AN ACT relating to pharmaceuticals.

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

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

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

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

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

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

(b) Billing and collections activities, including:

1. Contacting patients for copayments and coinsurance payments; and

2. Communicating with insurance companies;

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

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

(e) Initiating insurance prior authorizations for submission to the licensed pharmacy, including communications with the prescribing physician to collect, record, and transmit information to insurance companies, so long as the activity does not include the authorization or receipt of new or refill prescription orders;

(f) Answering and transferring telephone calls, whether or not such calls require accessing a patient record, so long as the call does not involve the

interpretation, evaluation, or implementation of a drug order; and

(g) Communicating with patients via telephone or electronically regarding refill reminders, so long as the communication does not involve the interpretation, evaluation, or implementation of a drug order and a pharmacist is readily available for patient consultation;

(3) "Association" means the Kentucky Pharmacists Association;

(4) "Board" means the Kentucky Board of Pharmacy;

(5) "Collaborative care agreement" means a written agreement between a pharmacist or pharmacists and a practitioner or practitioners that outlines a plan of cooperative management of patients' drug-related health care needs where:

(a) Patients' drug-related health care needs fall within the practitioner's or practitioners' statutory scope of practice;

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

(c) The agreement:

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

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

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

(6) "Compound" or "compounding" means the preparation or labeling of a drug pursuant to or in anticipation of a valid prescription drug order, including but not limited to packaging, intravenous admixture or manual combination of drug ingredients. "Compounding," as used in this chapter, shall not preclude simple reconstitution, mixing, or modification of drug products prior to administration by

nonpharmacists;

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

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

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

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

(a) Articles recognized as drugs or drug products in any official compendium or supplement thereto;

(b) Articles, other than food, intended to affect the structure or function of the body of man or other animals;

(c) Articles, including radioactive substances, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; or

(d) Articles intended for use as a component of any articles specified in paragraphs (a) to (c) of this subsection;

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

(a) Evaluation of prescription drug orders and patient records for:

1. Known allergies;

2. Rational therapy contraindications;

3. Appropriate dose and route of administration;

4. Appropriate directions for use; or

5. Duplicative therapies.

(b) Evaluation of prescription drug orders and patient records for drug-drug, drug-food, drug-disease, and drug-clinical laboratory interactions;

(c) Evaluation of prescription drug orders and patient records for adverse drug reactions; or

(d) Evaluation of prescription drug orders and patient records for proper utilization and optimal therapeutic outcomes;

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

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

(a) A person that holds an application approved under 21 U.S.C. sec. 355 or a license issued under 42 U.S.C. sec. 262 for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;

(b) A co-licensed partner of the person described in paragraph (a) of this subsection that obtains the product directly from a person described in this paragraph or paragraph (a) of this subsection;

(c) An affiliate of a person described in paragraph (a) or (b) of this subsection who receives the product directly from a person described in this paragraph or in paragraph (a) or (b) of this subsection~~[means any person, except a pharmacist compounding in the normal course of professional practice, within the Commonwealth engaged in the commercial production, preparation, propagation, compounding, conversion, or processing of a drug, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis, or both, and includes any packaging or~~

~~repackaging of a drug or the labeling or relabeling of its container]~~; ***or***

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

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

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

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

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

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

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

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

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

(a) Currently certified by the board to engage in the practice of pharmacy under the direction of a licensed pharmacist and who satisfactorily progresses toward meeting the requirements for licensure as a pharmacist;

(b) A graduate of an approved college or school of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) certificate, who is currently

licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

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

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

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

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

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

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

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

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

(22) ~~[(21)]~~ "Practice of pharmacy" means interpretation, evaluation, and implementation of medical orders and prescription drug orders; responsibility for dispensing prescription drug orders, including radioactive substances; participation in drug and drug-related device selection; administration of medications or biologics in the course of dispensing or maintaining a prescription drug order; the administration of adult immunizations pursuant to prescriber-approved protocols; the administration

of influenza vaccines to individuals nine (9) to thirteen (13) years of age pursuant to prescriber-approved protocols with the consent of a parent or guardian; the administration of immunizations to individuals fourteen (14) to seventeen (17) years of age pursuant to prescriber-approved protocols with the consent of a parent or guardian; the administration of immunizations to a child as defined in KRS 214.032, pursuant to protocols as authorized by KRS 315.500; drug evaluation, utilization, or regimen review; maintenance of patient pharmacy records; and provision of patient counseling and those professional acts, professional decisions, or professional services necessary to maintain and manage all areas of a patient's pharmacy-related care, including pharmacy-related primary care as defined in this section;

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

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

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

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

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

(25) ~~[(24)]~~ "Prescription drug order" means an original or new order from a practitioner for drugs, drug-related devices or treatment for a human or animal, including orders issued through collaborative care agreements or protocols authorized by the board. Lawful prescriptions result from a valid practitioner-patient relationship, are

intended to address a legitimate medical need, and fall within the prescribing practitioner's scope of professional practice;

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

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

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

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

(1) (a) A person shall not operate an outsourcing facility within this Commonwealth, physically or by means of the Internet, facsimile, phone, mail, or any other means, without first obtaining a permit from the board.

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

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

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

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

2. Submit a copy of a current inspection report resulting from an

inspection conducted by the United States Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the United States Food and Drug Administration.

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

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

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

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

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

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

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

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

2. Refuse to issue or renew any permit to operate if the outsourcing

facility fails to meet the requirements of this chapter and the administrative regulations promulgated by the board.

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

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

(5) (a) Each permit to operate an outsourcing facility, unless suspended or revoked, shall expire on June 30 following its date of issuance and be renewable annually thereafter upon proper application accompanied by the renewal fee as established by administrative regulations promulgated by the board. The renewal fee shall not exceed five hundred dollars ($500).

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

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

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

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

(b) Health and sanitation standards for areas within outsourcing facilities that

adhere to Current Good Manufacturing Practices published by the United States Food and Drug Administration.

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

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

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

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

(1) (a) Each out-of-state outsourcing facility that does business physically or by means of the Internet, facsimile, phone, mail, or any other means, inside this Commonwealth, shall hold a current outsourcing facility permit issued by the board.

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

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

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

2. The current in-state outsourcing facility permit.

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

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

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

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

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

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

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

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

b. Cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

(3) (a) Upon receipt of an application for a permit to operate an out-of-state outsourcing facility, accompanied by the permit fee required by subsection

(1) of this section, the board shall:

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

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

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

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

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

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

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

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

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

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

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

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

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

(b) An additional nonrefundable fee not to exceed the annual renewal fee may be assessed and set by administrative regulation as a delinquent renewal

penalty for failure to renew by June 30 of each year.

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

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

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

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

As used in KRS 315.400 to 315.412:

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

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

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

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

~~Marketing Act;~~

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

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

(4) ~~[(5)]~~ ***"Dispenser" means:***

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

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

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

(6) "Drug shipment" means ***a product not physically handled or stored by a wholesale distributor and that is exempt from Section 582 of the Federal Drug Quality and***

Security Act, except the notification requirements under clauses (ii), (iii), and (iv) of subsection (c)(4)(B) of Section 582 of the Federal Drug Quality and Security Act, provided that the manufacturer, repackager, or other wholesale distributor that distributes the product to the dispenser by means of a drop shipment for the wholesale distributor includes on the transaction information and transaction history to the dispenser the contact information of the wholesale distributor and provides the transaction information, transaction history, and transaction statement directly to the dispenser. Providing administrative services, including the processing of orders and payments, shall not by itself be construed as being involved in the handling, distribution, or storage of a product~~[the sale of a prescription drug to a wholesale distributor by the drug's manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, the manufacturer's exclusive distributor, or by an authorized distributor of record that purchased the product directly from the manufacturer, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor, and:~~

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

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

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

(7)~~[(6)]~~ "Emergency medical reasons" includes but is not limited to:

(a) Transfers of a prescription drug between health-care entities or between a

health-care entity and a retail pharmacy to alleviate a temporary shortage of a prescription drug arising from delays in or interruptions of the regular distribution schedules;

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

(c) The provision of emergency supplies of drugs to nearby nursing homes, home health agencies, or hospice organizations for emergency use when necessary drugs cannot be obtained; or

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

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

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

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

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

(a) Is counterfeit, diverted, or stolen;

(b) Is intentionally adulterated so that the product would result in serious adverse health consequences or death to humans;

(c) Is the subject of a fraudulent transaction; or

(d) Appears otherwise unfit for distribution so that the product would be reasonably likely to result in serious adverse health consequences or death

to humans;

(12) ~~[(9)]~~ "Manufacturer" means the same as defined in KRS 315.010;

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

(14) ~~[(10) "Manufacturer's exclusive distributor" means a distributor who:~~

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

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

~~(c) Is licensed under KRS 315.402; and~~

~~(d) Is an authorized distributor of record;~~

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

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

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

~~(c) An authorized distributor of record:~~

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

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

~~3. Then to another authorized distributor of record to a licensed health-care facility or~~

~~pharmacy, or a practitioner authorized by law to distribute a prescription drug to an end user; or~~

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

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

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

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

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

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

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

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

(a) Intracompany distribution of any product between members of an affiliate or within a manufacturer;

(b) The distribution of a product among hospitals or other health care entities that are under common control;

(c) The distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to Section 319 of the Federal Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason;

(d) The dispensing of a product pursuant to a prescription executed in accordance with Section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act;

(e) The distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with Section 503(d) of the Federal Food, Drug, and Cosmetic Act;

(f) The distribution of blood or blood components intended for transfusion;

(g) The distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

(h) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in Section 501(c)(3) of the Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(i) The distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

(j) The dispensing of a product approved under Section 512(c) of the Federal

Food, Drug, and Cosmetic Act;

(k) Products transferred to or from any facility that is licensed by the Nuclear Regulatory Commission or by the state pursuant to an agreement with the commission under Section 274 of the Federal Atomic Energy Act, 42 U.S.C. sec. 2021;

(l) A combination product that is not subject to approval under Section 505 of the Federal Drug Quality and Security Act or licensure under Section 351 of the Federal Public Health Service Act, and that is:

1. A product composed of a device and one (1) or more other regulated components such as a drug or drug device, a biologic or biologic device, or a drug and biologic or drug and biologic device that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

2. Two (2) or more separate products packaged together in a single package or as a unit and composed of a drug and device or device and biological product; or

3. Two (2) or more finished medical devices plus one (1) or more drug or biological products that are packaged together in what is referred to as a medical convenience kit as described in subparagraph (m) of this section;

(m) The distribution of a medical convenience kit or collection of finished medical devices which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user, if:

1. The medical convenience kit is assembled in an establishment that is registered with the federal Food and Drug Administration as a device manufacturer in accordance with Section 510(b)(2) of the Federal

Food, Drug, and Cosmetic Act;

2. The medical convenience kit does not contain a controlled substance that appears in a schedule contained in the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970;

3. In the case of a medical convenience kit that includes a product, the person that manufacturers the kit:

a. Purchased the product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer; and

b. Does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

4. In the case of a medical convenience kit that includes a product, the product is:

a. An intravenous solution intended for the replenishment of fluids and electrolytes;

b. A product intended to maintain the equilibrium of water and minerals in the body;

c. A product intended for irrigation or reconstitution;

d. An anesthetic;

e. An anticoagulant;

f. A vasopressor; or

g. A sympathomimetic;

(n) The distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes such as sodium, chloride, and potassium, or calories such as dextrose and amino acids;

(o) The distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(p) The distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(q) The distribution of a medical gas as defined in Section 575 of the Federal Food, Drug, and Cosmetic Act; or

(r) The distribution or sale of any licensed product under Section 351 of the Federal Public Health Service Act that meets the definition of a device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act;

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

(a) Intracompany sales or transfers;

(b) The sale, purchase, distribution, trade, or transfer of a prescription drug for emergency medical reasons;

(c) The distribution of prescription drug samples by a manufacturer or authorized distributor;

(d) Drug returns or transfers to the original manufacturer, original wholesale distributor, or transfers to a reverse distributor or third-party returns processor;

(e) The sale, purchase, or trade of a drug pursuant to a prescription;

(f) The delivery of a prescription drug by a common carrier;

(g) The purchase or acquisition by a health-care entity or pharmacy that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization, or health-care entities or pharmacies that are members of the group organization;

(h) The sale, purchase, distribution, trade, or transfer of a drug by a charitable health-care entity to a nonprofit affiliate of the organization as otherwise permitted by law;

(i) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy with another pharmacy or pharmacies; or

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

(21) ~~[(18)]~~ "Wholesale distributor" ***or "virtual wholesale distributer"*** means ***a person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or repackager engaged in wholesale distribution as defined by 21 U.S.C. sec. 353(e)(4) as amended by the Federal Drug Supply Chain Security Act*** ~~[an entity engaged in the wholesale distribution of prescription drugs, including but not limited to manufacturers, manufacturers' exclusive distributors, authorized distributors of record, drug wholesalers or distributors, third-party logistics providers, third-party returns processors, reverse distributors, and pharmacy warehouses and retail pharmacies that engage in the wholesale distribution of a prescription drug]~~.

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

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

(a) Within the borders of Kentucky; or

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

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

(a) Completion of an application; and

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

(3) A third-party logistics provider located in another state seeking to ship a

prescription drug into Kentucky shall provide documentation upon request by the by the board or its staff that the third-party logistics provider is licensed as a third-party logistics provider by:

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

(b) The United States Food and Drug Administration.

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

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

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

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

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

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

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

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

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

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

1. If a person, the name, address, Social Security number, and date of

birth;

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

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

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

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

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

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

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

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

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

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

(d) The furnishing by the applicant of false or fraudulent material in any

application;

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

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

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

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

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

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

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

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

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

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

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

(3) A third-party logistics provider shall not have, as an owner or designated

representative, anyone who has violated federal or state requirements for third-party logistics provider licensure and presented a threat of serious adverse health consequences or death to humans.

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

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

(a) The Drug Supply Chain Security Act of 2013 and rules promulgated thereunder; and

(b) The storage practices set out in 21 U.S.C. sec. 360eee-3(d)(2)(C)

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

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

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

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

(a) Be prescribed by administrative regulation promulgated by the board in an amount not to exceed two hundred fifty dollars ($250); and

(b) Not be increased by more than twenty-five dollars ($25) per year.

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

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

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

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

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

➔Section 12. KRS 194A.450 is repealed and reenacted as a new section of KRS Chapter 315 to read as follows:

For the purposes of ***Sections 12 to 17 of this Act*** ~~[KRS 194A.450 to 194A.458]~~:

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

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

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

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

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

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

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

➔Section 13. KRS 194A.452 is repealed and reenacted as a new section of KRS Chapter 315 to read as follows:

(1) The ***board*** ~~[Cabinet for Health and Family Services]~~ shall establish and maintain a legend drug repository program to support the donation of a legend drug or supplies

needed to administer a legend drug for use by an individual who meets the eligibility criteria specified by an administrative regulation promulgated by the ***board***~~[cabinet]~~. The repository program shall not accept any controlled substance.

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

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

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

(5) Nothing in this section or ***Section 14 of this Act***~~[KRS 194A.454]~~ shall require a health facility, pharmacy, pharmacist, or practitioner to participate in the program established in this section.

➔Section 14. KRS 194A.454 is repealed and reenacted as a new section of KRS Chapter 315 to read as follows:

(1) A legend drug or supplies used to administer a legend drug may be accepted and dispensed under the program established in ***Section 13 of this Act***~~[KRS 194A.452]~~ only if the following requirements are met:

(a) The legend drug or supplies needed to administer the legend drug is in its original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened;

(b) The legend drug is not classified as a controlled substance;

(c) The legend drug or supplies needed to administer a legend drug is not adulterated or misbranded, as determined by a pharmacist employed by, or

under contract with, the health facility or pharmacy, who shall inspect the drug or supplies needed to administer a legend drug before the drug or supplies are dispensed; and

(d) The legend drug or supplies needed to administer a legend drug are prescribed by a physician, advanced practice registered nurse, or physician assistant and dispensed by a pharmacist.

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

➔Section 15. KRS 194A.456 is repealed and reenacted as a new section of KRS Chapter 315 to read as follows:

(1) Unless the manufacturer of a legend drug or supply needed to administer a legend drug exercises bad faith or fails to exercise ordinary care, the manufacturer of a legend drug or supply shall not be subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of the drug or supply under the legend drug repository created under ***Section 13 of this Act***~~[KRS 194A.452]~~, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

(2) Health facilities, pharmacies, and health care providers shall be immune from civil liability for injury to or the death of an individual to whom a legend drug or supply is dispensed and shall not be subject to disciplinary action for unprofessional conduct for their acts or omissions related to donating, accepting, distributing, or dispensing a legend drug or supply under ***Sections 12 to 17 of this Act***~~[KRS 194A.450 to 194A.458]~~, unless the act or omission involves reckless, wanton, or intentional misconduct or the act or omission results from failure to exercise ordinary care.

➔Section 16. KRS 194A.458 is repealed and reenacted as a new section of KRS

Chapter 315 to read as follows:

The ***board***~~[Cabinet for Health and Family Services]~~ shall promulgate administrative regulations to establish:

(1) The requirements for health facilities and pharmacies to accept and dispense donated legend drugs or supplies needed to administer legend drugs under ***Sections 13 and 14 of this Act***~~[KRS 194A.452 and 194A.454]~~, including all of the following:

(a) Eligibility criteria for health facilities;

(b) Standards and procedures for accepting, safely storing, and dispensing donated legend drugs or supplies needed to administer legend drugs;

(c) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine if these are in their original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened; and

(d) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine that these are not adulterated or misbranded;

(2) Eligibility criteria for individuals to receive donated legend drugs or supplies needed to administer legend drugs dispensed under ***Sections 13 and 14 of this Act***~~[KRS 194A.452 and 194A.454]~~;

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

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

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

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

legend drugs;

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

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

➔SECTION 17. A NEW SECTION OF KRS CHAPTER 315 IS CREATED TO READ AS FOLLOWS:

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