

1 AN ACT relating to pharmaceutical drug safety and declaring an emergency.

2 ***Be it enacted by the General Assembly of the Commonwealth of Kentucky:***

3 ➔Section 1. KRS 315.010 is amended to read as follows:

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

5 (1) **"Active pharmaceutical ingredient" or "API" means any substance that is**
6 **intended:**

7 **(a) For incorporation into a finished drug product; and**

8 **(b) 1. To furnish pharmacological activity or other direct effect in the**
9 **diagnosis, cure, mitigation, treatment, or prevention of disease; or**

10 **2. To affect the structure or any function of the body;**

11 **(2)** "Administer" means the direct application of a drug to a patient or research subject
12 by injection, inhalation, or ingestion, whether topically or by any other means;

13 **(3)**~~(2)~~ "Administrative activities of a pharmacy" means the following functions
14 performed by a pharmacy adhering to all local, state, and federal patient privacy
15 laws:

16 (a) Investigating and researching a patient's insurance benefits and updating the
17 patient profile regarding insurance coverage;

18 (b) Billing and collections activities, including:

19 1. Contacting patients for copayments and coinsurance payments; and

20 2. Communicating with insurance companies;

21 (c) Performing patient financial assistance activities and updating patient records
22 accordingly;

23 (d) Opening faxes and accessing electronic prescriptions for the purposes of
24 setting up patient demographic and insurance profiles, excluding height,
25 weight, and allergy information, so long as the activity does not involve the
26 entering of a prescription order into the dispensing or medication management
27 system;

- 1 (e) Initiating insurance prior authorizations for submission to the licensed
2 pharmacy, including communications with the prescribing physician to
3 collect, record, and transmit information to insurance companies, so long as
4 the activity does not include the authorization or receipt of new or refill
5 prescription orders;
- 6 (f) Answering and transferring telephone calls, whether or not such calls require
7 accessing a patient record, so long as the call does not involve the
8 interpretation, evaluation, or implementation of a drug order; and
- 9 (g) Communicating with patients via telephone or electronically regarding refill
10 reminders, so long as the communication does not involve the interpretation,
11 evaluation, or implementation of a drug order and a pharmacist is readily
12 available for patient consultation;
- 13 ~~(4)~~~~(3)~~ **"Adulterated" has the same meaning as in 21 U.S.C. sec. 351 and KRS**
14 **217.055;**
- 15 **(5) "Adverse event" means any untoward medical occurrence associated with the use**
16 **of a drug product in humans, whether or not it is considered related to the drug**
17 **product;**
- 18 **(6)** "Association" means the Kentucky Pharmacists Association;
- 19 ~~(7)~~~~(4)~~ "Board" means the Kentucky Board of Pharmacy;
- 20 ~~(8)~~~~(5)~~ **"Chemical" means any substance not otherwise defined in this chapter that**
21 **is a biologically active substance intended to produce a therapeutic effect in the**
22 **body to diagnose, cure, mitigate, treat, or prevent disease;**
- 23 **(9)** "Collaborative care agreement" means a written agreement between a pharmacist or
24 pharmacists and a practitioner or practitioners that outlines a plan of cooperative
25 management of patients' drug-related health care needs where:
- 26 (a) Patients' drug-related health care needs fall within the practitioner's or
27 practitioners' statutory scope of practice;

1 (b) Patients are referred by the practitioner or practitioners to the pharmacist or
2 pharmacists; and

3 (c) The agreement:

4 1. Identifies the practitioner or practitioners and the pharmacist or
5 pharmacists who are parties to the agreement;

6 2. Specifies the drug-related regimen to be provided, and how drug therapy
7 is to be monitored; and

8 3. Stipulates the conditions for initiating, continuing, or discontinuing drug
9 therapy and conditions which warrant modifications to dose, dosage
10 regimen, dosage form, or route of administration;

11 ~~(10)~~~~(6)~~ "Compound" or "compounding":

12 (a) Means the preparation, combining, admixing, diluting, pooling, or
13 reconstituting of one (1) or more drugs, APIs, or chemicals; and

14 (b) Shall not include mixing, reconstituting, or other such acts that are
15 performed in accordance with directions contained in approved labeling
16 provided by the product's manufacturer and other manufacturer directions
17 consistent with that labeling~~[or labeling of a drug pursuant to or in~~

18 ~~anticipation of a valid prescription drug order, including but not limited to~~
19 ~~packaging, intravenous admixture, or manual combination of drug~~
20 ~~ingredients. "Compounding," as used in this chapter, shall not preclude simple~~
21 ~~reconstitution, mixing, or modification of drug products prior to~~
22 ~~administration by nonpharmacists];~~

23 ~~(11)~~~~(7)~~ "Confidential information" means information which is accessed or
24 maintained by a pharmacist in a patient's record, or communicated to a patient as
25 part of patient counseling, whether it is preserved on paper, microfilm, magnetic
26 media, electronic media, or any other form;

27 ~~(12)~~~~(8)~~ "Continuing education unit" means ten (10) contact hours of board approved

1 continuing pharmacy education. A "contact hour" means fifty (50) continuous
2 minutes without a break period;

3 ~~(13)~~⁽⁹⁾ **"Controlled substance" has the same meaning as in KRS 218A.010;**

4 **(14)** "Dispense" or "dispensing" means **the interpretation, evaluation, and**
5 **implementation of a prescription drug order, including the preparation, final**
6 **verification, and delivery of a drug or device to a patient or patient's agent in a**
7 **suitable container appropriately labeled for subsequent administration to, or use**
8 **by, a patient**~~[to deliver one (1) or more doses of a prescription drug in a suitable~~
9 ~~container, appropriately labeled for subsequent administration to or use by a patient~~
10 ~~or other individual entitled to receive the prescription drug];~~

11 ~~(15)~~⁽¹⁰⁾ "Drug" means any of the following:

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

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

- 24 (a) Evaluation of prescription drug orders and patient records for:
- 25 1. Known allergies;
 - 26 2. Rational therapy contraindications;
 - 27 3. Appropriate dose and route of administration;

- 1 4. Appropriate directions for use; or
- 2 5. Duplicative therapies;
- 3 (b) Evaluation of prescription drug orders and patient records for drug-drug,
- 4 drug-food, drug-disease, and drug-clinical laboratory interactions;
- 5 (c) Evaluation of prescription drug orders and patient records for adverse drug
- 6 reactions; or
- 7 (d) Evaluation of prescription drug orders and patient records for proper
- 8 utilization and optimal therapeutic outcomes;

9 ~~(17)~~~~(12)~~ "Immediate supervision" means under the physical and visual supervision of a

10 pharmacist;

11 ~~(18)~~~~(13)~~ **"Investigational drug" means a new drug or biologic that meets the criteria**

12 **for investigational use as set forth in KRS 217.075 and has not been approved for**

13 **general use by the United States Food and Drug Administration;**

14 ~~(19)~~ "Manufacturer" or "virtual manufacturer" of a product means:

- 15 (a) A person that holds an application approved under 21 U.S.C. sec. 355 or a
- 16 license issued under 42 U.S.C. sec. 262 for such product, or if such product is
- 17 not the subject of an approved application or license, the person who
- 18 manufactured the product;
- 19 (b) A co-licensed partner of the person described in paragraph (a) of this
- 20 subsection that obtains the product directly from a person described in this
- 21 paragraph or paragraph (a) of this subsection;
- 22 (c) An affiliate of a person described in paragraph (a) or (b) of this subsection
- 23 who receives the product directly from a person described in this paragraph or
- 24 in paragraph (a) or (b) of this subsection; or
- 25 (d) ~~[Any person,]~~ Except a **practitioner**~~[pharmacist]~~ compounding in the normal
- 26 course of professional practice, **any person within the Commonwealth**
- 27 **engaged in the production, preparation, propagation, compounding,**

1 conversion, or processing of a drug, either directly or indirectly, by
2 extraction from substances of natural origin or independently by means of
3 chemical synthesis, or both, and includes any packaging or repackaging of
4 a drug or the labeling or relabeling of its container;

5 ~~(20)~~~~(14)~~ "Medical order" means a lawful order of a specifically identified practitioner
6 for a specifically identified patient for the patient's health care needs. "Medical
7 order" may or may not include a prescription drug order;

8 ~~(21)~~~~(15)~~ "Misbranded" has the same meaning as in 21 U.S.C. sec. 352 and KRS
9 217.065;

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

14 ~~(23)~~~~(16)~~ "Outsourcing facility" means a facility at one (1) geographic location or
15 address that:

16 (a) Is engaged in the compounding of human sterile drugs without a patient-
17 specific prescription;

18 (b) Has registered as an outsourcing facility with the secretary of the United
19 States Department of Health and Human Services, Food and Drug
20 Administration; and

21 (c) Complies with all applicable state and federal requirements;

22 ~~(24)~~~~(17)~~ "Person" has the same meaning as in KRS 217.015;

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

25 ~~(26)~~~~(18)~~ "Pharmacist intern" means a natural person who is:

26 (a) Currently certified by the board to engage in the practice of pharmacy under
27 the direction of a licensed pharmacist and who satisfactorily progresses

1 toward meeting the requirements for licensure as a pharmacist;

2 (b) A graduate of an approved college or school of pharmacy or a graduate who
3 has established educational equivalency by obtaining a Foreign Pharmacy
4 Graduate Examination Committee (FPGEC) certificate, who is currently
5 licensed by the board for the purpose of obtaining practical experience as a
6 requirement for licensure as a pharmacist;

7 (c) A qualified applicant awaiting examination for licensure as a pharmacist or
8 the results of an examination for licensure as a pharmacist; or

9 (d) An individual participating in a residency or fellowship program approved by
10 the board for internship credit;

11 ~~(27)~~~~(19)~~ "Pharmacy" means every place where:

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

13 (b) Prescription drug orders are compounded under the direction of a pharmacist;
14 or

15 (c) A registered pharmacist maintains patient records and other information for
16 the purpose of engaging in the practice of pharmacy, whether or not
17 prescription drug orders are being dispensed;

18 ~~(28)~~~~(20)~~ "Pharmacy-related primary care" means the pharmacists' activities in patient
19 education, health promotion, and assistance in the selection and use of over-the-
20 counter drugs and appliances for the treatment of common diseases and injuries, as
21 well as those other activities falling within their statutory scope of practice;

22 ~~(29)~~~~(21)~~ "Pharmacy technician" means a natural person who works under the
23 immediate supervision, or general supervision if otherwise provided for by statute
24 or administrative regulation, of a pharmacist for the purpose of assisting a
25 pharmacist with the practice of pharmacy;

26 ~~(30)~~~~(22)~~ "Practice of pharmacy" means interpretation, evaluation, and implementation
27 of medical orders and prescription drug orders; responsibility for dispensing

1 prescription drug orders, including radioactive substances; participation in drug and
2 drug-related device selection; administration of medications or biologics in the
3 course of dispensing or maintaining a prescription drug order; the administration of
4 adult immunizations pursuant to prescriber-approved protocols; the administration
5 of immunizations to individuals five (5) to seventeen (17) years of age pursuant to
6 prescriber-approved protocols with the consent of a parent or guardian; the
7 administration of immunizations to a child as defined in KRS 214.032, pursuant to
8 protocols as authorized by KRS 315.500; drug evaluation, utilization, or regimen
9 review; maintenance of patient pharmacy records; and provision of patient
10 counseling and those professional acts, professional decisions, or professional
11 services necessary to maintain and manage all areas of a patient's pharmacy-related
12 care, including pharmacy-related primary care as defined in this section;

13 ~~(31)~~~~(23)~~ "Practitioner" has the same meaning as in KRS 217.015 and 218A.010, and
14 includes a pharmacist~~given in KRS 217.015(35)~~;

15 ~~(32)~~~~(24)~~ "Prescription drug" means a drug which:

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

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

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

26 (c) Is intended for administration by injection into the human body other than
27 through a natural orifice of the human body;

1 (d) Is a biological product as defined in 42 U.S.C. sec. 262;

2 (e) Is an API; or

3 (f) Is an investigational drug;

4 (33)[(25)] "Prescription drug order" means an original or new order from a practitioner
5 for drugs, drug-related devices or treatment for a human or animal, including orders
6 issued through collaborative care agreements or protocols authorized by the board.
7 Lawful prescriptions result from a valid practitioner-patient relationship, are
8 intended to address a legitimate medical need, and fall within the prescribing
9 practitioner's scope of professional practice;

10 (34)[(26)] "Responsible practitioner" means a licensed practitioner:

11 (a) With the independent authority to procure, prescribe, dispense, or
12 administer prescription drugs and devices; and

13 (b) Who is responsible for supervising the operations of a terminal distributor
14 of prescription drugs;

15 (35) "Sale" or "sell" includes any transaction or offer made by any person, as
16 principal proprietor, agent, or employee to:

17 (a) Deliver;

18 (b) Distribute;

19 (c) Broker;

20 (d) Exchange;

21 (e) Gift or otherwise give away; or

22 (f) Transfer by passage of title, physical movement, or both;

23 (36) "Serious adverse event" means an adverse event that results in one (1) or more of
24 the following:

25 (a) Death;

26 (b) A life-threatening adverse event;

27 (c) Inpatient hospitalization or prolongation of existing hospitalization;

1 (d) A persistent or significant incapacity or substantial disruption of the ability
 2 to conduct normal life functions; or

3 (e) A congenital anomaly or birth defect;

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

5 (38)~~(27)~~ "Supervision" means the presence of a pharmacist on the premises to which a
 6 pharmacy permit is issued, who is responsible, in whole or in part, for the
 7 professional activities occurring in the pharmacy;~~and~~

8 (39)~~(28)~~ "Terminal distributor of prescription drugs" or "terminal distributor":

9 (a) Means a person that:

10 1. Has possession, custody, or control of prescription drugs for any
 11 purpose other than for personal use and consumption; and

12 2. Procures prescription drugs for sale, administration, compounding, or
 13 dispensing by or under the supervision of a pharmacist or licensed
 14 practitioner authorized to prescribe drugs; and

15 (b) Shall not include a manufacturer, repackager, outsourcing facility, third-
 16 party logistics provider, wholesale distributor, pharmacy, or pharmacist;

17 (40) "United States Pharmacopeia" or "USP" means the independent, nonprofit,
 18 scientific organization that establishes public standards for the quality, purity,
 19 strength, and consistency of medicines, food ingredients, and dietary
 20 supplements; and

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

23 ➔Section 2. KRS 315.020 is amended to read as follows:

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

1 a pharmacist.

2 (2) *A terminal distributor shall designate a responsible practitioner to serve for each*
3 *permitted location who shall along with the terminal distributor, accept*
4 *responsibility for and supervision of the operation of the permitted location in*
5 *accordance with all applicable state and federal laws. The board shall promulgate*
6 *administrative regulations in accordance with KRS Chapter 13A to establish*
7 *criteria for a responsible practitioner.*

8 (3) ~~A~~~~No~~ manufacturer of pharmaceuticals who is not a pharmacist shall ~~fail to~~ place
9 a pharmacist in charge of his or her place of business ~~and~~~~or~~ shall **not** permit any
10 person to compound prescription drugs, medicines, or pharmaceuticals in his or her
11 place of business, except as provided by the board through the promulgation of
12 administrative regulations *in accordance with*~~pursuant to~~ KRS Chapter 13A.

13 ~~(4)~~~~(3)~~ Except as provided in subsection ~~(5)~~~~(4)~~ of this section, ~~a~~~~no~~ person shall
14 **not** engage in the practice of pharmacy unless licensed to practice under the
15 provisions of KRS Chapter 315.

16 ~~(5)~~~~(4)~~ The provisions of subsection ~~(4)~~~~(3)~~ of this section shall not apply to:

- 17 (a) Pharmacist interns performing professional practice activities under the
18 immediate supervision of a licensed pharmacist. The nature and scope of the
19 activities referred to in this paragraph shall be determined by the board
20 through administrative regulation promulgated pursuant to KRS Chapter 13A;
- 21 (b) Pharmacist interns and pharmacy technicians performing specifically
22 identified pharmacy practice activities while under the supervision of a
23 pharmacist. The nature and scope of the activities referred to in this paragraph
24 shall be determined by the board through administrative regulation
25 promulgated *in accordance with*~~pursuant to~~ KRS Chapter 13A;
- 26 (c) Other licensed health care professionals practicing within the statutory scope
27 of their professional practices; or

1 (d) Volunteer health practitioners providing services under KRS 39A.350 to
2 39A.366.

3 ~~(6)~~[(5)] (a) As used in this subsection:

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

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

- 19 1. The pharmacy has established controls to protect the confidentiality and
20 integrity of protected health information;
21 2. No part of the pharmacy's database is duplicated, downloaded, or
22 removed from the electronic database; and
23 3. The pharmacy is located in Kentucky and is permitted by the board.

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

26 (d) This subsection shall only apply to:

- 27 1. Pharmacies that are not open to the public and do not dispense to walk-

1 in patients in a retail setting; or

2 2. Hospitals licensed under KRS Chapter 216B.

3 (e) Nothing in this subsection shall be construed to authorize final product
4 verification and dispensing of a prescription from a location outside of or
5 other than a pharmacy.

6 (f) Nothing in this subsection permits pharmacists, pharmacy technicians, or
7 pharmacy interns to receive hard copy prescriptions outside of the premises of
8 a permitted pharmacy.

9 ~~(7)(6)~~ ~~[Effective April 1, 2009,]~~ An owner of a pharmacy shall not employ a person
10 to assist in the practice of pharmacy unless the person is registered as a pharmacy
11 technician by the board or exempt under KRS 315.135.

12 **(8) The board may enter into agreements with other states, federal agencies, and**
13 **other entities to exchange information concerning the permitting and inspection**
14 **of pharmacies and terminal distributors located within or outside of Kentucky**
15 **and to investigate alleged violations of the laws governing the distribution of**
16 **drugs. Any information received pursuant to the agreements is subject to the**
17 **same confidentiality requirements applicable to the agency or entity from which it**
18 **was received and shall not be released without prior authorization from that**
19 **agency or entity.**

20 ➔Section 3. KRS 315.035 is amended to read as follows:

21 (1) ~~A~~~~No~~ person shall **not** operate a pharmacy within this Commonwealth, physically
22 or by means of the internet, facsimile, phone, mail, or any other means, without
23 having first obtained a permit as provided for in KRS Chapter 315. An application
24 for a permit to operate a pharmacy shall be made to the board upon forms provided
25 by it and shall contain such information as the board requires, which may include
26 affirmative evidence of ability to comply with such reasonable standards and rules
27 and regulations as may be prescribed by the board. Each application shall be

1 accompanied by a reasonable permit fee to be set by administrative regulation
 2 promulgated by the board in accordance with~~[pursuant]~~ to KRS Chapter 13A, not
 3 to exceed two hundred fifty dollars (\$250).

4 (2) (a) Upon receipt of an application of a permit to operate a pharmacy,
 5 accompanied by the permit fee not to exceed two hundred fifty dollars (\$250),
 6 the board shall issue a permit if the pharmacy meets the standards and
 7 requirements of KRS Chapter 315 and the rules and administrative
 8 regulations of the board.

9 (b) The board shall refuse to renew any permit to operate unless the pharmacy
 10 meets the standards and requirements of KRS Chapter 315 and administrative
 11 regulations promulgated by the board in accordance with KRS Chapter
 12 13A~~[the rules and regulations of the board]~~.

13 (c) The board shall act upon an application for a permit to operate within thirty
 14 (30) days after the receipt thereof; provided, however, that the board may
 15 issue a temporary permit to operate in any instance where it considers
 16 additional time necessary for investigation and consideration before taking
 17 final action upon the application. In such event, the temporary permit shall be
 18 valid for a period of thirty (30) days, unless extended.

19 (3) In the review of an application for a permit for a pharmacy, the board may
 20 consider any previous:

21 (a) Compliance of the applicant and any affiliated persons or entities, including
 22 any entity under common ownership or control with the applicant; and

23 (b) Permit violations committed by any entity under common ownership or
 24 control with the applicant, or by any person who substantially participates
 25 in the ownership, management, or control of the applicant.

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

27 (5)~~(4)~~ Each permit to operate a pharmacy, unless sooner suspended or revoked, shall

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

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

13 ~~(7)~~⁽⁶⁾ The board may promulgate administrative~~[rules and]~~ regulations in
14 accordance with KRS Chapter 13A to ensure~~[assure]~~ that proper equipment and
15 reference material is on hand considering the nature of the pharmaceutical practice
16 conducted at the particular pharmacy and to ensure~~[assure]~~ reasonable health and
17 sanitation standards for areas within pharmacies which are not subject to health and
18 sanitation standards ~~of promulgated by~~ the Kentucky Cabinet for Health and
19 Family Services or a local health department.

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

21 ~~(9)~~⁽⁸⁾ Any pharmacy within the Commonwealth that dispenses more than twenty-
22 five percent (25%) of its total prescription volume as a result of an original
23 prescription order received or solicited by use of the internet, including but not
24 limited to electronic mail, shall, prior to obtaining a permit, obtain~~[receive and~~
25 ~~display in every medium in which it advertises itself a seal of]~~ approval for the
26 National Association of Boards of Pharmacy (NABP) Digital Pharmacy
27 Accreditation Program~~[certifying that it is a Verified Internet Pharmacy Practice~~

1 Site (~~VIPPS~~) or ~~[a seal certifying approval of]~~ a substantially similar program
2 approved by the Kentucky Board of Pharmacy. **The NABP Digital Pharmacy**
3 **Accreditation Program**~~[VIPPS]~~, or any other substantially similar program
4 approved by the Kentucky Board of Pharmacy, accreditation shall be maintained
5 and remain current.

6 ~~(10)~~~~(9)~~ Any pharmacy within the Commonwealth doing business by use of the
7 internet shall certify the percentage of its annual business conducted via the internet
8 and submit such supporting documentation as requested by the board, and in a form
9 or application required by the board, when it applies for permit or renewal.

10 ~~(11)~~~~(10)~~ A pharmacist may temporarily operate a pharmacy in an area not designated
11 on the permit as authorized in KRS 315.500.

12 ➔Section 4. KRS 315.0351 is amended to read as follows:

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

14 (a) Every person or pharmacy located outside this Commonwealth which does
15 business, physically or by means of the internet, facsimile, phone, mail, or any
16 other means, inside this Commonwealth within the meaning of KRS Chapter
17 315, shall hold a current pharmacy permit as provided in KRS 315.035(1) and
18 ~~(5)~~~~(4)~~ issued by the Kentucky Board of Pharmacy. The pharmacy shall be
19 designated an "out-of-state pharmacy" and the permit shall be designated an
20 "out-of-state pharmacy permit." The fee for the permit shall not exceed the
21 current in-state pharmacy permit fee as provided under KRS 315.035;

22 (b) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the
23 board shall disclose to the board the location, names, and titles of all principal
24 corporate officers and all pharmacists who are dispensing prescription drugs
25 to residents of the Commonwealth. A report containing this information shall
26 be made to the board on an annual basis and within thirty (30) days after any
27 change of office, corporate officer, or pharmacist;

- 1 (c) Every out-of-state pharmacy granted an out-of-state pharmacy permit shall
2 comply with all statutorily-authorized directions and requests for information
3 from any regulatory agency of the Commonwealth and from the board in
4 accordance with the provisions of this section. The out-of-state pharmacy
5 shall maintain at all times a valid unexpired permit, license, or registration to
6 conduct the pharmacy in compliance with the laws of the jurisdiction in which
7 it is a resident. As a prerequisite to seeking a permit from the Kentucky Board
8 of Pharmacy, the out-of-state pharmacy shall submit a copy of the most recent
9 inspection report resulting from an inspection conducted by the regulatory or
10 licensing agency of the jurisdiction in which it is located. Thereafter, the out-
11 of-state pharmacy granted a permit shall submit to the Kentucky Board of
12 Pharmacy a copy of any subsequent inspection report on the pharmacy
13 conducted by the regulatory or licensing body of the jurisdiction in which it is
14 located;
- 15 (d) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the
16 board shall maintain records of any controlled substances or dangerous drugs
17 or devices dispensed to patients in the Commonwealth so that the records are
18 readily retrievable from the records of other drugs dispensed;
- 19 (e) Records for all prescriptions delivered into Kentucky shall be readily
20 retrievable from the other prescription records of the out-of-state pharmacy;
- 21 (f) Each out-of-state pharmacy shall, during its regular hours of operation, but
22 not less than six (6) days per week and for a minimum of forty (40) hours per
23 week, provide a toll-free telephone service directly to the pharmacist in charge
24 of the out-of-state pharmacy and available to both the patient and each
25 licensed and practicing in-state pharmacist for the purpose of facilitating
26 communication between the patient and the Kentucky pharmacist with access
27 to the patient's prescription records. A toll-free number shall be placed on a

- 1 label affixed to each container of drugs dispensed to patients within the
2 Commonwealth;
- 3 (g) Each out-of-state pharmacy shall have a pharmacist in charge who is licensed
4 to engage in the practice of pharmacy by the Commonwealth that shall be
5 responsible for compliance by the pharmacy with the provisions of this
6 section and for the distribution and sale of dialysate solutions and devices
7 pursuant to subsection (2) of this section;
- 8 (h) Each out-of-state pharmacy shall comply with KRS 218A.202;
- 9 (i) Any out-of-state pharmacy that dispenses more than twenty-five percent
10 (25%) of its total prescription volume as a result of an original prescription
11 order received or solicited by use of the internet, including but not limited to
12 electronic mail, shall obtain~~receive and display in every medium in which it~~
13 ~~advertises itself a seal of~~ approval for the National Association of Boards of
14 Pharmacy (***NABP Digital Pharmacy Accreditation Program***)~~certifying that~~
15 ~~it is a Verified Internet Pharmacy Practice Site (VIPPS)}~~ or ~~[a seal certifying~~
16 ~~approval of~~ a substantially similar program approved by the Kentucky Board
17 of Pharmacy. ***The NABP Digital Pharmacy Accreditation***~~[VIPPS]~~, or any
18 other substantially similar accreditation, shall be maintained and remain
19 current;
- 20 (j) Any out-of-state pharmacy doing business in the Commonwealth of Kentucky
21 shall certify the percentage of its annual business conducted via the internet
22 and electronic mail and submit such supporting documentation as requested
23 by the board, and in a form or application required by the board, when it
24 applies for permit or renewal;
- 25 (k) Any pharmacy doing business within the Commonwealth of Kentucky shall
26 use the address on file with the Kentucky Board of Pharmacy as the return
27 address on the labels of any package shipped into or within the

1 Commonwealth. The return address shall be placed on the package in a clear
2 and prominent manner;~~and~~

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

6 (m) In the review of an application for a permit for an out-of-state pharmacy,
7 the board may consider any previous permit:

8 1. Compliance of the applicant and any affiliated persons or entities,
9 including any entity under common ownership or control with the
10 applicant; and

11 2. Violations committed by any entity under common ownership or
12 control with the applicant, or by any person who substantially
13 participates in the ownership, management, or control of the
14 applicant.

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

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

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

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

27 4. The dialysate solutions or devices are only delivered upon receipt of a

- 1 physician's prescription by a Kentucky licensed pharmacy and the
2 transmittal of an order from the Kentucky licensed pharmacy to the
3 manufacturer or manufacturer's agent; and
- 4 5. The manufacturer or manufacturer's agent delivers the dialysate
5 solutions or devices directly to:
- 6 a. A patient with end-stage renal disease or the patient's designee for
7 the patient's self-administration of dialysis therapy; or
8 b. A health-care provider or institution for administration or delivery
9 of dialysis therapy to a patient with end-stage renal disease.
- 10 (b) 1. A manufacturer or manufacturer's agent who sells or distributes
11 dialysate solutions or devices under this subsection shall employ or
12 contract with a pharmacist who is licensed to engage in the practice of
13 pharmacy by the Commonwealth to conduct a retrospective audit on ten
14 percent (10%) of the orders processed by that manufacturer or
15 manufacturer's agent each month.
- 16 2. On or before February 1 of each year, an annual summary of the
17 monthly audits shall be prepared and submitted to the board, in the form
18 prescribed by the board.
- 19 3. On or before June 1 of each year, the board shall compile the summaries
20 of monthly audits into a single report and submit that report to the
21 Interim Joint Committee on Health Services.
- 22 (c) Prescriptions and records of delivery for dialysate solutions or devices sold or
23 distributed under this subsection shall be maintained by the manufacturer or
24 manufacturer's agent for a minimum of two (2) years and shall be made
25 available to the board upon request.
- 26 (d) As used in this subsection, "dialysate solutions" means dextrose or icodextrin
27 when used to perform home peritoneal kidney dialysis.

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

3 ➔Section 5. KRS 315.121 is amended to read as follows:

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

8 (a) Unprofessional or unethical conduct;

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

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

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

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

20 (d) Knowing or having reason to know that a pharmacist, pharmacist intern, or
21 pharmacy technician is incapable of engaging or assisting in the practice of
22 pharmacy with reasonable skill, competence, and safety to the public and
23 failing to report any relevant information to the board;

24 (e) Knowingly making or causing to be made any false, fraudulent, or forged
25 statement or misrepresentation of a material fact in securing issuance or
26 renewal of a license, permit, or certificate;

27 (f) Engaging in fraud in connection with the practice of pharmacy or the

- 1 wholesale distribution or manufacturing of drugs;
- 2 (g) Engaging in or aiding and abetting an individual to engage or assist in the
3 practice of pharmacy without a license or falsely using the title of
4 "pharmacist," "pharmacist intern," "pharmacy technician," or other term
5 which might imply that the individual is a pharmacist, pharmacist intern, or
6 pharmacy technician;
- 7 (h) Being found by the board to be in violation of any provision of this chapter,
8 KRS Chapter 217, KRS Chapter 218A, or the administrative regulations
9 promulgated pursuant to these chapters;
- 10 (i) Violation of any order issued by the board to comply with any applicable law
11 or administrative regulation;
- 12 (j) Knowing or having reason to know that a person, pharmacist, pharmacist
13 intern, or pharmacy technician has engaged in or aided and abetted the
14 unlawful distribution of legend medications, and failing to report any relevant
15 information to the board;
- 16 (k) Failure to notify the board within fourteen (14) days of a change in one's
17 home address; or
- 18 (l) As provided in KRS 311.824(2), being convicted of a violation of KRS
19 311.823(2).
- 20 (2) Unprofessional or unethical conduct includes but is not limited to the following acts
21 of a pharmacist, pharmacist intern, or pharmacy technician:
- 22 (a) Publication or circulation of false, misleading, or deceptive statements
23 concerning the practice of pharmacy;
- 24 (b) Divulging or revealing to unauthorized persons patient information or the
25 nature of professional services rendered without the patient's express consent
26 or without order or direction of a court. In addition to members, inspectors, or
27 agents of the board, the following are considered authorized persons:

- 1 1. The patient, patient's agent, or another pharmacist acting on behalf of
- 2 the patient;
- 3 2. Certified or licensed health-care personnel who are responsible for care
- 4 of the patient;
- 5 3. Designated agents of the Cabinet for Health and Family Services for the
- 6 purposes of enforcing the provisions of KRS Chapter 218A;
- 7 4. Any federal, state, or municipal officer whose duty is to enforce the laws
- 8 of this state or the United States relating to drugs and who is engaged in
- 9 a specific investigation involving a designated person; or
- 10 5. An agency of government charged with the responsibility of providing
- 11 medical care for the patient, upon written request by an authorized
- 12 representative of the agency requesting such information;
- 13 (c) Selling, transferring, or otherwise disposing of accessories, chemicals, drugs,
- 14 or devices found in illegal traffic when the pharmacist, pharmacy intern, or
- 15 pharmacy technician knows or should have known of their intended use in
- 16 illegal activities;
- 17 (d) Engaging in conduct likely to deceive, defraud, or harm the public,
- 18 demonstrating a willful or careless disregard for the health, welfare, or safety
- 19 of a patient, or engaging in conduct which substantially departs from accepted
- 20 standards of pharmacy practice ordinarily exercised by a pharmacist or
- 21 pharmacy intern, with or without established proof of actual injury;
- 22 (e) Engaging in grossly negligent professional conduct, with or without
- 23 established proof of actual injury;
- 24 (f) Except as provided in KRS 315.500, selling, transferring, dispensing,
- 25 ingesting, or administering a drug for which a prescription drug order is
- 26 required, without having first received a prescription drug order for the drug;
- 27 (g) Willfully or knowingly failing to maintain complete and accurate records of

- 1 all drugs received, dispensed, or disposed of in compliance with federal and
2 state laws, rules, or administrative regulations;
- 3 (h) Obtaining any remuneration by fraud, misrepresentation, or deception;
- 4 (i) Accessing or attempting to access confidential patient information for persons
5 other than those with whom a pharmacist has a current pharmacist-patient
6 relationship and where such information is necessary to the pharmacist to
7 provide pharmacy care;
- 8 (j) Failing to exercise appropriate professional judgment in determining whether
9 a prescription drug order is lawful;
- 10 (k) Violating KRS 304.39-215; or
- 11 (l) Engaging in conduct that is subject to the penalties under KRS 304.99-060(4)
12 or (5).
- 13 (3) Any licensee, permit holder, or certificate holder entering an "Alford" plea,
14 pleading nolo contendere, or who is found guilty of a violation prescribed in
15 subsection (1)(c) of this section shall within thirty (30) days notify the board of that
16 plea or conviction. Failure to do so shall be grounds for suspension or revocation of
17 the license, certificate, or permit.
- 18 (4) Any person whose license, permit, or certificate has been revoked in accordance
19 with the provisions of this section, may petition the board for reinstatement. The
20 petition shall be made in writing and in a form prescribed by the board. The board
21 shall investigate all reinstatement petitions, and the board may reinstate a license,
22 permit, or certificate upon showing that the former holder has been rehabilitated
23 and is again able to engage in the practice of pharmacy with reasonable skill,
24 competency, and safety to the public. Reinstatement may be on the terms and
25 conditions that the board, based on competent evidence, reasonably believes
26 necessary to protect the health and welfare of the citizens of the Commonwealth.
- 27 (5) Upon exercising the power of revocation provided for in subsection (1) of this

1 section, the board may reasonably prohibit any petition for reinstatement for a
2 period up to and including five (5) years.

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

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

12 (b) No person may have his or her record expunged under this section more than
13 once.

14 The board shall promulgate administrative regulations under KRS Chapter 13A to
15 establish violations which are minor violations under this subsection. A violation
16 shall be deemed a minor violation if it does not demonstrate a serious inability to
17 practice the profession; assist in the practice of pharmacy; provide home medical
18 equipment and services; adversely affect the public health, safety, or welfare; or
19 result in economic or physical harm to a person; or create a significant threat of
20 such harm.

21 **(7) The board shall retain jurisdiction to investigate and to take disciplinary action**
22 **for acts or omissions committed while a person was licensed, permitted, or**
23 **certified by the board, notwithstanding the surrender, expiration, lapse, or**
24 **nonrenewal of the person's license, permit, or certification. Surrender,**
25 **expiration, lapse, or nonrenewal of a license, permit, or certification shall not**
26 **deprive the board of authority to enter findings of fact and conclusions of law,**
27 **impose discipline relating to the prior license, permit, or certification, or deny,**

1 *condition, restrict, or limit any future application for licensure, permitting, or*
2 *certification.*

3 ➔Section 6. KRS 315.131 is amended to read as follows:

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

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

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

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

20 (5) A licensee, permit holder, or certificate holder aggrieved by a final order of the
21 board may appeal to the Franklin Circuit Court in accordance with KRS Chapter
22 13B.

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

27 1.[(a)] Has violated a statute or administrative regulation the board is

1 empowered to enforce, and continued practice or operation by the
 2 licensee, certificate holder, or permit holder would create imminent risk
 3 of harm to the public; or

4 ~~2.1(b)~~ Suffers a mental or physical condition that through continued
 5 practice or operation could create an imminent risk of harm to the
 6 public.

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

13 **(c)** **The board may extend the temporary emergency suspension for one (1) or**
 14 **more additional periods not to exceed sixty (60) days provided that the:**

15 **1. Board has initiated proceedings under KRS Chapter 13B;**

16 **2. Board finds in writing that the immediate danger continues to exist;**

17 **and**

18 **3. Extension is not attributable to actions of the board.**

19 **(d)** **A temporary suspension shall not exceed more than one hundred eighty**
 20 **(180) days absent a final order.**

21 ➔Section 7. KRS 315.191 is amended to read as follows:

22 (1) The board is authorized to:

23 (a) Promulgate administrative regulations pursuant to KRS Chapter 13A
 24 necessary to regulate and control all matters set forth in this chapter relating to
 25 pharmacists, pharmacist interns, pharmacy technicians, pharmacies, **terminal**
 26 **distributors**, wholesale distributors, and manufacturers, to the extent that
 27 regulation and control of same have not been delegated to some other agency

1 of the Commonwealth, but administrative regulations relating to drugs shall
 2 be limited to the regulation and control of drugs procured, dispensed,
 3 compounded, or administered by licensed practitioners~~[sold pursuant to a~~
 4 ~~prescription drug order]~~. This chapter shall not be construed to authorize the
 5 board to promulgate administrative regulations relating to:

6 1. The practice of medicine, nursing, or any other profession or
 7 occupation licensed or regulated by another board or agency of the
 8 Commonwealth; or

9 2. [However,] Except as provided in KRS 315.038 and Section 9 of this
 10 Act, [nothing contained in this chapter shall be construed as authorizing
 11 the board to promulgate any administrative regulations relating to
 12 prices or fees or to advertising or the promotion of the sales or use of
 13 commodities or services;

14 (b) Issue subpoenas, schedule and conduct hearings, or appoint hearing officers to
 15 schedule and conduct hearings on behalf of the board on any matter under the
 16 jurisdiction of the board;

17 (c) Prescribe the time, place, method, manner, scope, and subjects of
 18 examinations, with at least two (2) examinations to be held annually;

19 (d) Issue and renew all licenses, certificates, and permits for all pharmacists,
 20 pharmacist interns, pharmacies, pharmacy technicians, terminal distributors,
 21 wholesale distributors, and manufacturers engaged in the manufacture,
 22 distribution, or dispensation of drugs;

23 (e) Investigate all complaints or violations of the state pharmacy and drug laws
 24 and the administrative regulations promulgated by the board, and bring all
 25 these cases to the notice of the proper law enforcement authorities;

26 (f) Promulgate administrative regulations in accordance with~~[, pursuant to]~~ KRS
 27 Chapter 13A~~[,]~~ that are necessary and to control the storage, retrieval,

- 1 dispensing, refilling, and transfer of prescription drug orders within and
2 between pharmacists and pharmacies licensed or issued a permit by it;
- 3 (g) Perform all other functions necessary to carry out the provisions of law and
4 the administrative regulations promulgated by the board relating to
5 pharmacists, pharmacist interns, pharmacy technicians, pharmacies, **terminal**
6 **distributors**, wholesale distributors, and manufacturers;
- 7 (h) Establish or approve programs for training, qualifications, and registration of
8 pharmacist interns;
- 9 (i) Assess reasonable fees, in addition to the fees specifically provided for in this
10 chapter and consistent with KRS 61.870 to 61.884, for services rendered to
11 perform its duties and responsibilities, including, but not limited to, the
12 following:
- 13 1. Issuance of duplicate certificates;
- 14 2. Mailing lists or reports of data maintained by the board;
- 15 3. Copies of documents; or
- 16 4. Notices of meetings;
- 17 (j) Seize any **drugs, chemicals, or devices**~~[drug or device]~~ found by the board to
18 constitute an imminent danger to public health and welfare;
- 19 (k) 1. Establish an advisory council to advise the board on statutes,
20 administrative regulations, and other matters within the discretion of the
21 board pertinent to the practice of pharmacy and regulation of
22 pharmacists, pharmacist interns, pharmacy technicians, pharmacies,
23 **terminal distributors, wholesale distributors, and manufacturers**~~[drug~~
24 ~~distribution, and drug manufacturing]~~. The council shall provide
25 recommendations for updating policies and procedures, including
26 administrative regulations relating to the practice of pharmacy.
- 27 2. The council shall consist of nine (9) pharmacists broadly representative

- 1 of the profession of pharmacy. For purposes of this subparagraph,
2 "broadly representative" means the following:
- 3 a. Two (2) pharmacists appointed by the Kentucky Pharmacists
4 Association;
 - 5 b. Two (2) pharmacists appointed by the Kentucky Independent
6 Pharmacy Alliance;
 - 7 c. One (1) pharmacist who practices or specializes primarily in a mail
8 order pharmacy appointed by the Kentucky Pharmacists
9 Association;
 - 10 d. One (1) pharmacist who practices or specializes primarily in a
11 long-term care pharmacy appointed by Kentucky Association of
12 Health Care Facilities;
 - 13 e. One (1) pharmacist who practices or specializes primarily in a
14 veterinary pharmacy appointed by the Kentucky Pharmacists
15 Association;
 - 16 f. One (1) pharmacist who practices or specializes primarily in a
17 hospital pharmacy appointed by the Kentucky Society of Health-
18 System Pharmacists; and
 - 19 g. One (1) pharmacist who practices in a specialized pharmacy that
20 solely or mostly provides medication to persons living with serious
21 health conditions requiring complex therapies, appointed by the
22 Kentucky Pharmacists Association.
- 23 3. Each pharmacist member shall be licensed by the board, a resident of
24 Kentucky, and employed for at least two (2) consecutive years in the
25 practice area he or she represents.
- 26 4. Members shall serve terms of up to four (4) years and may serve two (2)
27 consecutive terms, but shall not serve on the council for more than two

- 1 (2) consecutive terms. Members may continue to serve until their
2 successors are appointed.
- 3 5. Members shall be confirmed by roll call vote of the board at a meeting
4 conducted in accordance with the Open Meetings Act, KRS 61.805 to
5 61.850; and
- 6 (l) Promulgate administrative regulations *in accordance with KRS Chapter 13A*
7 establishing the qualifications that pharmacy technicians are required to attain
8 prior to engaging in pharmacy practice activities outside the immediate
9 supervision of a pharmacist.
- 10 (2) The board shall have other authority as may be necessary to enforce pharmacy laws
11 and administrative regulations of the board including, but not limited to:
- 12 (a) Joining or participating in professional organizations and associations
13 organized exclusively to promote improvement of the standards of practice of
14 pharmacy for the protection of public health and welfare or facilitate the
15 activities of the board; and
- 16 (b) Receiving and expending funds, in addition to its biennial appropriation,
17 received from parties other than the state, if:
- 18 1. The funds are awarded for the pursuit of a specific objective which the
19 board is authorized to enforce through this chapter, or which the board is
20 qualified to pursue by reason of its jurisdiction or professional expertise;
- 21 2. The funds are expended for the objective for which they were awarded;
- 22 3. The activities connected with or occasioned by the expenditure of the
23 funds do not interfere with the performance of the board's
24 responsibilities and do not conflict with the exercise of its statutory
25 powers;
- 26 4. The funds are kept in a separate account and not commingled with funds
27 received from the state; and

1 5. Periodic accountings of the funds are maintained at the board office for
2 inspection or review.

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

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

11 ➔Section 8. KRS 315.220 is amended to read as follows:

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

14 (a) Administer oaths;

15 (b) Enter ~~the~~^{upon} premises of all facilities issued a permit or license by the
16 board **and any facility suspected of operating as a pharmacy, terminal**
17 **distributor, wholesaler, or manufacturer**, at all reasonable times for the
18 purpose of:

19 1. Making inspections and carrying out the provisions of this chapter.

20 **Inspections:**

21 **a. Shall include areas of the facility where drugs or any other**
22 **chemicals are received, stored, compounded, or prepared for**
23 **dispensing or administration;**

24 **b. May include a review of records, including but not limited to**
25 **ownership information, invoices, purchase orders, certificates of**
26 **analysis, transaction information, compounding logs, medical**
27 **charts, prescription orders, or dispensing and administration**

- 1 information; and
- 2 c. If the pharmacy, terminal distributor, or manufacturer is
- 3 engaged in compounding, shall evaluate compliance with the
- 4 most current published version of the USP;
- 5 2. Conducting investigations;
- 6 3. Requiring production of books, papers, documents, records, or other
- 7 evidence for inspection or copying;
- 8 4. Seizing evidence;~~[or]~~
- 9 5. Seizing and quarantining drugs or any other chemicals if there is
- 10 probable cause to believe that the drug or chemical is:
- 11 a. An unapproved new drug;
- 12 b. Adulterated, misbranded, or counterfeit or otherwise
- 13 unauthorized for human or animal use;
- 14 c. Labeled in a manner that indicates the substance is for research
- 15 use only; or
- 16 d. Not compounded in accordance with USP or otherwise in
- 17 violation of this chapter; or
- 18 6. Securing oral or written statements;
- 19 (c) Employ special investigators;
- 20 (d) Expend funds for the purpose of obtaining evidence; and
- 21 (e) Issue subpoenas.
- 22 (2) As used in subsection (1) of this section, "records" includes~~[,]~~ but is not limited
- 23 to~~[,]~~ patient records.
- 24 (3) Any decision to inspect, copy, or seize books, papers, documents, records, or other
- 25 evidence shall be at the discretion of the officer, agent, or inspector of the board.
- 26 (4) Inspection, copying, or seizure of books, papers, documents, records, or other
- 27 evidence does not affect the confidential nature of those records, and the board shall

1 maintain the records so as to protect the confidentiality of the records.

2 (5) The board or its authorized representatives may investigate any location that the
3 board has reasonable cause to suspect is in violation of Section 9, 10, or 11 of this
4 Act.

5 (6) A pharmacist, pharmacy intern, pharmacy technician, terminal distributor,
6 manufacturer, outsourcing facility, third-party logistics provider, or wholesale
7 distributor shall:

8 (a) Cooperate with federal, state, and local government investigations; and

9 (b) Divulge all relevant information when requested by a government agency,
10 except when divulging the information is otherwise prohibited by state or
11 federal law, including the Kentucky Rules of Evidence.

12 ➔SECTION 9. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO
13 READ AS FOLLOWS:

14 (1) On or after January 1, 2027, a person shall not operate or engage in activities as
15 a terminal distributor of prescription drugs, including any prescription drugs that
16 are distributed, delivered, shipped, or offered for sale, administration,
17 compounding, or dispensing within or into this Commonwealth, without first
18 obtaining a permit from the board. An application for a permit to operate a
19 terminal distributor shall be made to the board upon forms provided by the board.
20 Each application shall be accompanied by a reasonable permit fee to be set by
21 administrative regulations promulgated by the board in accordance with KRS
22 Chapter 13A.

23 (2) (a) Upon receipt of an application for a permit to operate a terminal distributor
24 and the permit fee, the board shall issue a permit if the terminal distributor
25 meets the requirements of this chapter and administrative regulations
26 promulgated by the board in accordance with KRS Chapter 13A.

27 (b) The board shall refuse to renew any permit to operate unless the terminal

1 distributor meets the requirements of this chapter and administrative
2 regulations promulgated by the board in accordance with KRS Chapter
3 13A.

4 (c) The board shall act upon an application for a permit to operate within thirty
5 (30) days after the receipt of the application.

6 (d) The board may issue a temporary permit to operate if additional time is
7 necessary for investigation and consideration of the application before
8 taking final action. The temporary permit shall be valid for thirty (30) days,
9 unless extended by the board.

10 (3) In the review of an application for a permit for a terminal distributor, the board
11 may consider any previous permit:

12 (a) Compliance of the applicant and of any affiliated persons or entities
13 including any entity under common ownership or control with the
14 applicant; and

15 (b) Violations committed by any entity under common ownership or control
16 with the applicant, or by any person who substantially participates in the
17 ownership, management, or control of the applicant.

18 (4) The board shall:

19 (a) Require a separate permit for each location operated by a terminal
20 distributor;

21 (b) Require a permit to be issued to the physical address on the application;

22 (c) Require the primary business address or authorized service location for a
23 mobile or temporary facility authorized by the board be an authorized
24 location for procuring prescription drugs; and

25 (d) Prohibit a permit for a terminal distributor located in or operated from a
26 personal residence or any portion of a building used for residential
27 purposes.

- 1 (5) Each permit to operate as a terminal distributor, unless previously suspended or
2 revoked, shall expire on June 30 following its date of issuance and shall be
3 renewable annually thereafter upon proper application accompanied by the
4 renewal fee required by the board. An additional fee not to exceed the annual
5 renewal fee may be assessed as a delinquent renewal penalty for failure to renew
6 the permit by June 30 of each year.
- 7 (6) The board may deny, refuse to issue, refuse to renew, suspend, revoke, restrict, or
8 place conditions or limitations upon any permit issued to a terminal distributor if
9 the applicant, or any officer, owner, partner, member, manager, responsible
10 practitioner, agent, or employee of the applicant, has been found to have violated
11 any provision of this chapter, KRS Chapter 217 or 218A, or any administrative
12 regulation promulgated by the board, unless the applicant affirmatively
13 demonstrates to the satisfaction of the board that adequate safeguards have been
14 implemented to prevent recurrence of the violation.
- 15 (7) A permit to operate a terminal distributor shall not be transferable, except that a
16 buyer may operate the terminal distributor under the permit of the seller pending
17 a decision by the board of an application if the buyer has submitted a completed
18 application to the board at least five (5) days prior to the date of purchase of the
19 terminal distributor.
- 20 (8) Each terminal distributor shall comply with the provisions of KRS 218A.202
21 relating to the electronic system for monitoring controlled substances.
- 22 (9) A terminal distributor located in Kentucky doing business by use of the internet
23 shall:
- 24 (a) Certify the percentage of its annual business conducted via the internet and
25 submit supporting documentation as requested by the board;
- 26 (b) Obtain approval for the National Association of Boards of Pharmacy
27 (NABP) Digital Pharmacy Accreditation Program or a substantially similar

1 program approved by the board; and

2 (c) Maintain and keep current accreditation form the NABP Digital Pharmacy
3 Accreditation Program, or any other substantially similar program
4 approved by the Kentucky Board of Pharmacy.

5 (10) The following shall not be required to obtain a permit to operate as a terminal
6 distributor:

7 (a) A licensed practitioner prescribing drugs in their usual course of
8 professional practice unless the licensed practitioner also possesses, has
9 custody or control of, administers, or dispenses a prescription drug;

10 (b) A person possessing medications for asthma or anaphylaxis as permitted
11 under KRS 158.836;

12 (c) A person possessing medications for diabetes or seizure disorders as
13 permitted under KRS 158.838;

14 (d) A person possessing medications for health services in schools as permitted
15 under KRS 156.502;

16 (e) A person possessing overdose reversal drugs as permitted for the purposes
17 described in KRS 217.186;

18 (f) A person possessing nitrous oxide for use as a direct ingredient in food
19 pursuant to 21 C.F.R. 184.1545 or for testing or maintaining a plumbing or
20 heating, ventilation, and air conditioning system;

21 (g) A person possessing medical gases, sterile water, or sterile saline for direct
22 administration to patients or for the purpose of installation or maintenance
23 of home medical equipment as defined in KRS 309.402; or

24 (h) A facility that is owned and operated by the United States Department of
25 Defense, the United States Department of Veterans Affairs, or any other
26 federal agency.

27 (11) The board may promulgate administrative regulations in accordance with KRS

1 Chapter 13A to:

- 2 (a) Ensure reasonable health and sanitation standards for areas in the physical
3 location a terminal distributor that are not subject to health and sanitation
4 standards of the Cabinet for Health and Family Services or a local health
5 department; and
6 (b) Implement this section.

7 ➔SECTION 10. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO
8 READ AS FOLLOWS:

- 9 (1) Prescription drugs shall only be sold, distributed, administered, or possessed in
10 accordance with KRS Chapters 217 and 218A.
11 (2) Except for a transfer of prescription drugs exempted in KRS 315.400(19), a
12 pharmacy, terminal distributor, or person that is exempt from a permit under this
13 chapter shall not purchase prescription drugs from any person other than a
14 licensed manufacturer, outsourcing facility, third-party logistics provider, or
15 wholesale distributor.
16 (3) A pharmacy or terminal distributor shall not engage in the sale or transfer of, or
17 maintain possession, custody, or control of, prescription drugs at any
18 establishment or place other than the physical address listed on the permit issued
19 by the board unless the board has authorized a mobile or temporary location.
20 (4) This section shall not be construed to interfere with the performance of official
21 duties by any law enforcement official authorized by municipal, county, state, or
22 federal law to collect samples of any drug, regardless of its nature or who
23 possesses it.

24 ➔SECTION 11. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO
25 READ AS FOLLOWS:

- 26 (1) A pharmacy, terminal distributor, or any person shall not dispense any
27 compounded preparation for human use unless compounded in anticipation of or

1 pursuant to a valid prescription drug order.

2 (2) A pharmacy, terminal distributor, or any person shall not procure, administer,
3 compound, or dispense drugs or any other chemicals that are intended for
4 research-use only, unless the permitted pharmacy or terminal distributor is
5 engaged in a systematic research program and has obtained the necessary
6 approvals in accordance with KRS 217.075.

7 (3) A pharmacy, terminal distributor, or any other person shall not procure,
8 administer, compound, or dispense drugs or any other chemicals intended for
9 dispensing or administration to humans that are labeled not for use in humans.

10 (4) A pharmacy or terminal distributor engaged in compounding under the
11 supervision and direction of the pharmacist or responsible practitioner shall
12 compound in accordance with applicable chapters of the most current version of
13 USP for sterile and nonsterile compounding and shall only procure APIs from an
14 establishment registered with the United States Food and Drug Administration
15 and licensed by the board.

16 (5) A pharmacy or terminal distributor engaged in compounding under the
17 supervision and direction of a pharmacist or responsible practitioner shall
18 compound in compliance with the requirements of state and federal law,
19 including all applicable guidance documents published by the United States Food
20 and Drug Administration.

21 ➔SECTION 12. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO
22 READ AS FOLLOWS:

23 (1) A pharmacy or terminal distributor that becomes aware or receives a report of a
24 serious adverse event associated with a drug product procured, administered,
25 compounded, or dispensed by the pharmacy or terminal distributor shall report
26 the serious adverse event to the board in a manner and form prescribed by the
27 board within five (5) business days of becoming aware of or receiving the report.

- 1 (2) The board shall provide the professional licensing board that issued a
2 professional license to the responsible practitioner the following:
- 3 (a) Notification of any refusal of entry into the terminal distributor's permitted
4 location for inspection and investigation purposes;
- 5 (b) Inspection reports that identify any violations of this chapter;
- 6 (c) 1. Investigative material, including the original complaint.
7 2. If the investigation reveals the culpability of other professionally
8 licensed individuals, the board shall share the investigative material
9 and the original complaints with the relevant licensing boards;
- 10 (d) Any fines levied against the responsible practitioner; and
- 11 (e) Any unpaid fines levied against the responsible practitioner.
- 12 (3) The board shall advise the professional licensing board whether additional action
13 is needed to protect public health and safety. Any public disciplinary action taken
14 by professional licensing boards shall be shared with the board.
- 15 (4) No later than August 1, 2027, and each August 1 thereafter, the board shall
16 submit a comprehensive report to the Legislative Research Commission for
17 referral to the Interim Joint Committee on Health Services on its inspection and
18 investigation findings in the preceding year. The report shall include but is not
19 limited to:
- 20 (a) The total number of pharmacy and terminal distributor compounding
21 inspections conducted;
- 22 (b) The total number of consumer compounding complaints received against
23 pharmacies and terminal distributors;
- 24 (c) A summary of the most significant findings related to violations of
25 compounding and procurement of drugs;
- 26 (d) The identity and amount of any drugs or any other chemicals seized by the
27 board;

- 1 (e) A summary of serious adverse events reported to the board;
 2 (f) A summary of public disciplinary action taken by professional licensing
 3 boards against responsible practitioners or other licensed professionals;
 4 (g) An estimated cost to the board for inspections and investigations conducted
 5 pursuant to Section 8 of this Act;
 6 (h) The total amount of penalties levied and collected for violations of this
 7 chapter; and
 8 (i) Specific recommendations for legislative or regulatory changes, including
 9 any requests for additional enforcement powers or oversight.
 10 (5) This section shall not preclude the reporting of adverse events by outsourcing
 11 facilities as required under 21 U.S.C. sec. 353b(b)(5).

12 ➔SECTION 13. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO
 13 READ AS FOLLOWS:

14 Notwithstanding the existence or pursuit of any other civil or criminal remedy, the
 15 board may maintain, in its own name, an action to restrain or enjoin any violation of
 16 this chapter, regardless of whether there exists an adequate remedy at law.

17 ➔Section 14. KRS 315.990 is amended to read as follows:

- 18 (1) Except for the provisions of KRS 315.320, any person violating any provision of
 19 KRS Chapter 315 shall be fined for each offense not less than one hundred dollars
 20 (\$100) nor more than one thousand dollars (\$1,000) or imprisoned in the county jail
 21 for not more than six (6) months, or both. Each week that any provision of KRS
 22 315.020, 315.030, or 315.035 is violated shall also constitute a separate offense.
 23 (2) Any person convicted of willfully resisting, preventing, impeding, obstructing,
 24 threatening, or interfering with the officers, agents, or inspectors of the board in the
 25 administration of the provisions of this chapter shall be guilty of a Class A
 26 misdemeanor.
 27 (3) The board may levy an administrative fine not to exceed five thousand dollars

1 (\$5,000) for each offense, for any violation of KRS 315.121. All such fines shall be
2 deposited to the credit of the licensing board to be used by the board in carrying out
3 the provisions of this chapter.

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

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

14 (6) (a) Any person who intentionally, knowingly, or recklessly violates KRS
15 216B.200 to 216B.210 is guilty of a Class D felony.

16 (b) Any person who violates KRS 216B.200 to 216B.210 shall be fined not more
17 than one million dollars (\$1,000,000).

18 (c) Notwithstanding KRS 440.200, the Attorney General may demand from the
19 Governor of any other state the surrender of any person found in the other
20 state who is charged in Kentucky with the crime of violating KRS 216B.200
21 to 216B.210. The provisions for extradition under this subsection shall apply
22 to any such demand even if the person whose surrender is demanded was not
23 in Kentucky at the time of the commission of the crime. Neither the demand,
24 the oath, nor any proceedings for extradition pursuant to this section need
25 state or show that the person whose surrender is demanded has fled from
26 justice, or at the time of the commission of the crime was in Kentucky or the
27 other state.

1 (7) Any person in violation of subsection (1), (2), or (3) of Section 10 of this Act shall
2 be guilty of a Class A misdemeanor for the first offense and a Class D felony for
3 each subsequent offense.

4 (8) Unless another specific penalty is provided in this section, any person who
5 violates any provision of subsection (1), (2), or (3) of Section 11 of this Act shall
6 be guilty of a Class A misdemeanor for the first offense and a Class D felony for
7 each subsequent offense.

8 ➔Section 15. KRS 194A.800 is amended to read as follows:

9 (1) For the purposes of this section, "pilot program" means a program in a county or set
10 of counties, or a subset or subsets of the population, as designated by the Cabinet
11 for Health and Family Services and the Department for Behavioral Health,
12 Developmental and Intellectual Disabilities.

13 (2) A pilot program is established to analyze the outcomes and effectiveness of a
14 community pharmacy care delivery model for medication-assisted therapy for
15 treatment of substance abuse in order to ensure that the Commonwealth is:

16 (a) Using approaches that have been shown to be effective;

17 (b) Intervening early at important stages and transitions; and

18 (c) Intervening in appropriate settings and domains.

19 (3) Sources of data for the pilot program shall include, at a minimum, claims data from
20 the Department for Medicaid Services, including claims data from Medicaid
21 managed care organizations submitted to the Department for Medicaid Services.

22 (4) As funds are available, the Cabinet for Health and Family Services shall initiate a
23 pilot program to determine, collect, and analyze performance measurement data for
24 a community pharmacy care delivery model for noncontrolled medication-assisted
25 therapy as part of substance abuse treatment services to determine practices that
26 increase access to treatment, reduce frequency of relapse, provide better outcomes
27 for patients, and control health costs related to substance abuse treatment. Program

1 components shall:

- 2 (a) Use a community pharmacy care delivery model for noncontrolled
3 medication-assisted therapy for the treatment of substance abuse, as
4 authorized by the Kentucky Board of Pharmacy pursuant to a prescription
5 drug order as defined in KRS 315.010~~[(25)]~~;
- 6 (b) Include a wraparound services model that engages psychological and social
7 support for the patient;
- 8 (c) Establish collaborative relationships between detention facilities, drug courts,
9 community pharmacists, and practitioners who provide psychosocial
10 interventions to evaluate individuals' eligibility for participation in a
11 community pharmacy care delivery model for noncontrolled medication-
12 assisted therapy; and
- 13 (d) Include pilot program data collection designed to inform the outcomes and
14 effectiveness of a community pharmacy care delivery model for medication-
15 assisted therapy for treatment of substance abuse.
- 16 (5) By December 31, 2019, the Cabinet for Health and Family Services shall provide a
17 joint report to the Legislative Research Commission and the Office of the Governor
18 that:
- 19 (a) Details the findings of the pilot program; and
- 20 (b) Includes recommendations based on the pilot program's results for optimizing
21 substance abuse treatment services provided in community pharmacies.

22 ➔Section 16. KRS 217.215 is amended to read as follows:

- 23 (1) The Board of Pharmacy, its agents and inspectors shall have the same powers of
24 inspection and enforcement as the cabinet under KRS 217.005 to 217.215~~[, insofar~~
25 ~~as it relates to drugs in licensed pharmacies]~~.
- 26 (2) The Board of Pharmacy may establish regulations relating to the storage and
27 retrieval of prescription records in licensed pharmacies, including regulations

1 regarding computerized recordkeeping systems.

- 2 (3) (a) No prescription for any drug may be refilled by a pharmacist unless
3 authorized by the prescribing practitioner, except that, in emergency situations
4 in which such authorization may not be readily or easily obtained from the
5 practitioner, a pharmacist may:
- 6 1. Dispense up to a seventy-two (72) hour supply of maintenance
7 medication;
 - 8 2. Dispense greater than a seventy-two (72) hour supply of maintenance
9 medication if:
 - 10 a. The standard unit of dispensing for the drug exceeds a seventy-two
11 (72) hour supply;
 - 12 b. The pharmacist dispenses a supply of the drug that is equal to the
13 standard unit of dispensing for the drug; and
 - 14 c. The drug is used for insulin therapy or the treatment of chronic
15 respiratory diseases; and
 - 16 3. Dispense up to a thirty (30) day supply of maintenance medication in
17 emergency situations as authorized by KRS 315.500.
- 18 (b) Emergency refills dispensed under this subsection shall not be authorized for
19 any controlled substance or for any drug which is not essential to maintenance
20 of life or continuation of therapy in chronic disease conditions.
- 21 (c) The Board of Pharmacy shall promulgate administrative regulations to carry
22 out the provisions of this subsection.

23 ➔Section 17. KRS 217.913 is amended to read as follows:

24 The provisions of KRS 217.907 to 217.917 shall not apply to drug products compounded
25 by a pharmacist licensed pursuant to KRS Chapter 315, in a pharmacy ***or terminal***
26 ***distributor's permitted location*** operating under a permit ***authorized by the board*** ~~as~~
27 ~~required by KRS 315.035].~~

1 ➔Section 18. KRS 315.205 is amended to read as follows:

2 Upon the request of an individual or his or her parent or guardian, a pharmacist who
3 administers an immunization to an individual who is five (5) to seventeen (17) years of
4 age, as authorized in *the practice of pharmacy as defined in* KRS 315.010~~[(22)]~~, shall
5 provide notification of the immunization to the individual's primary care provider.

6 ➔Section 19. This Act may be cited as Jimmie's Law.

7 ➔Section 20. Whereas it is critical that the Kentucky Board of Pharmacy have the
8 authority to ensure the safety of the pharmaceutical drug supply for the health and well-
9 being of the citizens of the Commonwealth, an emergency is declared to exist, and this
10 Act takes effect upon its passage and approval by the Governor or upon its otherwise
11 becoming a law.