

1 AN ACT relating to kidney dialysis.

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

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

- 4 (1) Every person or pharmacy located outside this Commonwealth, **except those that**
5 **only provide the services described in subsection (13) of this section,** which does
6 business, physically or by means of the Internet, facsimile, phone, mail, or any other
7 means, inside this Commonwealth within the meaning of KRS Chapter 315, shall
8 hold a current pharmacy permit as provided in KRS 315.035(1) and (4) issued by
9 the Kentucky Board of Pharmacy. The pharmacy shall be designated an "out-of-
10 state pharmacy" and the permit shall be designated an "out-of-state pharmacy
11 permit." The fee for the permit shall not exceed the current in-state pharmacy permit
12 fee as provided under KRS 315.035.
- 13 (2) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board
14 shall disclose to the board the location, names, and titles of all principal corporate
15 officers and all pharmacists who are dispensing prescription drugs to residents of
16 the Commonwealth. A report containing this information shall be made to the board
17 on an annual basis and within thirty (30) days after any change of office, corporate
18 officer, or pharmacist.
- 19 (3) Every out-of-state pharmacy granted an out-of-state pharmacy permit shall comply
20 with all statutorily-authorized directions and requests for information from any
21 regulatory agency of the Commonwealth and from the board in accordance with the
22 provisions of this section. The out-of-state pharmacy shall maintain at all times a
23 valid unexpired permit, license, or registration to conduct the pharmacy in
24 compliance with the laws of the jurisdiction in which it is a resident. As a
25 prerequisite to seeking a permit from the Kentucky Board of Pharmacy, the out-of-
26 state pharmacy shall submit a copy of the most recent inspection report resulting
27 from an inspection conducted by the regulatory or licensing agency of the

1 jurisdiction in which it is located. Thereafter, the out-of-state pharmacy granted a
2 permit shall submit to the Kentucky Board of Pharmacy a copy of any subsequent
3 inspection report on the pharmacy conducted by the regulatory or licensing body of
4 the jurisdiction in which it is located.

5 (4) Every out-of-state pharmacy granted an out-of-state pharmacy permit by the board
6 shall maintain records of any controlled substances or dangerous drugs or devices
7 dispensed to patients in the Commonwealth so that the records are readily
8 retrievable from the records of other drugs dispensed.

9 (5) Records for all prescriptions delivered into Kentucky shall be readily retrievable
10 from the other prescription records of the out-of-state pharmacy.

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

19 (7) Each out-of-state pharmacy shall have a pharmacist in charge who is licensed to
20 engage in the practice of pharmacy by the Commonwealth that shall be responsible
21 for compliance by the pharmacy with the provisions of this section.

22 (8) Each out-of-state pharmacy shall comply with KRS 218A.202.

23 (9) Any out-of-state pharmacy that dispenses more than twenty-five percent (25%) of
24 its total prescription volume as a result of an original prescription order received or
25 solicited by use of the Internet, including but not limited to electronic mail, shall
26 receive and display in every medium in which it advertises itself a seal of approval
27 for the National Association of Boards of Pharmacy certifying that it is a Verified

1 Internet Pharmacy Practice Site (VIPPS) or a seal certifying approval of a
2 substantially similar program approved by the Kentucky Board of Pharmacy.
3 VIPPS, or any other substantially similar accreditation, shall be maintained and
4 remain current.

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

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

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

17 **(13) This section shall not apply to the sale or distribution of dialysate drugs or**
18 **devices necessary to perform home peritoneal kidney dialysis to patients with end-**
19 **stage renal disease, provided that the following criteria are met:**

20 **(a) The dialysate drugs, composed of dextrose or icodextrin, or devices are**
21 **approved or cleared by the federal Food and Drug Administration as**
22 **required by federal law;**

23 **(b) The dialysate drugs or devices are lawfully held by a manufacturer or**
24 **manufacturer's agent that is properly registered or licensed with the board**
25 **as a manufacturer, wholesale distributor, or third-party logistics provider**
26 **under KRS Chapter 315;**

27 **(c) The dialysate drugs or devices are held and delivered in their original,**

1 sealed packaging from the manufacturing facility;

2 (d) The dialysate drugs or devices are delivered only upon receipt of a
3 physician's prescription by a Kentucky licensed pharmacy, and the
4 transmittal of an order from the Kentucky licensed pharmacy to the
5 manufacturer or the manufacturer's agent; and

6 (e) The manufacturer or manufacturer's agent delivers the dialysate drugs or
7 devices directly to:

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

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

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

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

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

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

27 (4) Nothing in this chapter shall interfere with the activities of a physician assistant as

1 authorized in KRS Chapter 311.

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

4 **(6) Nothing in this chapter shall be construed to prevent, restrict, or otherwise**
5 **interfere with the sale or distribution of dialysate drugs or devices necessary to**
6 **perform home peritoneal kidney dialysis to patients with end-stage renal disease,**
7 **provided the requirements of subsection (13) of Section 1 of this Act are satisfied.**
8 **No rule or administrative regulation shall be adopted or promulgated by the**
9 **Board of Pharmacy under this chapter that requires the sale or distribution of the**
10 **dialysate drugs or devices necessary to perform home peritoneal kidney dialysis**
11 **by a licensed pharmacist or under the supervision of a licensed pharmacist.**

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

13 As used in KRS 315.400 to 315.412:

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

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

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

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

24 (3) "Counterfeit prescription drug" means a drug which, or the container or labeling of
25 which, without authorization, bears the trademark, trade name, or other identifying
26 mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor,
27 packer, or distributor other than the person or persons who in fact manufactured,

1 processed, packed, or distributed the drug and which thereby falsely purports or is
2 represented to be the product of, or to have been packed or distributed by, the other
3 drug manufacturer, processor, packer, or distributor;

4 (4) "Dispenser" means:

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

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

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

17 (6) "Drop shipment" means a product not physically handled or stored by a wholesale
18 distributor and that is exempt from Section 582 of the federal Drug Quality and
19 Security Act, except the notification requirements under clauses (ii), (iii), and (iv) of
20 subsection (c)(4)(B) of Section 582 of the federal Drug Quality and Security Act,
21 provided that the manufacturer, repackager, or other wholesale distributor that
22 distributes the product to the dispenser by means of a drop shipment for the
23 wholesale distributor includes on the transaction information and transaction history
24 to the dispenser the contact information of the wholesale distributor and provides
25 the transaction information, transaction history, and transaction statement directly to
26 the dispenser. Providing administrative services, including the processing of orders
27 and payments, shall not by itself be construed as being involved in the handling,

- 1 distribution, or storage of a product;
- 2 (7) "Emergency medical reasons" includes but is not limited to:
- 3 (a) Transfers of a prescription drug between health-care entities or between a
- 4 health-care entity and a retail pharmacy to alleviate a temporary shortage of a
- 5 prescription drug arising from delays in or interruptions of the regular
- 6 distribution schedules;
- 7 (b) Sales of drugs for use in the treatment of acutely ill or injured persons to
- 8 nearby emergency medical services providers, firefighting organizations, or
- 9 licensed health-care practitioners in the same marketing or service area;
- 10 (c) The provision of emergency supplies of drugs to nearby nursing homes, home
- 11 health agencies, or hospice organizations for emergency use when necessary
- 12 drugs cannot be obtained; or
- 13 (d) Transfers of prescription drugs by a retail pharmacy to another retail pharmacy
- 14 to alleviate a temporary shortage;
- 15 (8) "End user" means a patient or consumer that uses a prescription drug as prescribed
- 16 by an authorized health-care professional;
- 17 (9) "Exclusive distributor" means the wholesale distributor that directly purchased the
- 18 product from the manufacturer and is the sole distributor of that manufacturer's
- 19 product to a subsequent repackager, wholesale distributor, or dispenser;
- 20 (10) "FDA" means the United States Food and Drug Administration and any successor
- 21 agency;
- 22 (11) "Illegitimate product" means a product for which credible evidence shows that the
- 23 product:
- 24 (a) Is counterfeit, diverted, or stolen;
- 25 (b) Is intentionally adulterated so that the product would result in serious adverse
- 26 health consequences or death to humans;
- 27 (c) Is the subject of a fraudulent transaction; or

- 1 (d) Appears otherwise unfit for distribution so that the product would be
2 reasonably likely to result in serious adverse health consequences or death to
3 humans;
- 4 (12) "Manufacturer" means the same as defined in KRS 315.010;
- 5 (13) "Medical gas wholesaler" means a person licensed to distribute, transfer, wholesale,
6 deliver, or sell medical gases on drug orders to suppliers or other entities licensed to
7 use, administer, or distribute medical gas;
- 8 (14) "Pharmacy warehouse" means a physical location for prescription drugs that acts as
9 a central warehouse and performs intracompany sales or transfers of prescription
10 drugs to a group of pharmacies under common ownership and control;
- 11 (15) "Prescription drug" means the same as defined in KRS 315.010;
- 12 (16) "Repackager" means a person who owns or operates an establishment that repacks
13 and relabels a product or package for further sale, or distribution without a further
14 transaction;
- 15 (17) "Reverse distributor" means every person who acts as an agent for pharmacies, drug
16 wholesalers, manufacturers, or other entities by receiving, taking inventory, and
17 managing the disposition of outdated or nonsalable drugs;
- 18 (18) "Third-party logistics provider" means an entity that contracts with a manufacturer,
19 wholesale distributor, repackager, or dispenser to provide and coordinate
20 warehousing or other logistics services on behalf of a manufacturer, wholesale
21 distributor, repackager, or dispenser, but does not take title to the drug or have
22 responsibility to direct the sale of the drug. A third-party logistics provider shall be
23 considered as part of the normal distribution channel;
- 24 (19) "Transaction" means the transfer of product between persons in which a change of
25 ownership occurs, with the following exemptions:
- 26 (a) Intracompany distribution of any product between members of an affiliate or
27 within a manufacturer;

- 1 (b) The distribution of a product among hospitals or other health care entities that
2 are under common control;
- 3 (c) The distribution of a product for emergency medical reasons, including a
4 public health emergency declaration pursuant to Section 319 of the federal
5 Public Health Service Act, except that a drug shortage not caused by a public
6 health emergency shall not constitute an emergency medical reason;
- 7 (d) The dispensing of a product pursuant to a prescription executed in accordance
8 with Section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act;
- 9 (e) The distribution of product samples by a manufacturer or a licensed wholesale
10 distributor in accordance with Section 503(d) of the Federal Food, Drug, and
11 Cosmetic Act;
- 12 (f) The distribution of blood or blood components intended for transfusion;
- 13 (g) The distribution of minimal quantities of product by a licensed retail
14 pharmacy to a licensed practitioner for office use;
- 15 (h) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a
16 drug by a charitable organization described in Section 501(c)(3) of the Internal
17 Revenue Code of 1986 to a nonprofit affiliate of the organization to the extent
18 otherwise permitted by law;
- 19 (i) The distribution of a product pursuant to the sale or merger of a pharmacy or
20 pharmacies or a wholesale distributor or wholesale distributors, except that
21 any records required to be maintained for the product shall be transferred to
22 the new owner of the pharmacy or pharmacies or wholesale distributor or
23 wholesale distributors;
- 24 (j) The dispensing of a product approved under Section 512(c) of the Federal
25 Food, Drug, and Cosmetic Act;
- 26 (k) Products transferred to or from any facility that is licensed by the Nuclear
27 Regulatory Commission or by the state pursuant to an agreement with the

1 commission under Section 274 of the federal Atomic Energy Act, 42 U.S.C.
2 sec. 2021;

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

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

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

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

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

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

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

- 1 3. In the case of a medical convenience kit that includes a product, the
2 person that manufactures the kit:
- 3 a. Purchased the product directly from the pharmaceutical
4 manufacturer or from a wholesale distributor that purchased the
5 product directly from the pharmaceutical manufacturer; and
6 b. Does not alter the primary container or label of the product as
7 purchased from the manufacturer or wholesale distributor; and
- 8 4. In the case of a medical convenience kit that includes a product, the
9 product is:
- 10 a. An intravenous solution intended for the replenishment of fluids
11 and electrolytes;
- 12 b. A product intended to maintain the equilibrium of water and
13 minerals in the body;
- 14 c. A product intended for irrigation or reconstitution;
- 15 d. An anesthetic;
- 16 e. An anticoagulant;
- 17 f. A vasopressor; or
18 g. A sympathomimetic;
- 19 (n) The distribution of an intravenous product that, by its formulation, is intended
20 for the replenishment of fluids and electrolytes such as sodium, chloride, and
21 potassium, or calories such as dextrose and amino acids;
- 22 (o) The distribution of an intravenous product used to maintain the equilibrium of
23 water and minerals in the body, such as dialysis solutions;
- 24 (p) The distribution of a product that is intended for irrigation, or sterile water,
25 whether intended for such purposes or for injection;
- 26 (q) The distribution of a medical gas as defined in Section 575 of the Federal
27 Food, Drug, and Cosmetic Act; or

- 1 (r) The distribution or sale of any licensed product under Section 351 of the
2 federal Public Health Service Act that meets the definition of a device under
3 Section 201(h) of the Federal Food, Drug, and Cosmetic Act;
- 4 (20) "Wholesale distribution" means the distribution of a prescription drug to persons
5 other than an end user, **unless the end user is a patient as established in subsection**
6 **(13) of Section 1 of this Act**, but does not include:
- 7 (a) Intracompany sales or transfers;
- 8 (b) The sale, purchase, distribution, trade, or transfer of a prescription drug for
9 emergency medical reasons;
- 10 (c) The distribution of prescription drug samples by a manufacturer or authorized
11 distributor;
- 12 (d) Drug returns or transfers to the original manufacturer, original wholesale
13 distributor, or transfers to a reverse distributor or third-party returns processor;
- 14 (e) The sale, purchase, or trade of a drug pursuant to a prescription;
- 15 (f) The delivery of a prescription drug by a common carrier;
- 16 (g) The purchase or acquisition by a health-care entity or pharmacy that is a
17 member of a group purchasing organization of a drug for its own use from the
18 group purchasing organization, or health-care entities or pharmacies that are
19 members of the group organization;
- 20 (h) The sale, purchase, distribution, trade, or transfer of a drug by a charitable
21 health-care entity to a nonprofit affiliate of the organization as otherwise
22 permitted by law;
- 23 (i) The sale, transfer, merger, or consolidation of all or part of the business of a
24 pharmacy with another pharmacy or pharmacies; or
- 25 (j) The distribution of a prescription drug to a health-care practitioner or to
26 another pharmacy if the total number of units transferred during a twelve (12)
27 month period does not exceed five percent (5%) of the total number of all

1 units dispensed by the pharmacy during the immediate twelve (12) month
2 period; and

3 (21) "Wholesale distributor" or "virtual wholesale distributor" means a person other than
4 a manufacturer, a manufacturer's co-licensed partner, a third-party logistics
5 provider, or repackager engaged in wholesale distribution as defined by 21 U.S.C.
6 sec. 353(e)(4) as amended by the federal Drug Supply Chain Security Act.