

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 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;
- (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;
- (5) "Drop shipment" means 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;
- (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;
- (7) "End user" means a patient or consumer that uses a prescription drug as prescribed by an authorized health-care professional;
- (8) "FDA" means the United States Food and Drug Administration and any successor agency;
- (9) "Manufacturer" means the same as defined in KRS 315.010;
- (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;
- (14) "Prescription drug" means the same as defined in KRS 315.010;
- (15) "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;
- (16) "Third-party logistics provider" means an entity that contracts with a manufacturer to provide or coordinate the warehousing, distribution, or other similar services on behalf of a manufacturer, 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;
- (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

- (18) "Wholesale distributor" means 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.

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