

1 AN ACT relating to licensure.

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) "Administer" means the direct application of a drug to a patient or research subject
6 by injection, inhalation, or ingestion, whether topically or by any other means;
- 7 (2) "Administrative activities of a pharmacy" means the following functions performed
8 by a pharmacy adhering to all local, state, and federal patient privacy laws:
- 9 (a) Investigating and researching a patient's insurance benefits and updating the
10 patient profile regarding insurance coverage;
- 11 (b) Billing and collections activities, including:
- 12 1. Contacting patients for copayments and coinsurance payments; and
13 2. Communicating with insurance companies;
- 14 (c) Performing patient financial assistance activities and updating patient records
15 accordingly;
- 16 (d) Opening faxes and accessing electronic prescriptions for the purposes of
17 setting up patient demographic and insurance profiles, excluding height,
18 weight, and allergy information, so long as the activity does not involve the
19 entering of a prescription order into the dispensing or medication management
20 system;
- 21 (e) Initiating insurance prior authorizations for submission to the licensed
22 pharmacy, including communications with the prescribing physician to
23 collect, record, and transmit information to insurance companies, so long as
24 the activity does not include the authorization or receipt of new or refill
25 prescription orders;
- 26 (f) Answering and transferring telephone calls, whether or not such calls require
27 accessing a patient record, so long as the call does not involve the

- 1 interpretation, evaluation, or implementation of a drug order; and
- 2 (g) Communicating with patients via telephone or electronically regarding refill
3 reminders, so long as the communication does not involve the interpretation,
4 evaluation, or implementation of a drug order and a pharmacist is readily
5 available for patient consultation;
- 6 (3) "Association" means the Kentucky Pharmacists Association;
- 7 (4) "Board" means the Kentucky Board of Pharmacy;
- 8 (5) "Collaborative care agreement" means a written agreement between a pharmacist or
9 pharmacists and a practitioner or practitioners that outlines a plan of cooperative
10 management of patients' drug-related health care needs where:
- 11 (a) Patients' drug-related health care needs fall within the practitioner's or
12 practitioners' statutory scope of practice;
- 13 (b) Patients are referred by the practitioner or practitioners to the pharmacist or
14 pharmacists; and
- 15 (c) The agreement:
- 16 1. Identifies the practitioner or practitioners and the pharmacist or
17 pharmacists who are parties to the agreement;
- 18 2. Specifies the drug-related regimen to be provided, and how drug therapy
19 is to be monitored; and
- 20 3. Stipulates the conditions for initiating, continuing, or discontinuing drug
21 therapy and conditions which warrant modifications to dose, dosage
22 regimen, dosage form, or route of administration;
- 23 (6) "Compound" or "compounding" means the preparation or labeling of a drug
24 pursuant to or in anticipation of a valid prescription drug order, including but not
25 limited to packaging, intravenous admixture or manual combination of drug
26 ingredients. "Compounding," as used in this chapter, shall not preclude simple
27 reconstitution, mixing, or modification of drug products prior to administration by

- 1 nonpharmacists;
- 2 (7) "Confidential information" means information which is accessed or maintained by a
3 pharmacist in a patient's record, or communicated to a patient as part of patient
4 counseling, whether it is preserved on paper, microfilm, magnetic media, electronic
5 media, or any other form;
- 6 (8) "Continuing education unit" means ten (10) contact hours of board approved
7 continuing pharmacy education. A "contact hour" means fifty (50) continuous
8 minutes without a break period;
- 9 (9) "Dispense" or "dispensing" means to deliver one (1) or more doses of a prescription
10 drug in a suitable container, appropriately labeled for subsequent administration to
11 or use by a patient or other individual entitled to receive the prescription drug;
- 12 (10) "Drug" means any of the following:
- 13 (a) Articles recognized as drugs or drug products in any official compendium or
14 supplement thereto;
- 15 (b) Articles, other than food, intended to affect the structure or function of the
16 body of man or other animals;
- 17 (c) Articles, including radioactive substances, intended for use in the diagnosis,
18 cure, mitigation, treatment or prevention of disease in man or other animals;
19 or
- 20 (d) Articles intended for use as a component of any articles specified in
21 paragraphs (a) to (c) of this subsection;
- 22 (11) "Drug regimen review" means retrospective, concurrent, and prospective review by
23 a pharmacist of a patient's drug-related history, including but not limited to the
24 following areas:
- 25 (a) Evaluation of prescription drug orders and patient records for:
- 26 1. Known allergies;
- 27 2. Rational therapy contraindications;

- 1 3. Appropriate dose and route of administration;
- 2 4. Appropriate directions for use; or
- 3 5. Duplicative therapies.
- 4 (b) Evaluation of prescription drug orders and patient records for drug-drug, drug-
- 5 food, drug-disease, and drug-clinical laboratory interactions;
- 6 (c) Evaluation of prescription drug orders and patient records for adverse drug
- 7 reactions; or
- 8 (d) Evaluation of prescription drug orders and patient records for proper
- 9 utilization and optimal therapeutic outcomes;
- 10 (12) "Immediate supervision" means under the physical and visual supervision of a
- 11 pharmacist;
- 12 (13) "Manufacturer" means any person, except a pharmacist compounding in the normal
- 13 course of professional practice, within the Commonwealth engaged in the
- 14 commercial production, preparation, propagation, compounding, conversion, or
- 15 processing of a drug, either directly or indirectly, by extraction from substances of
- 16 natural origin or independently by means of chemical synthesis, or both, and
- 17 includes any packaging or repackaging of a drug or the labeling or relabeling of its
- 18 container;
- 19 (14) "Medical order" means a lawful order of a specifically identified practitioner for a
- 20 specifically identified patient for the patient's health care needs. "Medical order"
- 21 may or may not include a prescription drug order;
- 22 (15) "Nonprescription drugs" means nonnarcotic medicines or drugs which may be sold
- 23 without a prescription and are prepackaged and labeled for use by the consumer in
- 24 accordance with the requirements of the statutes and regulations of this state and the
- 25 federal government;
- 26 (16) **"Outsourcing facility" means a facility at one (1) geographic location or address**
- 27 **that:**

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

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

9 (18)~~[(17)]~~ "Pharmacist intern" means a natural person who is:

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

22 (19)~~[(18)]~~ "Pharmacy" means every place where:

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

1 prescription drug orders are being dispensed;

2 ~~(20)~~~~(19)~~ "Pharmacy-related primary care" means the pharmacists' activities in patient
3 education, health promotion, and assistance in the selection and use of over-the-
4 counter drugs and appliances for the treatment of common diseases and injuries, as
5 well as those other activities falling within their statutory scope of practice;

6 ~~(21)~~~~(20)~~ "Pharmacy technician" means a natural person who works under the
7 immediate supervision, or general supervision if otherwise provided for by statute
8 or administrative regulation, of a pharmacist for the purpose of assisting a
9 pharmacist with the practice of pharmacy;

10 ~~(22)~~~~(21)~~ "Practice of pharmacy" means interpretation, evaluation, and implementation
11 of medical orders and prescription drug orders; responsibility for dispensing
12 prescription drug orders, including radioactive substances; participation in drug and
13 drug-related device selection; administration of medications or biologics in the
14 course of dispensing or maintaining a prescription drug order; the administration of
15 adult immunizations pursuant to prescriber-approved protocols; the administration
16 of influenza vaccines to individuals nine (9) to thirteen (13) years of age pursuant to
17 prescriber-approved protocols with the consent of a parent or guardian; the
18 administration of immunizations to individuals fourteen (14) to seventeen (17) years
19 of age pursuant to prescriber-approved protocols with the consent of a parent or
20 guardian; the administration of immunizations to a child as defined in KRS
21 214.032, pursuant to protocols as authorized by KRS 315.500; drug evaluation,
22 utilization, or regimen review; maintenance of patient pharmacy records; and
23 provision of patient counseling and those professional acts, professional decisions,
24 or professional services necessary to maintain and manage all areas of a patient's
25 pharmacy-related care, including pharmacy-related primary care as defined in this
26 section;

27 ~~(23)~~~~(22)~~ "Practitioner" has the same meaning given in KRS 217.015(35);

1 ~~(24)~~~~[(23)]~~ "Prescription drug" means a drug which:

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

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

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

12 ~~(25)~~~~[(24)]~~ "Prescription drug order" means an original or new order from a practitioner
13 for drugs, drug-related devices or treatment for a human or animal, including orders
14 issued through collaborative care agreements or protocols authorized by the board.
15 Lawful prescriptions result from a valid practitioner-patient relationship, are
16 intended to address a legitimate medical need, and fall within the prescribing
17 practitioner's scope of professional practice;

18 ~~(26)~~~~[(25)]~~ "Society" means the Kentucky Society of Health-Systems Pharmacists;

19 ~~(27)~~~~[(26)]~~ "Supervision" means the presence of a pharmacist on the premises to which a
20 pharmacy permit is issued, who is responsible, in whole or in part, for the
21 professional activities occurring in the pharmacy; and

22 ~~(28)~~~~[(27)]~~ "Wholesaler" means any person who legally buys drugs for resale or
23 distribution to persons other than patients or consumers.

24 ➔SECTION 2. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO
25 READ AS FOLLOWS:

26 *(1) (a) A person shall not operate an outsourcing facility within this*
27 *Commonwealth, physically or by means of the Internet, facsimile, phone,*

1 mail, or any other means, without first obtaining a permit from the board.

2 (b) An application for a permit to operate an outsourcing facility shall be made
3 to the board upon forms provided by the board and shall contain such
4 information as the board requires, which may include affirmative evidence
5 of the ability to comply with the requirements of this chapter and the
6 administrative regulations promulgated by the board.

7 (c) Each application shall be accompanied by a nonrefundable permit fee to be
8 set by administrative regulation promulgated by the board, not to exceed
9 five hundred dollars (\$500).

10 (2) (a) As a prerequisite to obtaining or renewing a permit from the board, the
11 outsourcing facility shall:

12 1. Register as an outsourcing facility with the United States Secretary of
13 Health and Human Services in accordance with 21 U.S.C. sec. 353b;
14 and

15 2. Submit a copy of a current inspection report resulting from an
16 inspection conducted by the United States Food and Drug
17 Administration that indicates compliance with the requirements of
18 state and federal law and regulations, including all applicable
19 guidance documents and Current Good Manufacturing Practices
20 published by the United States Food and Drug Administration.

21 (b) 1. The inspection report required pursuant to paragraph (a)2. of this
22 subsection shall be deemed current for the purposes of this section if
23 the inspection was conducted no more than:

24 a. One (1) year prior to the date of submission of an application for
25 a permit to the board; or

26 b. Two (2) years prior to the date of submission of an application
27 for renewal of a permit to the board.

- 1 2. If the outsourcing facility has not been inspected by the United States
2 Food and Drug Administration within the period required under
3 subparagraph 1. of this paragraph, the board may:
- 4 a. Accept an inspection report or other documentation from
5 another entity that is satisfactory to the board; or
- 6 b. Cause an inspection to be conducted by its duly authorized agent
7 and charge an inspection fee in an amount sufficient to cover
8 the costs of the inspection.
- 9 (3) (a) Upon receipt of an application of a permit to operate an outsourcing facility
10 accompanied by the permit fee prescribed by administrative regulation, the
11 board shall:
- 12 1. Issue a permit if the outsourcing facility meets the requirements of
13 this chapter and the administrative regulations promulgated by the
14 board; or
- 15 2. Refuse to issue or renew any permit to operate if the outsourcing
16 facility fails to meet the requirements of this chapter and the
17 administrative regulations promulgated by the board.
- 18 (b) The board shall act upon an application for a permit to operate within thirty
19 (30) days after the receipt of the application. The board may issue a
20 temporary permit to operate in any instance where it considers additional
21 time necessary for investigation and consideration before taking final
22 action upon the application. The temporary permit shall be valid for a
23 period of thirty (30) days, unless extended.
- 24 (4) A separate permit to operate shall be required for each outsourcing facility.
- 25 (5) (a) Each permit to operate an outsourcing facility, unless suspended or
26 revoked, shall expire on June 30 following its date of issuance and be
27 renewable annually thereafter upon proper application accompanied by the

1 renewal fee as established by administrative regulations promulgated by the
2 board. The renewal fee shall not exceed five hundred dollars (\$500).

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

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

11 (7) The board may promulgate administrative regulations to ensure:

12 (a) That proper equipment and reference material is on hand considering the
13 nature of the pharmaceutical practice conducted at the particular
14 outsourcing facility; and

15 (b) Health and sanitation standards for areas within outsourcing facilities that
16 adhere to Current Good Manufacturing Practices published by the United
17 States Food and Drug Administration.

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

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

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

25 ➔SECTION 3. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO
26 READ AS FOLLOWS:

27 (1) (a) Each out-of-state outsourcing facility that does business physically or by

1 means of the Internet, facsimile, phone, mail, or any other means, inside
2 this Commonwealth, shall hold a current outsourcing facility permit issued
3 by the board.

4 (b) An application for a permit to operate an out-of-state outsourcing facility
5 shall be made to the board upon forms provided by it and shall contain such
6 information as the board requires, which may include affirmative evidence
7 of ability to comply with reasonable standards and regulations as may be
8 prescribed by the board.

9 (c) Each application shall be accompanied by a permit fee to be set by
10 administrative regulation promulgated by the board. The fee shall not
11 exceed:

12 1. Two hundred fifty dollars (\$250); or

13 2. The current in-state outsourcing facility permit.

14 (2) (a) As a prerequisite to obtaining or renewing a permit from the board, the out-
15 of-state outsourcing facility shall:

16 1. Register as an outsourcing facility with the United States Secretary of
17 Health and Human Services in accordance with 21 U.S.C. sec. 353b;
18 and

19 2. Submit a copy of a current inspection report resulting from an
20 inspection conducted by the United States Food and Drug
21 Administration that indicates compliance with the requirements of
22 state and federal law and regulations, including all applicable
23 guidance documents and Current Good Manufacturing Practices
24 published by the United States Food and Drug Administration.

25 (b) 1. The inspection report required pursuant to paragraph (b) of this
26 subsection shall be deemed current for the purposes of this section if
27 the inspection was conducted no more than:

- 1 a. One (1) year prior to the date of submission of an application for
2 a permit to the board; or
- 3 b. Two (2) years prior to the date of submission of an application
4 for renewal of a permit to the board.
- 5 2. If the out-of-state outsourcing facility has not been inspected by the
6 United States Food and Drug Administration within the required
7 period required under subparagraph 1. of this paragraph, the board
8 may:
- 9 a. Accept an inspection report or other documentation from
10 another entity that is satisfactory to the board; or
- 11 b. Cause an inspection to be conducted by its duly authorized agent
12 and may charge an inspection fee in an amount sufficient to
13 cover the costs of the inspection.
- 14 (3) (a) Upon receipt of an application for a permit to operate an out-of-state
15 outsourcing facility, accompanied by the permit fee required by subsection
16 (1) of this section, the board shall:
- 17 1. Issue a permit if the out-of-state outsourcing facility meets the
18 requirements of this chapter and the administrative regulations
19 promulgated by the board; or
- 20 2. Refuse to renew any permit to operate unless the out-of-state
21 outsourcing facility meets the requirements of this chapter and the
22 administrative regulations promulgated by the board.
- 23 (b) The board shall act upon an application for a permit to operate within thirty
24 (30) days after the receipt thereof. The board may issue a temporary permit
25 to operate in any instance where it considers additional time necessary for
26 investigation and consideration before taking final action upon the
27 application. The temporary permit shall be valid for a period of thirty (30)

1 days, unless extended.

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

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

10 (6) (a) An out-of-state outsourcing facility granted an out-of-state outsourcing
11 facility permit shall comply with all requests for information within three
12 (3) business days of a written request by the board or its agents.

13 (b) An out-of-state outsourcing facility shall maintain at all times a valid
14 unexpired permit, license, or registration to conduct the outsourcing facility
15 in compliance with the laws of the jurisdiction in which it is a resident.

16 (c) As a prerequisite to seeking a permit from the board, the out-of-state
17 outsourcing facility shall submit a copy of the most recent inspection report
18 resulting from an inspection conducted by the regulatory or licensing
19 agency of the jurisdiction in which it is located. Thereafter, the out-of-state
20 outsourcing facility granted a permit shall submit to the board a copy of any
21 subsequent inspection report of the outsourcing facility conducted by the
22 regulatory or licensing body of the jurisdiction in which it is located.

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

26 (8) Each out-of-state outsourcing facility shall, during its regular hours of operation,
27 but not less than five (5) days per week and for a minimum of forty (40) hours per

1 week, provide a toll-free telephone service directly to the pharmacist in charge of
2 the out-of-state outsourcing facility for the purpose of facilitating
3 communication. A toll-free number shall be placed on a label affixed to each
4 container of drugs dispensed to an entity within the Commonwealth.

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

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

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

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

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

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

26 (14) Each out-of-state outsourcing facility shall compound in compliance with the
27 requirements of state and federal law and regulations, to include all applicable

1 guidance documents and Current Good Manufacturing Practices published by
2 the United States Food and Drug Administration.

3 ➔Section 4. KRS 315.400 is amended to read as follows:

4 As used in KRS 315.400 to 315.412:

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

6 (a) Has established an ongoing relationship with a manufacturer to distribute the
7 manufacturer's prescription drug. An ongoing relationship exists between a
8 wholesale distributor and a manufacturer if the wholesale distributor,
9 including any affiliated group of the wholesale distributor as defined in
10 Section 1504 of the Internal Revenue Code, has a written agreement for
11 distribution in effect; and

12 (b) Is listed on the manufacturer's current list of authorized distributors of record;

13 (2) "Co-licensed partner" means two (2) or more entities that have the right to engage in
14 the manufacturing or marketing or both of a prescription drug consistent with the
15 Federal Drug Administration's implementation of the federal Prescription Drug
16 Marketing Act;

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

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

26 (5) "Dispenser" means:

27 (a) A retail pharmacy, hospital pharmacy, a group of chain pharmacies under

1 common ownership and control that do not act as a wholesale distributor,
2 or any other person authorized by law to dispense or administer prescription
3 drugs, and the affiliated warehouse distribution centers of such entities
4 under common ownership and control that do not act as a wholesale
5 distributor; but

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

8 **(6)** "Drop shipment" means the sale of a prescription drug to a wholesale distributor by
9 the drug's manufacturer, the manufacturer's co-licensed partner, the manufacturer's
10 third-party logistics provider, the manufacturer's exclusive distributor, or by an
11 authorized distributor of record that purchased the product directly from the
12 manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party
13 logistics provider, or the manufacturer's exclusive distributor, and:

14 (a) The wholesale distributor takes title to but not physical possession of the drug;
15 (b) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or
16 other person authorized by law to dispense or administer a prescription drug;
17 and

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

23 ~~(Z)~~~~(6)~~ "Emergency medical reasons" includes but is not limited to:

24 (a) Transfers of a prescription drug between health-care entities or between a
25 health-care entity and a retail pharmacy to alleviate a temporary shortage of a
26 prescription drug arising from delays in or interruptions of the regular
27 distribution schedules;

- 1 (b) Sales of drugs for use in the treatment of acutely ill or injured persons to
2 nearby emergency medical services providers, firefighting organizations, or
3 licensed health-care practitioners in the same marketing or service area;
- 4 (c) The provision of emergency supplies of drugs to nearby nursing homes, home
5 health agencies, or hospice organizations for emergency use when necessary
6 drugs cannot be obtained; or
- 7 (d) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy
8 to alleviate a temporary shortage;
- 9 ~~(8)~~~~(7)~~ "End user" means a patient or consumer that uses a prescription drug as
10 prescribed by an authorized health-care professional;
- 11 ~~(9)~~~~(8)~~ "FDA" means the United States Food and Drug Administration and any
12 successor agency;
- 13 ~~(10)~~~~(9)~~ "Manufacturer" means the same as defined in KRS 315.010;
- 14 ~~(11)~~~~(10)~~ "Manufacturer's exclusive distributor" means a distributor who:
- 15 (a) Contracts with a manufacturer to provide or coordinate the warehousing,
16 distributing, or other similar services on behalf of a manufacturer;
- 17 (b) Takes title of the prescription drug but does not have responsibility to direct
18 the sale of the manufacturer's prescription drug;
- 19 (c) Is licensed under KRS 315.402; and
- 20 (d) Is an authorized distributor of record;
- 21 ~~(12)~~~~(11)~~ "Normal distribution channel" means a chain of custody for a prescription
22 drug from a manufacturer, a manufacturer's co-licensed partner, a manufacturer's
23 third-party logistics provider, or a manufacturer's exclusive distributor that goes
24 directly, by drop shipment or by intracompany transfer, to:
- 25 (a) A pharmacy or other designated person authorized by law to distribute a
26 prescription drug to an end user;
- 27 (b) A pharmacy warehouse that performs intracompany sales or transfers of

1 prescription drugs to a group of pharmacies under common ownership and
2 control to a patient, pursuant to a prescription for a patient, or to a person
3 authorized by law to administer a prescription drug for use by a patient;

4 (c) An authorized distributor of record:

- 5 1. Then to a pharmacy or other designated person authorized by law to
6 distribute a prescription drug to an end user;
- 7 2. Then to a pharmacy warehouse as specified in paragraph (b) of this
8 subsection; or
- 9 3. Then to another authorized distributor of record to a licensed health-care
10 facility or pharmacy, or a practitioner authorized by law to distribute a
11 prescription drug to an end user; or

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

15 ~~(13)~~~~(12)~~ "Pedigree" means a document or electronic file containing information that
16 records each distribution of a prescription drug;

17 ~~(14)~~~~(13)~~ "Pharmacy warehouse" means a physical location for prescription drugs that
18 acts as a central warehouse and performs intracompany sales or transfers of
19 prescription drugs to a group of pharmacies under common ownership and control;

20 ~~(15)~~~~(14)~~ "Prescription drug" means the same as defined in KRS 315.010;

21 ~~(16)~~~~(15)~~ **"Repackager" means a person who owns or operates an establishment that**
22 **repacks and relabels a product or package for further sale, or distribution**
23 **without a further transaction;**

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

27 ~~(18)~~~~(16)~~ "Third-party logistics provider" means an entity that contracts with a

1 manufacturer, **wholesale distributor, repackager, or dispenser** to provide ~~and~~ ~~or~~
2 coordinate ~~the~~ warehousing ~~,~~ ~~distribution,~~ or other **logistics** ~~similar~~ services on
3 behalf of a manufacturer, **wholesale distributor, repackager, or dispenser** but does
4 not take title to the drug or have responsibility to direct the sale of the ~~the~~
5 ~~manufacturer's~~ drug. A third-party logistics provider ~~who is a licensed wholesale~~
6 ~~distributor under KRS 315.402 and is a manufacturer's authorized distributor of~~
7 ~~record~~ shall be considered as part of the normal distribution channel;

8 **(19)** ~~(17)~~ "Wholesale distribution" means the distribution of a prescription drug to
9 persons other than an end user, but does not include:

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

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

6 ~~(20)~~~~[(18)]~~ "Wholesale distributor" means an entity engaged in the wholesale distribution
 7 of prescription drugs, including but not limited to manufacturers, manufacturers'
 8 exclusive distributors, authorized distributors of record, drug wholesalers or
 9 distributors,~~[third-party logistics providers,]~~ third-party returns processors, reverse
 10 distributors, and pharmacy warehouses and retail pharmacies that engage in the
 11 wholesale distribution of a prescription drug.

12 ➔SECTION 5. A NEW SECTION OF KRS 315.400 TO 315.412 IS CREATED
 13 TO READ AS FOLLOWS:

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

16 **(a) Within the borders of Kentucky; or**

17 **(b) To a location outside the borders of Kentucky.**

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

20 **(a) Completion of an application; and**

21 **(b) Payment of a renewal fee as established by administrative regulations**
 22 **promulgated by the board.**

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

27 **(a) The state from which the third-party logistics provider ships, if that state**

- 1 licenses third-party logistics providers; or
 2 (b) The United States Food and Drug Administration.
 3 (4) A third-party logistics provider license shall be valid only for the name,
 4 ownership, and location listed on the license. Changes of name, ownership, or
 5 location shall require a new third-party logistics provider license.
 6 (5) Changes in information required for licensure shall be reported to the board, in
 7 writing, within ten (10) days of the change.
 8 (6) A third-party logistics provider shall not operate from a place of residence.
 9 (7) A third-party logistics provider facility shall be located apart and separate from
 10 any retail pharmacy licensed by the board.
 11 (8) A third-party logistics provider shall publicly display all licenses and have the
 12 most recent state and federal inspection reports readily available.

13 ➔SECTION 6. A NEW SECTION OF KRS 315.400 TO 315.412 IS CREATED
 14 TO READ AS FOLLOWS:

- 15 (1) An applicant for licensure as a third-party logistics provider shall submit a
 16 satisfactorily completed board-approved application along with the required fee.
 17 New applicants shall provide, at minimum, the following:
 18 (a) The applicant's full name, all trade or business names used, full business
 19 address, and telephone number;
 20 (b) Type of ownership, whether individual, partnership, limited liability
 21 company, or corporation;
 22 (c) Name of the owner or owners, including:
 23 1. If a person, the name, address, Social Security number, and date of
 24 birth;
 25 2. If other than a person, the name, address, Social Security number,
 26 and date of birth of each partner, limited liability company member, or
 27 corporate officer and corporate director, and the federal employer

- 1 identification number;
2 3. If a corporation, the state of incorporation; and
3 4. If a publicly traded corporation, the information described in
4 subparagraph 2. of this paragraph is not required for corporate
5 officers and corporate directors; and
6 (d) Upon the board's written request, a list of all manufacturers, wholesale
7 distributors, and dispensers for whom the third-party logistics provider
8 provides services.

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

11 ➔SECTION 7. A NEW SECTION OF KRS 315.400 TO 315.412 IS CREATED
12 TO READ AS FOLLOWS:

13 (1) The board shall consider, at a minimum, the following factors in determining the
14 eligibility for initial licensure and renewal of third-party logistics providers:

15 (a) A finding by a law enforcement agency or regulatory agency that the
16 applicant or any owners of an applicant has violated federal, state, or local
17 laws;

18 (b) Suspension, revocation, or any other sanction against a license currently or
19 previously held by the applicant or any of its owners for a violation of
20 federal or state law;

21 (c) A finding that the applicant or any of its owners are guilty of or pleaded
22 guilty or nolo contendere to violating federal, state, or local laws;

23 (d) The furnishing by the applicant of false or fraudulent material in any
24 application;

25 (e) Failure to maintain or make available to the board or to federal, state, or
26 local law enforcement officials the records required to be maintained by
27 third-party logistics providers; and

1 (f) Any other factors or qualifications that the board considers relevant to and
 2 consistent with the public health and safety. Any factors inconsistent with
 3 federal standards shall not be applied.

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

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

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

13 ➔SECTION 8. A NEW SECTION OF KRS 315.400 TO 315.412 IS CREATED
 14 TO READ AS FOLLOWS:

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

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

20 (a) Providing third-party logistics services involving prescription drugs;

21 (b) A violation of 21 U.S.C. sec. 331(i) or (k); or

22 (c) A violation of 18 U.S.C. sec. 1365 relating to product tampering.

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

27 ➔SECTION 9. A NEW SECTION OF KRS 315.400 TO 315.412 IS CREATED

1 TO READ AS FOLLOWS:

- 2 (1) A third-party logistics provider shall operate in compliance with all applicable
3 federal, state, and local laws and regulations, including but not limited to:
4 (a) The Drug Supply Chain Security Act of 2013 and rules promulgated
5 thereunder; and
6 (b) The storage practices set out in 21 U.S.C. sec. 360eee-3(d)(2)(C)
7 (2) A third-party logistics provider shall allow the board and authorized federal,
8 state, and local law enforcement officials to enter and inspect its premises and
9 delivery vehicles, to audit its records and written operating procedures, and to
10 confiscate prescription drugs and records to the extent authorized by law, rule, or
11 regulation.
12 (3) Failure to operate in compliance with all applicable federal, state, and local laws
13 and regulations shall constitute unprofessional conduct pursuant to KRS
14 315.121(1)(a).

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

- 17 (1) A medical gas wholesaler, whether located within the Commonwealth or
18 operating within the Commonwealth from a location outside the Commonwealth,
19 shall be licensed by the board. Each license application shall be a fee which
20 shall:
21 (a) Be prescribed by administrative regulation promulgated by the board in an
22 amount not to exceed two hundred fifty dollars (\$250); and
23 (b) Not be increased by more than twenty-five dollars (\$25) per year.
24 (2) A medical gas wholesaler shall be required to maintain accurate records of all
25 drugs handled. Records shall be made available to agents of the board for
26 inspection upon request.
27 (3) Failure to report to the board or willful submission of inaccurate information

1 shall be grounds for disciplinary action under KRS 315.131.

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

4 ➔Section 11. KRS 315.205 is amended to read as follows:

5 Upon the request of an individual or his or her parent or guardian, a pharmacist who
6 administers an immunization to an individual who is fourteen (14) to seventeen (17) years
7 of age or an influenza vaccine to an individual who is nine (9) to thirteen (13) years of
8 age, as authorized in KRS 315.010~~(22)~~~~[(21)]~~, shall provide notification of the
9 immunization to the individual's primary care provider.