

DIVISION 62

DRUG DISTRIBUTION AGENT

855-062-0003

Application

~~(1) Any person who is involved in the manufacture or wholesale distribution of a drug that is intended for distribution, dispensing or administration in Oregon, but who does not at any time have possession of any of the Active Product Ingredients (API) or the final product, and does not participate in the actual manufacturing process, must register under these rules as a Drug Distribution Agent, except that any such person, registered with the FDA as a manufacturer, who is accountable to the FDA for the purity and integrity of a drug must register as a manufacturer under Division 60 of this chapter of rules.~~

~~(2)~~ **(1)** The following persons must register as a Drug Distribution Agent under this ~~d~~**D**ivision of rules:

(a) A broker;

(b) An import broker;

(c) An agent for a foreign manufacturer who is registered with the **Food and Drug Administration** (FDA);

(d) Sales and marketing office for a drug;

(e) A Drug Order Contractor;

(f) A Third-Party Logistics Provider; and

~~(f)~~ **(g)** A person registered with the FDA as the holder of a New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA) that contracts with a third-party for the manufacture of a drug but does not take physical possession of the drug, does not have its name on the label and is not accountable to the FDA for the purity and integrity of the drug.

~~(3)~~ **(2)** Any person who would otherwise be required to register as a ~~w~~**W**holesaler under Division 65 of this ~~e~~**C**hapter of rules but who does not at any time have possession of a drug intended for distribution must register as a Drug Distribution Agent under this ~~d~~**D**ivision of rules.

~~(4)~~ **(3)** A person whose sole purpose is the marketing, brokering or arranging the initial distribution of drugs manufactured by a registered manufacturer, but does not take physical possession of a product must register as a Drug Distribution Agent.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-062-0005

Definitions

(1) "Broker" means a person engaged in the marketing, offering, or contracting for wholesale distribution and sale of a drug into, within, or out of Oregon and who does not take physical possession of the drug.

(2) "Closed Door Pharmacy" means a pharmacy that provides pharmaceutical services to a defined and exclusive group of patients and is not open for dispensing to the general patient population and cannot be registered as a wholesale distributor.

(3) "Co-Manufacturing Partner" means a pharmaceutical manufacturer that has entered into an agreement with another pharmaceutical manufacturer to engage in a business activity or occupation related to the manufacture or distribution of a prescription drug.

(4) "Common Carrier" means an organization that is available to the public to transport a product or service using its facilities, or those of other carriers.

~~(4)~~ **(5)** "Drug": In this **D**ivision of rules, the term "drug" shall mean any drug and any prescription device as these terms are defined in ORS 689.005.

(6) "Illegitimate Product" means a product for which credible evidence shows that the product is:

(a) Counterfeit, diverted, or stolen;

(b) Intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) The subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would be reasonably likely to result in serious adverse health consequences or death.

~~(5)~~ **(7)** "Manufacturer" means any person, including a manufacturer's co-manufacturing partner, that is engaged in the manufacture of a drug, is responsible or otherwise accountable to the **Food and Drug Administration (FDA)** for the manufacture of the drug, or is the private label manufacturer or distributor of product bearing its NDC number that is intended for sale, distribution, dispensing or administration in Oregon, and who holds one or more of the following registrations or licenses with the FDA:

(a) A New Drug Application number (NDA);

(b) An Abbreviated New Drug application number (ANDA);

(c) A Labeler Code number (LC) or National Drug Code Number (NDC);

(d) An FDA Central File Number (CFN);

(e) An FDA Establishment Identifier number (FEI);

(f) A Biologic License Application (BLA);

(g) An Outsourcing Facility.

~~(6)~~ **(8)** “Manufacture” means the preparation, propagation, compounding, or processing of a drug or device intended for human or animal use. Manufacture includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user, except when the process is part of a shared pharmacy service agreement as defined in OAR 855-006-0005.

(9) "Pedigree" for the purpose of this Division consists of:

(a) “Transaction History” means a statement in paper or electronic form, including the transaction information for each prior transaction going back to the manufacturer of the product.

(b) “Transaction Information” must include, but is not limited to:

(A) The proprietary or established name or names of the product;

(B) The strength and dosage form of the product;

(C) The National Drug Code number of the product;

(D) The container size;

(E) The number of containers;

(F) The lot number of the product;

(G) The date of the transaction;

(H) The date of the shipment, if more than 24 hours after the date of the transaction;

(I) The business name and address of the person from whom ownership is being transferred; and

(J) The business name and address of the person to whom ownership is being transferred.

(c) “Transaction Statement” is a statement, in paper or electronic form, that the entity transferring ownership in a transaction is compliant with FDA regulations set forth by the Drug Quality and Security Act and includes, but is not limited to:

(A) Confirmation that the entity is authorized or registered as required under the Drug Supply Chain Security Act;

(B) Acknowledgement that product is received from an authorized or registered entity, as required under the Drug Supply Chain Security Act;

(C) Confirmation of receipt of transaction information and of transaction statement from the prior owner of the product, as required under the Drug Supply Chain Security Act;

(D) Verification that a suspect or illegitimate product was not knowingly shipped;

(E) Confirmation that systems and processes are in place to comply with verification requirements under the Drug Supply Chain Security Act;

(F) Confirmation that false transaction information was not knowingly provided; and

(G) Confirmation that transaction history was not knowingly altered.

(7) **(10)** “Person” means individual, corporation, partnership, association, joint-stock company, business trust or unincorporated organization.

(11) “Suspect Product” means a product for which there is reason to believe that such product is:

(a) Potentially counterfeit, diverted, or stolen;

(b) Potentially intentionally adulterated such that the product would result in serious adverse health consequences or death to humans;

(c) Potentially the subject of a fraudulent transaction; or

(d) Otherwise unfit for distribution such that the product would result in serious adverse health consequences or death to humans.

(12) “Third-Party Logistics Provider” means an entity that provides or coordinates warehousing, or other logistics services of a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a product, but does not take ownership of the product, and not have responsibility to direct the sale or disposition of the product.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-062-0050

Prohibited Practices

(1) The following practices are expressly prohibited:

(a) A Drug Distribution Agent may not participate in the purchase of a drug from a closed-door pharmacy;

(b) A Drug Distribution Agent may not participate in any way in the sale, distribution or transfer of a drug to a person who is required by the laws and rules of Oregon to be registered with the Board and who is not appropriately registered. Before authorizing or facilitating the distribution of a drug, a Drug Distribution Agent must verify that the person supplying or receiving the drug is appropriately registered with the Board.

(2) A Drug Distribution Agent may not perform, cause the performance of, or aid the performance of any of the following:

(a) The manufacture, repackaging, sale, delivery, holding, or offering for sale of a drug that is adulterated, misbranded, counterfeit, suspected counterfeit, or is otherwise unfit for distribution;

(b) The adulteration, misbranding, or counterfeiting of a drug;

(c) The receipt of a drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit, and the delivery or proffered delivery of the drug for pay or otherwise;

(d) The alteration, mutilation, destruction, obliteration, or removal of the whole or a part of the labeling of a drug or the commission of another act with respect to a drug that results in the drug being misbranded;

(e) The forging, counterfeiting, simulating, or falsely representing a drug using a mark, stamp, tag, label, or other identification device;

(f) The purchase or receipt of a drug from a person that is not registered to distribute drugs to the purchaser or recipient;

(g) The sale or transfer of a drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug, to purchase or receive drugs from the person selling or transferring the drug;

(h) The failure to maintain or provide records as required under these rules;

(i) Providing the Board, a representative of the Board, or a state or federal official with false or fraudulent records or making false or fraudulent statements regarding a matter related to these rules;

(j) Participating in the wholesale distribution of a drug that was:

(A) Purchased by a public or private hospital or other health care entity under the terms of an "own-use" contract; or

(B) Donated or supplied at a reduced price to a charitable organization; or

(C) Stolen or obtained by fraud or deceit; or

(D) Illegally imported into the USA.

(k) Facilitating the distribution or attempting to facilitate the distribution of a drug by fraud, deceit, or misrepresentation;

~~(l)~~ **(l)** Facilitating the distribution of a drug that was previously dispensed by a retail pharmacy or a practitioner;

(m) Failing to report an act prohibited by any of the rules in OAR Chapter 855 to the appropriate state or federal authorities.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155