AN ACT relating to dialysate drugs and devices.

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

➔Section 1. KRS 315.0351 is amended to read as follows:

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

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

(b) ~~[(2)]~~ Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board shall disclose to the board the location, names, and titles of all principal corporate officers and all pharmacists who are dispensing prescription drugs to residents of the Commonwealth. A report containing this information shall be made to the board on an annual basis and within thirty (30) days after any change of office, corporate officer, or pharmacist**;** ~~[.]~~

(c) ~~[(3)]~~ Every out-of-state pharmacy granted an out-of-state pharmacy permit shall comply with all statutorily-authorized directions and requests for information from any regulatory agency of the Commonwealth and from the board in accordance with the provisions of this section. The out-of-state pharmacy shall maintain at all times a valid unexpired permit, license, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction in which it is a resident. As a prerequisite to seeking a permit from the Kentucky Board of Pharmacy, the out-of-state pharmacy shall submit a

copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. Thereafter, the out-of-state pharmacy granted a permit shall submit to the Kentucky Board of Pharmacy a copy of any subsequent inspection report on the pharmacy conducted by the regulatory or licensing body of the jurisdiction in which it is located**;** ~~[.]~~

(d) ~~[(4)]~~ Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board shall maintain records of any controlled substances or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed**;** ~~[.]~~

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

(f) ~~[(6)]~~ Each out-of-state pharmacy shall, during its regular hours of operation, but not less than six (6) days per week and for a minimum of forty (40) hours per week, provide a toll-free telephone service directly to the pharmacist in charge of the out-of-state pharmacy and available to both the patient and each licensed and practicing in-state pharmacist for the purpose of facilitating communication between the patient and the Kentucky pharmacist with access to the patient's prescription records. A toll-free number shall be placed on a label affixed to each container of drugs dispensed to patients within the Commonwealth**;** ~~[.]~~

(g) ~~[(7)]~~ Each out-of-state pharmacy shall have a pharmacist in charge who is licensed to engage in the practice of pharmacy by the Commonwealth that shall be responsible for compliance by the pharmacy with the provisions of this section**;** ~~[.]~~

(h) ~~[(8)]~~ Each out-of-state pharmacy shall comply with KRS 218A.202**;** ~~[.]~~

(i) ~~[(9)]~~ Any out-of-state pharmacy that dispenses more than twenty-five percent

(25%) of its total prescription volume as a result of an original prescription order received or solicited by use of the Internet, including but not limited to electronic mail, shall receive and display in every medium in which it advertises itself a seal of approval for the National Association of Boards of Pharmacy certifying that it is a Verified Internet Pharmacy Practice Site (VIPPS) or a seal certifying approval of a substantially similar program approved by the Kentucky Board of Pharmacy. VIPPS, or any other substantially similar accreditation, shall be maintained and remain current***;*** ~~[.]~~

(j) ~~[(10)]~~ Any out-of-state pharmacy doing business in the Commonwealth of Kentucky shall certify the percentage of its annual business conducted via the Internet and electronic mail and submit such supporting documentation as requested by the board, and in a form or application required by the board, when it applies for permit or renewal***;*** ~~[.]~~

(k) ~~[(11)]~~ Any pharmacy doing business within the Commonwealth of Kentucky shall use the address on file with the Kentucky Board of Pharmacy as the return address on the labels of any package shipped into or within the Commonwealth. The return address shall be placed on the package in a clear and prominent manner***; and*** ~~[.]~~

(l) ~~[(12)]~~ The Kentucky Board of Pharmacy may waive the permit requirements of this chapter for an out-of-state pharmacy that only does business within the Commonwealth of Kentucky in limited transactions.

(2) (a) This section shall not apply to the sale or distribution of dialysate drugs or devices necessary to perform home peritoneal kidney dialysis to patients with end-stage renal disease, if:

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

2. The dialysate drugs or devices are lawfully held by a manufacturer or

manufacturer's agent that is properly registered with or licensed by the board as a manufacturer, wholesale distributer, or third-party logistics provider under this chapter;

3. The dialysate drugs or devices are held and delivered in their original, sealed packaging from an Food and Drug Administration approved manufacturing facility;

4. The dialysate drugs or devices are only delivered upon receipt of a physician's prescription by a licensed pharmacy and the transmittal of an order from the licensed pharmacy to the manufacturer or manufacturer's agent; and

5. The manufacturer or manufacturer's agent delivers the dialysate drugs or devices directly to:

a. A patient with end-stage renal disease or the patient's designee for the patient's self-administration of dialysis therapy; or

b. A health care provider or institution for administration or delivery of dialysis therapy to a patient with end-stage renal disease.

(b) 1. A manufacturer or manufacturer's agent who sells or distributes dialysate drugs or devices under this subsection shall employ or contract with a pharmacist who is licensed to engage in the practice of pharmacy by the Commonwealth to conduct a retrospective audit on ten percent (10%) of the orders processed by that manufacturer or manufacturer's agent each month.

2. On or before February 1 of each year, an annual summary of the monthly audits shall be prepared and submitted to the board, in the form prescribed by the board.

3. On or before June 1 of each year, the board shall compile the

summaries of monthly audits into a single report and submit that report to the Interim Joint Committee on Health and Welfare and Family Services.

(c) Prescriptions and records of delivery for dialysate drugs or devices sold or distributed under this subsection shall be maintained by the manufacturer or manufacturer's agent for a minimum of two (2) years and shall be made available to the board upon request.

➔Section 2. KRS 315.040 is amended to read as follows:

(1) Nothing in this chapter shall be construed to prevent, restrict, or otherwise interfere with the sale of nonprescription drugs in their original packages by any retailer. No rule or regulation shall be adopted by the Board of Pharmacy under this chapter which shall require the sale of nonprescription drugs by a licensed pharmacist or under the supervision of a licensed pharmacist.

(2) Nothing in this chapter shall interfere with the professional activities of any licensed practicing physician, or prevent the physician from keeping any drug or medicine that he or she may need in his or her practice, from compounding the physician's own medications, or from dispensing or supplying to patients any article that seems proper to the physician.

(3) Nothing in this chapter pertaining to the use of collaborative care agreements shall apply in any hospital or other health facility operated by a hospital without the express written permission of the hospital's governing body. Collaborative care agreements may be restricted by the policies and procedures of the facility.

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

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

(6) Nothing in this chapter shall be construed to prevent, restrict, or otherwise

interfere with the sale or distribution of dialysate drugs or devices necessary to perform home peritoneal dialysis to patients with end-stage renal disease, provided that the requirements established in subsection (2) of Section 1 of this Act are satisfied. No rule or administrative regulation shall be adopted or promulgated by the board under this chapter that requires the sale or distribution of dialysate drugs or devices necessary to perform home peritoneal dialysis by a licensed pharmacist or under the supervision of a licensed pharmacist.

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

(3) "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) "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) "Drop 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;

(7) "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) "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) "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) "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) "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) "Prescription drug" means the same as defined in KRS 315.010;

(16) "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) "Third-party logistics provider" means an entity that contracts with a manufacturer, wholesale distributor, repackager, or dispenser to provide and coordinate warehousing or other logistics 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 drug. A third-party logistics provider 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 paragraph (m) of this subsection;

(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) "Wholesale distribution" means the distribution of a prescription drug to persons

other than an end user ***or to the end user pursuant to subsection (2) of Section 1 of this Act***, 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) "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.