West's Annotated Code of Maryland
Health Occupations (Refs & Annos)
Title 12. Pharmacists and Pharmacies (Refs & Annos)
Subtitle 6c. Wholesale Distributor Permitting and Prescription Drug Integrity Act (Refs & Annos)

MD Code, Health Occupations, § 12-6C-01

§ 12-6C-01. Definitions

Effective: March 14, 2021

Currentness

In general

(a) In this subtitle the following words have the meanings indicated.

Authenticate

(b) "Authenticate" means to affirmatively verify, before any wholesale distribution of a prescription drug occurs, that each transaction listed on the pedigree for the prescription drug has occurred.

Authorized distributor of record

(c) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug.

Co-licensed partner

(d) "Co-licensed partner" means a person in a relationship in which two or more persons have the right to engage in the manufacturing or marketing of a prescription drug, consistent with the U.S. Food and Drug Administration's implementation of the federal Prescription Drug Marketing Act.

Co-licensed product

(e) "Co-licensed product" means a product of co-licensed partners.

Designated representative

(f) "Designated representative" means an individual who:

(1) Is designated by a wholesale distributor;

(2) Serves as the primary contact of the wholesale distributor with the Board; and

(3) Is actively involved in and aware of the daily operation of the wholesale distributor.

Drop shipment

(g) "Drop shipment" means the sale of a prescription drug:

(1) To a wholesale distributor by:

(i) The manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third party logistics provider, or manufacturer's exclusive distributor; and

(2) Through which:

(i) The wholesale distributor or a pharmacy warehouse takes title to but not physical possession of the prescription drug;

(ii) The wholesale distributor invoices the pharmacy, pharmacy warehouse, or other person authorized by law to dispense or administer the prescription drug to a patient; and

(iii) The pharmacy, pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from:

1. The manufacturer; or

2. The manufacturer's third party logistics provider or the manufacturer's exclusive distributor.

Facility

(h) "Facility" means a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale.

Intracompany sales

(i) "Intracompany sales" means a:

(1) Transaction or transfer of prescription drugs between a division, subsidiary, parent, or affiliated or related company under common ownership and control of a corporate entity, other than a transaction or transfer of prescription drugs from a pharmacy to a wholesale distributor; or

(2) Transaction or transfer of a co-licensed product between co-licensed partners.

Manufacturer

(j) "Manufacturer" means a person licensed or approved by the U.S. Food and Drug Administration to engage in the manufacture of prescription drugs or prescription devices, consistent with the definition of "manufacturer" under the U.S. Food and Drug Administration's regulations and guidelines implementing the Prescription Drug Marketing Act.

Manufacturer's exclusive distributor

(k) "Manufacturer's exclusive distributor" means a person who:

(1) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; and

(2) Takes title to the manufacturer's prescription drug, but does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug.

Normal distribution channel

(l) "Normal distribution channel" means a chain of custody for a prescription drug that, directly or by drop shipment, goes:

(1) From:

(i) A manufacturer of the prescription drug; or

(ii) The manufacturer's co-licensed partner, third party logistics provider, or manufacturer's exclusive distributor; and

(2) To:

(i) A pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(ii) A wholesale distributor to a pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iii) A wholesale distributor to a pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient;

(iv) A pharmacy warehouse to the pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the prescription drug to a patient; or

(v) An authorized distributor of record to another authorized distributor of record solely for distribution to an office-based health care practitioner authorized by law to dispense or administer the prescription drug to a patient.

Ongoing relationship

(m) "Ongoing relationship" means a relationship that exists between a wholesale distributor, including any affiliated group of the wholesale distributor, as defined in § 1504 of the Internal Revenue Code, and a manufacturer when the wholesale distributor:

(1) Has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; and

(2) Is listed on the manufacturer's current list of authorized distributors of record.

Pedigree

(n) "Pedigree" means a document or electronic file containing information that records each wholesale distribution of a prescription drug.

Pharmacy warehouse

(o) "Pharmacy warehouse" means a physical location for storage of prescription drugs that:

(1) Serves as a central warehouse; and

(2) Performs intracompany sales or transfers of the prescription drugs to a group of pharmacies that are under common ownership and control with the pharmacy warehouse.

Prescription device

(p) "Prescription device" means any device required by federal law or regulation to be dispensed only by a prescription.

Prescription drug

(q)(1) "Prescription drug" means any drug required by federal law or regulation to be dispensed only by a prescription.

(2) "Prescription drug" includes:

(i) A biological product; and

(ii) Finished dosage forms and bulk drug substances subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act.

(3) “Prescription drug” does not include blood and blood components intended for transfusion or biological products that are also medical devices.

Repackage

(r)(1) “Repackage” means to repackage or otherwise change the container, wrapper, or labeling of a prescription drug to further the distribution of the prescription drug.

(2) “Repackage” does not include changes to a container, wrapper, or labeling of a prescription drug completed by the pharmacist responsible for dispensing the prescription drug to a patient.

Repackager

(s) “Repackager” means a person who repackages prescription drugs.

Third party logistics provider

(t) “Third party logistics provider” means a person who:

(1) Contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer; but

(2) Does not take title to the prescription drug or have general responsibility to direct the prescription drug’s sale or disposition.

Wholesale distribution

(u)(1) “Wholesale distribution” means the distribution of prescription drugs or prescription devices to persons other than a consumer or patient.

(2) “Wholesale distribution” does not include:

(i) Intracompany sales;

(ii) The sale, purchase, distribution, trade, or transfer of a prescription drug or an offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons;

(iii) The sale, purchase, distribution, trade, or transfer of a prescription drug or prescription device by the Department for public health purposes;

(iv) The distribution of samples of a prescription drug by a manufacturer's representative;

(v) Prescription drug returns conducted by a hospital, health care entity, or charitable institution in accordance with 21 C.F.R. § 203.23;

(vi) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed health care practitioners for office use;

(vii) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase, or trade a prescription drug, or the dispensing of a prescription drug in accordance with a prescription;

(viii) The sale, transfer, merger, or consolidation of all or part of the business of a pharmacy to or with another pharmacy, whether accomplished as a purchase and sale of stock or business assets;

(ix) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record if:

1. The manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply the prescription drug; and

2. The supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(x) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, if the common carrier does not store, warehouse, or take legal ownership of the prescription drug; or

(xi) The sale or transfer from a pharmacy or pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to:

1. The original wholesale distributor;

2. The original manufacturer; or

3. A third party returns processor.

Wholesale distributor

(v)(1) "Wholesale distributor" means a person that is engaged in the wholesale distribution of prescription drugs or prescription devices.

(2) "Wholesale distributor" includes:

(i) A manufacturer;

(ii) A repackager;

(iii) An own-label distributor;

(iv) A private-label distributor;

(v) A jobber;

(vi) A broker;

(vii) A warehouse, including a manufacturer's or distributor's warehouse;

(viii) A manufacturer's exclusive distributor or an authorized distributor of record;

(ix) A drug wholesaler or distributor;

(x) An independent wholesale drug trader;

(xi) A third party logistics provider;

(xii) A pharmacy that conducts wholesale distribution, if the wholesale distribution business accounts for more than 5% of the pharmacy's annual sales; and

(xiii) A pharmacy warehouse that conducts wholesale distribution.

Wholesale distributor permit

(w) "Wholesale distributor permit" means a permit issued by the Board under this subtitle to distribute prescription drugs or prescription devices into, out of, or within the State as a wholesale distributor.

Credits

Added by Acts 2007, c. 352, § 1, eff. July 1, 2007; Acts 2007, c. 353, § 1, eff. July 1, 2007. Amended by Acts 2008, c. 36, § 6, eff. April 8, 2008; Acts 2010, c. 239, § 1, eff. Oct. 1, 2010; Acts 2010, c. 240, § 1, eff. Oct. 1, 2010; Acts 2012, c. 66, § 1, eff. April 10, 2012; Acts 2013, c. 298, § 1, eff. Oct. 1, 2013; Acts 2013, c. 621, § 1, eff. Oct. 1, 2013; Acts 2021, c. 4, § 1, eff. March 13, 2021; Acts 2021, c. 28, § 1, eff. March 14, 2021.

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