

1 AN ACT relating to pharmaceutical manufacturers.

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

3 ➔Section 1. KRS 315.400 is amended to read as follows:

4 As used in KRS 315.400 to 315.412:

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

- 1 (b) Does not include a person who dispenses only products to be used in animals
2 in accordance with 21 U.S.C. sec. 360b(a)(4) and (5);
- 3 (5) "Distribution" or "distribute" means the sale, purchase, trade, delivery, handling,
4 storage, or receipt of a product, and does not include the dispensing of a product
5 pursuant to a prescription executed in accordance with Section 503(b)(1) of the
6 federal Drug Quality and Security Act or the dispensing of a product approved
7 under Section 512(b) of the federal Drug Quality and Security Act;
- 8 (6) "Drop shipment" means a product not physically handled or stored by a wholesale
9 distributor and that is exempt from Section 582 of the federal Drug Quality and
10 Security Act, except the notification requirements under clauses (ii), (iii), and (iv)
11 of subsection (c)(4)(B) of Section 582 of the federal Drug Quality and Security Act,
12 provided that the manufacturer, repackager, or other wholesale distributor that
13 distributes the product to the dispenser by means of a drop shipment for the
14 wholesale distributor includes on the transaction information and transaction history
15 to the dispenser the contact information of the wholesale distributor and provides
16 the transaction information, transaction history, and transaction statement directly
17 to the dispenser. Providing administrative services, including the processing of
18 orders and payments, shall not by itself be construed as being involved in the
19 handling, distribution, or storage of a product;
- 20 (7) "Emergency medical reasons" includes but is not limited to:
- 21 (a) Transfers of a prescription drug between health-care entities or between a
22 health-care entity and a retail pharmacy to alleviate a temporary shortage of a
23 prescription drug arising from delays in or interruptions of the regular
24 distribution schedules;
- 25 (b) Sales of drugs for use in the treatment of acutely ill or injured persons to
26 nearby emergency medical services providers, firefighting organizations, or
27 licensed health-care practitioners in the same marketing or service area;

- 1 (c) The provision of emergency supplies of drugs to nearby nursing homes, home
2 health agencies, or hospice organizations for emergency use when necessary
3 drugs cannot be obtained; or
- 4 (d) Transfers of prescription drugs by a retail pharmacy to another retail
5 pharmacy to alleviate a temporary shortage;
- 6 (8) "End user" means a patient or consumer that uses a prescription drug as prescribed
7 by an authorized health-care professional;
- 8 (9) "Exclusive distributor" means the wholesale distributor that directly purchased the
9 product from the manufacturer and is the sole distributor of that manufacturer's
10 product to a subsequent repackager, wholesale distributor, or dispenser;
- 11 (10) "FDA" means the United States Food and Drug Administration and any successor
12 agency;
- 13 (11) "Illegitimate product" means a product for which credible evidence shows that the
14 product:
- 15 (a) Is counterfeit, diverted, or stolen;
- 16 (b) Is intentionally adulterated so that the product would result in serious adverse
17 health consequences or death to humans;
- 18 (c) Is the subject of a fraudulent transaction; or
- 19 (d) Appears otherwise unfit for distribution so that the product would be
20 reasonably likely to result in serious adverse health consequences or death to
21 humans;
- 22 (12) "Manufacturer" means the same as defined in KRS 315.010;
- 23 (13) "Medical gas wholesaler" means a person licensed to distribute, transfer, wholesale,
24 deliver, or sell medical gases on drug orders to suppliers or other entities licensed to
25 use, administer, or distribute medical gas;
- 26 (14) "Pharmacy warehouse" means a physical location for prescription drugs that acts as
27 a central warehouse and performs intracompany sales or transfers of prescription

- 1 drugs to a group of pharmacies under common ownership and control;
- 2 (15) "Prescription drug" means the same as defined in KRS 315.010;
- 3 (16) "Repackager" means a person who owns or operates an establishment that repacks
4 and relabels a product or package for further sale, or distribution without a further
5 transaction;
- 6 (17) "Reverse distributor" means every person who acts as an agent for pharmacies, drug
7 wholesalers, manufacturers, or other entities by receiving, taking inventory, and
8 managing the disposition of outdated or nonsalable drugs;
- 9 (18) "Third-party logistics provider" means an entity that contracts with a manufacturer,
10 wholesale distributor, repackager, or dispenser to provide and coordinate
11 warehousing or other logistics services on behalf of a manufacturer, wholesale
12 distributor, repackager, or dispenser, but does not take title to the drug or have
13 responsibility to direct the sale of the drug. A third-party logistics provider shall be
14 considered as part of the normal distribution channel;
- 15 (19) "Transaction" means the transfer of product between persons in which a change of
16 ownership occurs, with the following exemptions:
- 17 (a) Intracompany distribution of any product between members of an affiliate or
18 within a manufacturer;
- 19 (b) The distribution of a product among hospitals or other health care entities that
20 are under common control;
- 21 (c) The distribution of a product for emergency medical reasons, including a
22 public health emergency declaration pursuant to Section 319 of the federal
23 Public Health Service Act, except that a drug shortage not caused by a public
24 health emergency shall not constitute an emergency medical reason;
- 25 (d) The dispensing of a product pursuant to a prescription executed in accordance
26 with Section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act;
- 27 (e) The distribution of product samples by a manufacturer or a licensed wholesale

- 1 distributor in accordance with Section 503(d) of the Federal Food, Drug, and
2 Cosmetic Act;
- 3 (f) The distribution of blood or blood components intended for transfusion;
- 4 (g) The distribution of minimal quantities of product by a licensed retail
5 pharmacy to a licensed practitioner for office use;
- 6 (h) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a
7 drug by a charitable organization described in Section 501(c)(3) of the
8 Internal Revenue Code of 1986 to a nonprofit affiliate of the organization to
9 the extent otherwise permitted by law;
- 10 (i) The distribution of a product pursuant to the sale or merger of a pharmacy or
11 pharmacies or a wholesale distributor or wholesale distributors, except that
12 any records required to be maintained for the product shall be transferred to
13 the new owner of the pharmacy or pharmacies or wholesale distributor or
14 wholesale distributors;
- 15 (j) The dispensing of a product approved under Section 512(c) of the Federal
16 Food, Drug, and Cosmetic Act;
- 17 (k) Products transferred to or from any facility that is licensed by the Nuclear
18 Regulatory Commission or by the state pursuant to an agreement with the
19 commission under Section 274 of the federal Atomic Energy Act, 42 U.S.C.
20 sec. 2021;
- 21 (l) A combination product that is not subject to approval under Section 505 of the
22 federal Drug Quality and Security Act or licensure under Section 351 of the
23 federal Public Health Service Act, and that is:
- 24 1. A product composed of a device and one (1) or more other regulated
25 components such as a drug or drug device, a biologic or biologic device,
26 or a drug and biologic or drug and biologic device that are physically,
27 chemically, or otherwise combined or mixed and produced as a single

1 entity;

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

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

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

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

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

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

21 a. Purchased the product directly from the pharmaceutical
22 manufacturers~~[manufacturer]~~ or from a wholesale distributor that
23 purchased the product directly from the pharmaceutical
24 manufacturers~~[manufacturer]~~; and

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

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

- 1 product is:
- 2 a. An intravenous solution intended for the replenishment of fluids
- 3 and electrolytes;
- 4 b. A product intended to maintain the equilibrium of water and
- 5 minerals in the body;
- 6 c. A product intended for irrigation or reconstitution;
- 7 d. An anesthetic;
- 8 e. An anticoagulant;
- 9 f. A vasopressor; or
- 10 g. A sympathomimetic;
- 11 (n) The distribution of an intravenous product that, by its formulation, is intended
- 12 for the replenishment of fluids and electrolytes such as sodium, chloride, and
- 13 potassium, or calories such as dextrose and amino acids;
- 14 (o) The distribution of an intravenous product used to maintain the equilibrium of
- 15 water and minerals in the body, such as dialysis solutions;
- 16 (p) The distribution of a product that is intended for irrigation, or sterile water,
- 17 whether intended for such purposes or for injection;
- 18 (q) The distribution of a medical gas as defined in Section 575 of the Federal
- 19 Food, Drug, and Cosmetic Act; or
- 20 (r) The distribution or sale of any licensed product under Section 351 of the
- 21 federal Public Health Service Act that meets the definition of a device under
- 22 Section 201(h) of the Federal Food, Drug, and Cosmetic Act;
- 23 (20) "Wholesale distribution" means the distribution of a prescription drug to persons
- 24 other than an end user or to the end user pursuant to KRS 315.0351(2), but does not
- 25 include:
- 26 (a) Intracompany sales or transfers;
- 27 (b) The sale, purchase, distribution, trade, or transfer of a prescription drug for

- 1 emergency medical reasons;
- 2 (c) The distribution of prescription drug samples by a manufacturer or authorized
3 distributor;
- 4 (d) Drug returns or transfers to the original manufacturer, original wholesale
5 distributor, or transfers to a reverse distributor or third-party returns
6 processor;
- 7 (e) The sale, purchase, or trade of a drug pursuant to a prescription;
- 8 (f) The delivery of a prescription drug by a common carrier;
- 9 (g) The purchase or acquisition by a health-care entity or pharmacy that is a
10 member of a group purchasing organization of a drug for its own use from the
11 group purchasing organization, or health-care entities or pharmacies that are
12 members of the group organization;
- 13 (h) The sale, purchase, distribution, trade, or transfer of a drug by a charitable
14 health-care entity to a nonprofit affiliate of the organization as otherwise
15 permitted by law;
- 16 (i) The sale, transfer, merger, or consolidation of all or part of the business of a
17 pharmacy with another pharmacy or pharmacies; or
- 18 (j) The distribution of a prescription drug to a health-care practitioner or to
19 another pharmacy if the total number of units transferred during a twelve (12)
20 month period does not exceed five percent (5%) of the total number of all
21 units dispensed by the pharmacy during the immediate twelve (12) month
22 period; and
- 23 (21) "Wholesale distributor" or "virtual wholesale distributor" means a person other than
24 a manufacturer, a manufacturer's co-licensed partner, a third-party logistics
25 provider, or repackager engaged in wholesale distribution as defined by 21 U.S.C.
26 sec. 353(e)(4) as amended by the federal Drug Supply Chain Security Act.