

1 AN ACT relating to the Board of Pharmacy.

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 any
4 information the board requires, which may include affirmative evidence of
5 the applicant's ability to comply with the reasonable standards and
6 regulations as may be prescribed by the board.

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

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

12 (a) 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; and

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

20 (3) (a) The inspection report required pursuant to subsection (2) of this section
21 shall be deemed current for the purposes of this section if the inspection
22 was conducted:

23 1. No more than one (1) year prior to the date of submission of an
24 application for a permit to the board; or

25 2. No more than two (2) years prior to the date of submission of an
26 application for renewal of a permit to the board.

27 (b) If the outsourcing facility has not been inspected by the United States Food

1 and Drug Administration within the period required under subparagraph 1.
2 of paragraph (a) of this subsection, the board may:

3 1. Accept an inspection report or other documentation from another
4 entity that is satisfactory to the board; or

5 2. Cause an inspection to be conducted by its duly authorized agent and
6 charge an inspection fee in an amount sufficient to cover the costs of
7 the inspection.

8 (4) (a) Upon receipt of an application for a permit to operate an outsourcing
9 facility accompanied by the permit fee prescribed by administrative
10 regulation, the board shall:

11 1. Issue a permit if the outsourcing facility meets the standards and
12 requirements of this chapter and administrative regulations
13 promulgated by the board; or

14 2. Refuse to issue or renew any permit to operate if the outsourcing
15 facility fails to meet the standards and requirements of this chapter
16 and administrative regulations promulgated by the board.

17 (b) The board shall act upon an application for a permit to operate within thirty
18 (30) days of the receipt of the application. The board may issue a temporary
19 permit to operate in any instance where it considers additional time
20 necessary for investigation and consideration before taking final action on
21 the application. The temporary permit shall be valid for a period of thirty
22 (30) days, unless extended.

23 (5) A separate permit to operate shall be required for each outsourcing facility.

24 (6) (a) Each permit to operate an outsourcing facility, unless suspended or
25 revoked, shall expire on June 30 following its date of issuance and be
26 renewable annually thereafter upon proper application accompanied by the
27 renewal fee as established by an administrative regulation of the board. The

1 nonrefundable renewal fee shall not exceed five hundred dollars (\$500).

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

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

10 (8) The board may promulgate administrative regulations to ensure:

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

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

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

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

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

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

26 (1) (a) Each out-of-state outsourcing facility that does business, physically or by
27 means of the Internet, facsimile, phone, mail, or any other means, inside

1 this Commonwealth shall hold a current outsourcing facility permit issued
2 by the board.

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

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

11 1. Exceed five hundred dollars (\$500); or

12 2. Exceed the current fee for an in-state outsourcing facility permit.

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

15 (a) Register as an outsourcing facility with the United States Secretary of
16 Health and Human Services in accordance with 21 U.S.C. sec. 353b; and

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

23 (3) (a) The inspection report required pursuant to paragraph (b) of subsection (2)
24 of this section shall be deemed current for the purposes of this section if the
25 inspection was conducted:

26 1. No more than one (1) year prior to the date of submission of an
27 application for a permit to the board; or

1 2. No more than two (2) years prior to the date of submission of an
2 application for renewal of a permit to the board.

3 (b) If the out-of-state outsourcing facility has not been inspected by the United
4 States Food and Drug Administration within the period required under
5 subparagraph 1. of paragraph (a) of this subsection, the board may:

6 1. Accept an inspection report or other documentation from another
7 entity that is satisfactory to the board; or

8 2. Cause an inspection to be conducted by its duly authorized agent and
9 charge a nonrefundable inspection fee in an amount sufficient to
10 cover the costs of the inspection.

11 (4) (a) Upon receipt of an application to operate an out-of-state outsourcing
12 facility, accompanied by the permit fee required by subsection (1) of this
13 section, the board shall:

14 1. Issue a permit if the out-of-state outsourcing facility meets the
15 standards and requirements of this chapter and administrative
16 regulations promulgated by the board; or

17 2. Refuse to renew any permit to operate unless the out-of-state
18 outsourcing facility meets the standards and requirements of this
19 chapter and administrative regulations promulgated by the board.

20 (b) The board shall act upon an application for a permit to operate within thirty
21 (30) days after the receipt thereof. The board may issue a temporary permit
22 to operate in any instance where it considers additional time necessary for
23 investigation and consideration before taking final action upon the
24 application, and the temporary permit shall be valid for a period of thirty
25 (30) days, unless extended.

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

- 1 (6) Each out-of-state outsourcing facility granted an out-of-state outsourcing facility
2 permit by the board shall disclose to the board the location, names, and titles of
3 all principal corporate officers and all pharmacists who are dispensing
4 prescription drugs to entities within the Commonwealth. A report containing this
5 information shall be made to the board on an annual basis and within thirty (30)
6 days after any change of office, corporate officer, or pharmacist.
- 7 (7) (a) An out-of-state outsourcing facility granted an out-of-state outsourcing
8 facility permit shall comply with all requests for information within three
9 (3) business days of a written request by the board or its agents.
- 10 (b) An out-of-state outsourcing facility shall maintain at all times a valid
11 unexpired permit, license, or registration to conduct the outsourcing facility
12 in compliance with the laws of the jurisdiction in which it is a resident.
- 13 (c) As a prerequisite to seeking a permit from the board, the out-of-state
14 outsourcing facility shall submit a copy of the most recent inspection report
15 resulting from an inspection conducted by the regulatory or licensing
16 agency of the jurisdiction in which it is located. Thereafter, the out-of-state
17 outsourcing facility granted a permit shall submit to the board a copy of any
18 subsequent inspection report of the outsourcing facility conducted by the
19 regulatory or licensing body of the jurisdiction in which it is located.
- 20 (8) Each out-of-state outsourcing facility granted an out-of-state outsourcing facility
21 permit by the board shall maintain records of any controlled substances or
22 dangerous drugs.
- 23 (9) Each out-of-state outsourcing facility shall, during its regular hours of operation,
24 but not less than five (5) days per week and for a minimum of forty (40) hours per
25 week, provide a toll-free telephone service directly to the pharmacist in charge of
26 the out-of-state outsourcing facility for the purpose of facilitating
27 communication. A toll-free number shall be placed on a label affixed to each

1 container of drugs dispensed to an entity within the Commonwealth.

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

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

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

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

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

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

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

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

1 As used in KRS 315.400 to 315.412:

- 2 (1) "Authorized distributor of record" means a wholesale distributor that:
- 3 (a) Has established an ongoing relationship with a manufacturer to distribute the
- 4 manufacturer's prescription drug. An ongoing relationship exists between a
- 5 wholesale distributor and a manufacturer if the wholesale distributor,
- 6 including any affiliated group of the wholesale distributor as defined in
- 7 Section 1504 of the Internal Revenue Code, has a written agreement for
- 8 distribution in effect; and
- 9 (b) Is listed on the manufacturer's current list of authorized distributors of record;
- 10 (2) "Co-licensed partner" means two (2) or more entities that have the right to engage in
- 11 the manufacturing or marketing or both of a prescription drug consistent with the
- 12 Federal Drug Administration's implementation of the federal Prescription Drug
- 13 Marketing Act;
- 14 (3) "Co-licensed product" means a prescription drug manufactured by two (2) or more
- 15 co-licensed partners;
- 16 (4) "Counterfeit prescription drug" means a drug which, or the container or labeling of
- 17 which, without authorization, bears the trademark, trade name, or other identifying
- 18 mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor,
- 19 packer, or distributor other than the person or persons who in fact manufactured,
- 20 processed, packed, or distributed the drug and which thereby falsely purports or is
- 21 represented to be the product of, or to have been packed or distributed by, the other
- 22 drug manufacturer, processor, packer, or distributor;
- 23 (5) **"Dispenser" means a retail pharmacy, hospital pharmacy, a group of chain**
- 24 **pharmacies under common ownership and control that do not act as a wholesale**
- 25 **distributor, or any other person authorized by law to dispense or administer**
- 26 **prescription drugs, and the affiliated warehouses or distribution centers of such**
- 27 **entities under common ownership and control that do not act as a wholesale**

1 *distributor. "Dispenser" shall not include a person who dispenses only products*
2 *to be used in animals in accordance with 21 U.S.C. sec. 360b(a)(4) and (5);*

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

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

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

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

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

19 (a) Transfers of a prescription drug between health-care entities or between a
20 health-care entity and a retail pharmacy to alleviate a temporary shortage of a
21 prescription drug arising from delays in or interruptions of the regular
22 distribution schedules;

23 (b) Sales of drugs for use in the treatment of acutely ill or injured persons to
24 nearby emergency medical services providers, firefighting organizations, or
25 licensed health-care practitioners in the same marketing or service area;

26 (c) The provision of emergency supplies of drugs to nearby nursing homes, home
27 health agencies, or hospice organizations for emergency use when necessary

1 drugs cannot be obtained; or

2 (d) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy
3 to alleviate a temporary shortage;

4 ~~(8)~~~~(7)~~ "End user" means a patient or consumer that uses a prescription drug as
5 prescribed by an authorized health-care professional;

6 ~~(9)~~~~(8)~~ "FDA" means the United States Food and Drug Administration and any
7 successor agency;

8 ~~(10)~~~~(9)~~ "Manufacturer" means the same as defined in KRS 315.010;

9 ~~(11)~~~~(10)~~ "Manufacturer's exclusive distributor" means a distributor who:

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

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

14 (c) Is licensed under KRS 315.402; and

15 (d) Is an authorized distributor of record;

16 ~~(12)~~~~(11)~~ "Normal distribution channel" means a chain of custody for a prescription
17 drug from a manufacturer, a manufacturer's co-licensed partner, a manufacturer's
18 third-party logistics provider, or a manufacturer's exclusive distributor that goes
19 directly, by drop shipment or by intracompany transfer, to:

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

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

26 (c) An authorized distributor of record:

27 1. Then to a pharmacy or other designated person authorized by law to

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

7 (d) A nonprofit organization under state contract to distribute prescription drugs

8 to pharmacies pursuant to the state's emergency response plan and the

9 subsequent distribution of those prescription drugs to pharmacies;

10 ~~(13)~~~~(12)~~ "Pedigree" means a document or electronic file containing information that

11 records each distribution of a prescription drug;

12 ~~(14)~~~~(13)~~ "Pharmacy warehouse" means a physical location for prescription drugs that

13 acts as a central warehouse and performs intracompany sales or transfers of

14 prescription drugs to a group of pharmacies under common ownership and control;

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

16 **(16) "Repackager" means a person who owns or operates an establishment that**

17 **repacks and relabels a product or package for further sale or distribution without**

18 **a further transaction;**

19 ~~(17)~~~~(15)~~ "Reverse distributor" means every person who acts as an agent for

20 pharmacies, drug wholesalers, manufacturers, or other entities by receiving, taking

21 inventory, and managing the disposition of outdated or nonsalable drugs;

22 ~~(18)~~~~(16)~~ "Third-party logistics provider" means an entity that contracts with a

23 manufacturer, **wholesale distributor, repackager, or dispenser** to provide ~~and~~~~or~~

24 coordinate ~~the~~ warehousing~~, distribution,~~ or other **logistics** ~~similar~~ services on

25 behalf of a manufacturer, **wholesale distributor, repackager, or dispenser** but does

26 not take title to the drug or have responsibility to direct the sale of the ~~the~~

27 ~~manufacturer's~~ drug. A third-party logistics provider ~~who is a licensed wholesale~~

1 ~~distributor under KRS 315.402 and is a manufacturer's authorized distributor of~~
2 ~~record~~ shall be considered as part of the normal distribution channel;

3 (19)~~(17)~~ "Wholesale distribution" means the distribution of a prescription drug to
4 persons other than an end user, but does not include:

- 5 (a) Intracompany sales or transfers;
- 6 (b) The sale, purchase, distribution, trade, or transfer of a prescription drug for
7 emergency medical reasons;
- 8 (c) The distribution of prescription drug samples by a manufacturer or authorized
9 distributor;
- 10 (d) Drug returns or transfers to the original manufacturer, original wholesale
11 distributor, or transfers to a reverse distributor or third-party returns processor;
- 12 (e) The sale, purchase, or trade of a drug pursuant to a prescription;
- 13 (f) The delivery of a prescription drug by a common carrier;
- 14 (g) The purchase or acquisition by a health-care entity or pharmacy that is a
15 member of a group purchasing organization of a drug for its own use from the
16 group purchasing organization, or health-care entities or pharmacies that are
17 members of the group organization;
- 18 (h) The sale, purchase, distribution, trade, or transfer of a drug by a charitable
19 health-care entity to a nonprofit affiliate of the organization as otherwise
20 permitted by law;
- 21 (i) The sale, transfer, merger, or consolidation of all or part of the business of a
22 pharmacy with another pharmacy or pharmacies; or
- 23 (j) The distribution of a prescription drug to a health-care practitioner or to
24 another pharmacy if the total number of units transferred during a twelve (12)
25 month period does not exceed five percent (5%) of the total number of all
26 units dispensed by the pharmacy during the immediate twelve (12) month
27 period; and

1 ~~(20)~~~~(18)~~ "Wholesale distributor" means an entity engaged in the wholesale distribution
 2 of prescription drugs, including but not limited to manufacturers, manufacturers'
 3 exclusive distributors, authorized distributors of record, drug wholesalers or
 4 distributors, ~~third-party logistics providers,~~ third-party returns processors, reverse
 5 distributors, and pharmacy warehouses and retail pharmacies that engage in the
 6 wholesale distribution of a prescription drug.

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

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

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

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

13 *(2) A license issued under subsection (1) of this section shall be renewed annually*
 14 *upon:*

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

16 *(b) Payment of a nonrefundable renewal fee established by the board through*
 17 *the promulgation of an administrative regulation.*

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

22 *(a) The state from which the third-party logistics provider ships, if that state*
 23 *licenses third-party logistics providers; or*

24 *(b) The United States Food and Drug Administration.*

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

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

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

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

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

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

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

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

15 (b) Type of ownership, whether individual, partnership, limited liability
16 company, or corporation;

17 (c) Name of the owner or owners, including:

18 1. If a person, the name, address, Social Security number, and date of
19 birth;

20 2. If other than a person, the name, address, and Social Security number
21 and date of birth of each partner, limited liability company member, or
22 corporate officer and corporate director and the federal employer
23 identification number;

24 3. If a corporation, the state of incorporation;

25 4. If a publicly traded corporation, the information described in
26 subparagraph 2. of this paragraph is not required for corporate
27 officers and corporate directors; and

1 (d) Upon the board's written request, a list of all manufacturers, wholesale
 2 distributors, repackagers, and dispensers for whom the third-party logistics
 3 provider provides services.

4 (2) Renewal applicants shall provide the items listed in subsection (1) of this section
 5 and any other information the board deems necessary to protect the public health
 6 and safety as promulgated by administrative regulation.

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

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

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

13 (a) A finding by a law enforcement agency or regulatory agency that the
 14 applicant or any of its owners has violated federal, state, or local laws;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24 ➔SECTION 9. A NEW SECTION OF KRS 315.400 TO 315.412 IS CREATED
 25 TO READ AS FOLLOWS:

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

- 1 (a) The Drug Supply Chain Security Act of 2013 and rules promulgated
2 thereunder; and
3 (b) The storage practices set out in 21 U.S.C. sec. 360eee-3(d)(2)(C).
4 (2) A third-party logistics provider shall allow the board and authorized federal,
5 state, and local law enforcement officials to enter and inspect its premises and
6 delivery vehicles, to audit its records and written operating procedures, and to
7 confiscate prescription drugs and records to the extent authorized by law, rule, or
8 regulation.
9 (3) Failure to operate in compliance with all applicable federal, state, and local laws
10 and regulations shall constitute unprofessional conduct pursuant to KRS
11 315.121(1)(a).

12 ➔SECTION 10. A NEW SECTION OF KRS 315.400 TO 315.412 IS CREATED
13 TO READ AS FOLLOWS:

- 14 (1) A medical gas wholesaler, whether located within the Commonwealth or
15 operating within the Commonwealth from a location outside the Commonwealth,
16 shall be licensed by the board. Each license application shall include a
17 nonrefundable fee which shall:
18 (a) Be prescribed by administrative regulation promulgated by the board in an
19 amount not to exceed two hundred fifty dollars (\$250); and
20 (b) Not be increased by more than twenty-five dollars (\$25) per year.
21 (2) A medical gas wholesaler shall be required to maintain accurate records of all
22 drugs handled. Records shall be made available to agents of the board for
23 inspection upon request.
24 (3) Failure to report to the board or willful submission of inaccurate information
25 shall be grounds for disciplinary action under KRS 315.131.
26 (4) The board shall promulgate administrative regulations to specify the criteria for
27 licensure and discipline of a medical gas wholesaler.

1 ➔Section 11. 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 fourteen (14) to seventeen (17) years
4 of age or an influenza vaccine to an individual who is nine (9) to thirteen (13) years of
5 age, as authorized in KRS 315.010(22)[~~(21)~~], shall provide notification of the
6 immunization to the individual's primary care provider.