Baldwin's Kentucky Revised Statutes Annotated Currentness
Title XXVI. Occupations and Professions
Chapter 315. Pharmacists and Pharmacies (Refs & Annos)

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.

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 or provide home medical equipment and services within the Commonwealth.

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) “Association” means the Kentucky Pharmacists Association;

(3) “Board” means the Kentucky Board of Pharmacy;

(4) “Collaborative care agreement” means a written agreement between a specifically identified individual practitioner and a pharmacist who is specifically identified, whereby the practitioner outlines a plan of cooperative management of a specifically identified individual patient's drug-related health care needs that fall within the practitioner's statutory scope of practice. The agreement shall be limited to specification of the

drug-related regimen to be provided and any tests which may be necessarily incident to its provisions; stipulated conditions for initiating, continuing, or discontinuing drug therapy; directions concerning the monitoring of drug therapy and stipulated conditions which warrant modifications to dose, dosage regimen, dosage form, or route of administration;

(5) “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;

(6) “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;

(7) “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;

(8) “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;

(9) “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;

(10) “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;

(11) “Immediate supervision” means under the physical and visual supervision of a pharmacist;

(12) “Manufacturer” means any person, except a pharmacist compounding in the normal course of professional practice, within the Commonwealth engaged in the commercial production, preparation, propagation, compounding, conversion, or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or repackaging of a drug or the labeling or relabeling of its container;

(13) “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;

(14) “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;

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

(16) “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;

(17) “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;

(18) “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;

(19) “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 influenza vaccines to individuals nine (9) to thirteen (13) years of age pursuant to prescriber-approved protocols with the consent of a parent or guardian; the administration of immunizations to individuals fourteen (14) 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;

(20) “Practitioner” has the same meaning given in KRS 217.015(35);

(21) “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;

(22) “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. 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;

(23) “Pharmacy-related primary care” means the pharmacists' activities in patient education, health promotion, 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;

(24) “Society” means the Kentucky Society of Health-Systems Pharmacists;

(25) “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

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

➡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) 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 .

➡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.

➡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.

➡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

(1) 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 permit.” The fee for the permit shall not exceed the current in-state pharmacy permit fee as provided under KRS 315.035.

(2) 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.

(3) 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.

(4) 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.

(5) Records for all prescriptions delivered into Kentucky shall be readily retrievable from the other prescription records of the out-of-state pharmacy.

(6) 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.

(7) 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.

(8) Each out-of-state pharmacy shall comply with KRS 218A.202.

(9) 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.

(10) 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.

(11) 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.

(12) 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.

➡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.

➡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 shall be construed to interfere with the activities of a midlevel health care practitioner as provided in KRS 216.925.

(4) 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.

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

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

➡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, shall have fulfilled the requirements of KRS 214.615(1), 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).

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.

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, and shall include, at least one (1) time every ten (10) years, the course described in KRS 214.610(1), but they shall not require more than an average of one and one-half (1-1/2) continuing education units (CEU) per year. The board may in its discretion require completion of the course described in KRS 214.610(1) more frequently.

(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.

315.070 Pharmacist holding license on May 30, 1938 to secure renewal of license only--Repealed

315.080 Licensed assistant pharmacist--Repealed

315.085 Assistant pharmacists may be examined and licensed as licensed pharmacists--Repealed

315.090 Wording required on license certificate--Repealed

315.100 False representations prohibited--Repealed

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.

➡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.

➡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.

➡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, the wholesale distribution or manufacturing of drugs, or the provision of home medical equipment and services 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 or the following:

1. A felony;

2. An act involving moral turpitude or gross immorality; or

3. A violation of the pharmacy, drug, or home medical equipment 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, pharmacy technician, or home medical equipment and services provider is incapable of engaging or assisting in the practice of pharmacy or providing home medical equipment and services 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, the wholesale distribution or manufacturing of drugs, or the provision of home medical equipment and services;

(g) Engaging in or aiding and abetting an individual to engage or assist in the practice of pharmacy or the provision of home medical equipment and services without a license or falsely using the title of "pharmacist," "pharmacist intern," "pharmacy technician," "home medical equipment and services provider," "provider," or other term which might imply that the individual is a pharmacist, pharmacist

intern, pharmacy technician, or home medical equipment and services provider;

(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; or

(k) Failure to notify the board within fourteen (14) days of a change in one's home address.

(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; or

(j) Failing to exercise appropriate professional judgment in determining whether a prescription drug order is lawful.

(3) Unprofessional or unethical conduct includes but is not limited to the following acts of a home medical equipment and services provider:

(a) 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 sick or disabled person, or engaging in conduct which substantially departs from accepted standards of providing home medical equipment and services ordinarily exercised by a home medical equipment and services provider, with or without established proof of actual injury;

(b) Engaging in grossly negligent professional conduct, with or without established proof of actual injury;

(c) Obtaining any remuneration by fraud, misrepresentation, or deception;

(d) Providing home medical equipment and services that carry a legend or require a prescription without a

medical order from a licensed health care practitioner; or

(e) Willfully or knowingly failing to maintain complete and accurate records of home medical equipment and services provided in compliance with federal and state laws, rules, or administrative regulations.

(4) 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.

(5) 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 or to provide home medical equipment and services 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.

(6) 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.

(7) 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.

➡ **315.123 Suspension or revocation of pharmacy permit, grounds--Repealed**

➡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(5), to demonstrate that he can resume the competent practice of pharmacy or the provision of home medical equipment or services with reasonable skill and safety to patients.

➡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.

➡315.127 Revocation or suspension of pharmacist's license--Repealed

➡315.130 Portion of fees to be turned over to association--Repealed

➡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.

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.

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.

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.

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.

315.140 Forfeiture of license--Repealed

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.

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.

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.

315.170 Compensation and expenses of board members and secretary-treasurer--Repealed

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.

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.

315.190 Functions of board--Repealed

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, manufacturers, and home medical equipment and services providers, 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 and home medical equipment and services shall be limited to the regulation and control of drugs sold pursuant to a prescription drug order or home medical equipment sold pursuant to a medical 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:

1. Licenses for home medical equipment and services providers engaged in providing home medical equipment and services; and

2. 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 and home medical equipment 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, manufacturers, and home medical equipment and services providers;

(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, drug manufacturing, and home medical equipment and services. 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, the profession of providing home medical equipment and services, 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;

(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; and

(m) Oversee and administer the licensure of home medical equipment and services providers pursuant to KRS 315.510 to 315.524.

(2) The board shall have other authority as may be necessary to enforce pharmacy and home medical equipment 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 and of providing home medical equipment and services 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 home medical equipment, 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.

315.192 Board of Pharmacy not to prohibit sale and dispensing of laetrile

The Kentucky Board of Pharmacy shall make no rule or regulation which would prohibit the sale and dispensing of amygdalin (laetrile) by a duly licensed pharmacist.

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.

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.

315.200 For whom prescriptions to be refilled

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

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 fourteen (14) to seventeen (17) years of age or an influenza vaccine to an individual who is nine (9) to thirteen (13) years of age, as authorized in KRS 315.010(19), shall provide notification of the immunization to the individual's primary care provider.

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.

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.

➡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.

➡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.

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.

➡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.

➡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.

➡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.

➡ 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.

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.

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.

Distribution of Prescription Drugs

➡ **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 partner” means two (2) or more entities that have the right to engage in the manufacturing or marketing or both of a prescription drug consistent with the Federal Drug Administration's implementation of the federal Prescription Drug Marketing Act;

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

(4) “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;

(5) “Drop shipment” means the sale of a prescription drug to a wholesale distributor by the drug's manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, the manufacturer's exclusive distributor, or by an authorized distributor of record that purchased the product directly from the manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor, and:

(a) The wholesale distributor takes title to but not physical possession of the drug;

(b) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer a prescription drug; and

(c) The pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer a prescription drug receives delivery directly from the manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, the manufacturer's exclusive distributor, or an authorized distributor of record;

(6) “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;

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

(8) “FDA” means the United States Food and Drug Administration and any successor agency;

(9) “Manufacturer” means the same as defined in KRS 315.010;

(10) “Manufacturer's exclusive distributor” means a distributor who:

(a) Contracts with a manufacturer to provide or coordinate the warehousing, distributing, or other similar services on behalf of a manufacturer;

(b) Takes title of the prescription drug but does not have responsibility to direct the sale of the manufacturer's prescription drug;

(c) Is licensed under KRS 315.402; and

(d) Is an authorized distributor of record;

(11) “Normal distribution channel” means a chain of custody for a prescription drug from a manufacturer, a manufacturer's co-licensed partner, a manufacturer's third-party logistics provider, or a manufacturer's exclusive distributor that goes directly, by drop shipment or by intracompany transfer, to:

(a) A pharmacy or other designated person authorized by law to distribute a prescription drug to an end user;

(b) A pharmacy warehouse that performs intracompany sales or transfers of prescription drugs to a group of pharmacies under common ownership and control to a patient, pursuant to a prescription for a patient, or to a person authorized by law to administer a prescription drug for use by a patient;

(c) An authorized distributor of record:

1. Then to a pharmacy or other designated person authorized by law to distribute a prescription drug to an

end user;

2. Then to a pharmacy warehouse as specified in paragraph (b) of this subsection; or

3. Then to another authorized distributor of record to a licensed health-care facility or pharmacy, or a practitioner authorized by law to distribute a prescription drug to an end user; or

(d) A nonprofit organization under state contract to distribute prescription drugs to pharmacies pursuant to the state's emergency response plan and the subsequent distribution of those prescription drugs to pharmacies;

(12) “Pedigree” means a document or electronic file containing information that records each distribution of a prescription drug;

(13) “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;

(14) “Prescription drug” means the same as defined in KRS 315.010;

(15) “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;

(16) “Third-party logistics provider” means an entity that contracts with a manufacturer to provide or coordinate the warehousing, distribution, or other similar services on behalf of a manufacturer, but does not take title to the drug or have responsibility to direct the sale of the manufacturer's drug. A third-party logistics provider who is a licensed wholesale distributor under KRS 315.402 and is a manufacturer's authorized distributor of record shall be considered as part of the normal distribution channel;

(17) “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

(18) “Wholesale distributor” means an entity engaged in the wholesale distribution of prescription drugs, including but not limited to manufacturers, manufacturers' exclusive distributors, authorized distributors of record, drug wholesalers or distributors, third-party logistics providers, third-party returns processors, reverse distributors, and pharmacy warehouses and retail pharmacies that engage in the wholesale distribution of a prescription drug.

➡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.

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 [FN1] 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.

[FN1] 21 U.S.C.A. § 301.

➡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.

➡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.

➡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.

➡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).

Emergency Authority for Pharmacists

➡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.

➡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).

Home Medical Equipment and Services Provider Licensure Act

➡315.510 Short title

KRS 315.510 to 315.524 shall be known and may be cited as the Home Medical Equipment and Services Provider Licensure Act.

➡315.512 Definitions for KRS 315.510 to 315.524

As used in KRS 315.510 to 315.524, unless the context requires otherwise:

(1) “Applicant” means a person who applies for licensure by the board as a home medical equipment and services provider;

(2) “Board” means the Kentucky Board of Pharmacy established in KRS 315.150;

(3) “Home medical equipment” means durable medical equipment which:

(a) Withstands repeated use;

(b) Is primarily and customarily used to serve a medical purpose;

(c) Is generally not useful to a person in the absence of illness or injury; and

(d) Is appropriate for use in the home;

(4) “Providing home medical equipment and services” means the sale, lease, rental, delivery, installation, maintenance, replacement, or instruction in the use of home medical equipment, related equipment and supplies, and mobility enhancing equipment used by a sick or disabled person to allow the person to be maintained in his or her residence and which is funded through a third-party payor;

(5) “Home medical equipment and services provider” or “provider” means a person engaged in the business of providing home medical equipment and services, either directly or through a contractual arrangement, to an unrelated sick or disabled person in the residence of that person; and

(6) “Person” has the same meaning as in KRS 446.010.

➡315.514 License required to provide or hold oneself out as providing home medical equipment and services; exemptions

(1) No person shall provide home medical equipment and services, or use the title “home medical equipment and services provider” in connection with his or her profession or business, without a license issued by the board.

(2) Unless home medical equipment and services are provided through a separate legal entity, nothing in KRS 315.510 to 315.524 or any administrative regulations promulgated thereunder shall be construed as preventing or restricting the practices, services, or activities of the following:

(a) A person licensed or registered in this state under any other law who is engaging in the profession or occupation for which he or she is licensed or registered;

(b) Health care practitioners who lawfully prescribe or order home medical equipment and services, or who use home medical equipment and services to treat their patients;

(c) Home health agencies that do not engage in the provision of home medical equipment and services;

(d) Hospitals that provide home medical equipment and services only as an integral part of patient care;

(e) Manufacturers and wholesale distributors of home medical equipment who do not sell, lease, or rent home medical equipment directly to a patient;

(f) Pharmacies that are engaged in the sale, lease, or rental of home medical equipment and services;

(g) An employee of a person licensed under KRS 315.510 to 315.524;

(h) Hospice programs that do not involve the sale, lease, or rental of home medical equipment and services;

(i) Skilled nursing facilities that do not involve the sale, lease, or rental of home medical equipment and services; and

(j) Government agencies, including fire districts which provide emergency medical services.

➡315.516 Legend or order from health care practitioner required

A person licensed under KRS 315.510 to 315.524 shall provide home medical equipment and services that carry a legend or require an order from a licensed health care practitioner.

➡315.518 Application for license; fee; record retention; administrative regulations; confidentiality

(1) A home medical equipment and services provider shall be licensed by the board under KRS 315.510 to 315.524 prior to engaging in providing home medical equipment and services in the Commonwealth. Each license application shall be accompanied by a reasonable fee prescribed by administrative regulation not to exceed two hundred dollars ($200) initially per year or increase more than twenty-five dollars ($25) per year up to a maximum of four hundred dollars ($400). Upon receipt of an application for a license to operate as a home medical equipment and services provider, the board shall issue a license if the provider meets the standards and requirements of this chapter and the administrative regulations of the board.

(2) Home medical equipment and services providers shall be required to maintain adequate records of all home medical equipment and services provided as established by administrative regulation by the board. Records shall be made available to agents of the board for inspection at reasonable times. The board may require by administrative regulation that home medical equipment and services providers periodically report to the board all home medical equipment and services provided.

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

(4) The board shall promulgate an administrative regulation pursuant to KRS Chapter 13A to specify the criteria for licensure.

(5) 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.

➡315.520 Issuance and renewal of licenses; separate license required for each location; display of license; transfer of license prohibited

(1) The board shall refuse to renew any license to operate unless the home medical equipment and services provider meets the standards and requirements of KRS 315.510 to 315.524 and the administrative regulations of the board. The board shall act upon an application for a license within thirty (30) days after the receipt thereof.

(2) A separate license shall be required for each location of a home medical equipment and services provider.

(3) A home medical equipment and services provider shall display its license at its place of business.

(4) Each license as a home medical equipment and services provider, unless sooner suspended or revoked, shall expire on September 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 dollars ($200) initially per year nor to increase more than twenty-five dollars ($25) per year up to a maximum of four hundred dollars ($400). 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 September 30 of each year.

(5) Licenses to operate shall be issued only for the premises and persons named in the application and shall not be transferable.

➡315.522 Reciprocity with bordering states

(1) The board may permit an out-of-state home medical equipment and services provider to obtain a license on the basis of reciprocity if:

(a) The out-of-state provider physically located in one (1) of the bordering states possesses a valid license from another jurisdiction that grants the same privileges to persons licensed by the Commonwealth as the Commonwealth grants to persons licensed by the other jurisdiction;

(b) The requirements for licensure in the bordering state are substantially similar to the requirements under

KRS 315.510 to 315.524; and

(c) The out-of-state provider seeking licensure states that he or she has studied, is familiar with, and shall abide by KRS 315.510 to 315.524 and the administrative regulations promulgated thereunder.

(2) If the requirements for licensure under KRS 315.510 to 315.524 and the administrative regulations promulgated thereunder are more restrictive than the standards of the other jurisdiction, then the out-of-state provider shall comply with the additional requirements of KRS 315.510 to 315.524 to obtain a reciprocal license.

315.524 Providing home medical equipment and services without license; penalty

(1) A person who engages in the business of providing home medical equipment and services and who is required to be licensed under KRS 315.510 to 315.524 and who knowingly provides home medical equipment and services without a license issued under this chapter commits a Class A misdemeanor.

(2) Each day a violation of this section continues constitutes a separate offense.

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.

➡ **315.991 Penalties--Repealed**

END OF DOCUMENT