315.400 Definitions for KRS 315.400 to 315.412.

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, 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.

History: Amended 2017 Ky. Acts ch. 136, sec. 4, effective June 29, 2017. -- Created 2008 Ky. Acts ch. 124, sec. 3, effective July 15, 2008.