharmacist intern:

- (1) Completes, or has completed as part of pharmacy school curriculum, a practical training program accredited by the Accreditation Council for Pharmacy Education (ACPE) that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; and
- (2) Possesses a current certificate in basic cardiopulmonary resuscitation.

Section 4. Pharmacy Technician Requirements. A pharmacy technician may administer a vaccine under the general supervision of a pharmacist to an individual if the pharmacy technician:

- (1) Completes a minimum of two (2) hours of immunization-related continuing education accredited by the Accreditation Council for Pharmacy Education (ACPE) per each state registration period;
- (2) Completes, or has completed, a practical training program accredited by the Accreditation Council for Pharmacy Education (ACPE) that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines; and
- (3) Possesses a current certificate in basic cardiopulmonary resuscitation.

GENERIC LABELING STATEMENT

The Kentucky Board of Pharmacy has addressed generic labeling and has come up with these alternatives when product selection is utilized. Alternatives the Board recognizes in lieu of using just the name of the drug dispensed on the label of the prescription container when product selection [substitution] is made are as follows:

- 1) Methyldopa “generic substitution made for” Aldomet;
- 2) Methyldopa “dispensed in place of” Aldomet;
- 3) Methyldopa “substituted for” Aldomet;
- 4) Methyldopa “dispensed for” Aldomet;
- 5) Methyldopa “generic as” Aldomet.

The label must refrain from wording such as ‘same as’ or any inference that the substitution is the same as the trade name drug. Using only the trade name and the generic name on the label is not acceptable when denoting drug product selection. These alternatives were adopted by the Board to meet the requirement when the physician requests that both names appear on the label. This also should help those pharmacists supplying nursing homes and are required to have the name of the medication as it appears on the physician’s order in the chart.