

## BOARD OF PHARMACY

### DIVISION 65

#### WHOLESALE DRUG OUTLETS

##### 855-065-0001

###### Application

(1) These rules (OAR 855-065-0001 to 855-065-0013) apply to any person, including any business entity, located in or outside Oregon that engages in the wholesale distribution of prescription or non-prescription drugs in Oregon except that a manufacturer that is registered under ~~OAR 855-060-0001~~ **division 60 of this chapter of rules** does not also need to register as a wholesale distributor under these rules if they only distribute their own products or those manufactured by a Co-Manufacturing Partner as defined in OAR 855-065-0005(6).

**(2) Any person that participates in the wholesale distribution of a drug but that does not at any time take physical possession or ownership of any drug must register as Drug Distribution Agent in accordance with OAR 855-062-0020, however a person that is registered with the Board as a manufacturer or a wholesaler does not also need to register as a Drug Distribution Agent.**

Stat. Auth.: ORS 689.205

Stats.Implemented: ORS 689.155

##### 855-065-0005

###### Definitions

(1) "Authenticate" means to verify that each transaction listed on the pedigree and other accompanying documentation has occurred and is accurately recorded.

(2) "Authorized Distributor of Record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated

group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with either or both of the following:

- (a) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; or
- (b) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer no less than monthly.
- (3) "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 brokered substance.
- (4) "Chain Pharmacy Warehouse" means a physical location for drugs that acts as a central warehouse and performs intra company sales or transfers of drugs to a group of chain pharmacies that have the same common ownership and control.
- (5) "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.
- (6) "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.
- (7) "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.
- (8) "Contraband Drug" means a drug that is counterfeit, stolen, misbranded, obtained by fraud, or purchased by an entity for its own use and placed in commerce in violation of an own-use agreement for that drug.
- (9) "Cooperative Pharmacy Warehouse" means a physical location for drugs that acts as a central warehouse and is owned, operated or affiliated with a group purchasing organization or pharmacy buying cooperative and distributes drugs exclusively to its members. To be considered part of the Normal Chain of Distribution as defined in section (16) of this rule, a Cooperative Pharmacy Warehouse must also be listed as an Authorized Distributor of Record for that manufacturer.
- (10) "Designated Representative" means an individual designated by each wholesale distributor registered by the Board who will serve as the primary contact person for the wholesale distributor with the Board and who is responsible for managing the company's operations at that registered location.
- (11) "Drop Shipment" means a drug transaction whereby the manufacturer, that manufacturer's co-manufacturing partner, that manufacturer's third-party logistics

provider, or that manufacturer's exclusive distributor delivers a drug directly to a chain pharmacy warehouse, a cooperative pharmacy warehouse, a pharmacy, or other person authorized to administer or dispense prescription drugs to a patient, but transfers title to the drug to a wholesale distributor. A drop shipment shall be considered as part of a normal chain of distribution as defined in section (16) of this rule.

(12) "Drug Sample" means a unit of a drug that is intended to promote the sale of the drug, but which is not itself for sale.

(13) "Intra Company Transfer" means the transfer of any drug between a division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity.

(14) "Manufacturer" means anyone, including a manufacturer's co-manufacturing partner, who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, except when the process is part of a shared pharmacy service agreement as defined in OAR 855-006-0005(20).

(15) "Manufacturer's Exclusive Distributor" means an entity, including a manufacturer's wholly owned distributor, that contracts with a manufacturer who is registered under ~~OAR 855-060-0001~~ **division 60 of this chapter of rules**, to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and takes title to that manufacturer's drug, but does not have general responsibility to direct the drug's sale or disposition. To be considered part of the Normal Chain of Distribution as defined in section (16) of this rule, a Manufacturer's Exclusive Distributor must also be listed as an Authorized Distributor of Record for that manufacturer.

(16) "Normal Chain of Distribution" means a chain of distribution, including a drop-shipment, for a prescription drug that goes from: a manufacturer; a manufacturer's co-manufacturing partner; a manufacturer's exclusive distributor; or a manufacturer's third-party logistics provider to:

(a) A pharmacy or a person authorized to administer or dispense a prescription drug to a patient; or

(b) A manufacturer's authorized distributor of record, to a pharmacy or a person authorized to administer or dispense a prescription drug to a patient; or

(c) A manufacturer's authorized distributor of record, to a chain pharmacy warehouse, to that chain pharmacy warehouse's intra company pharmacy, to a patient or a person authorized to administer or dispense a prescription drug to a patient; or

(d) A chain pharmacy warehouse, to that chain pharmacy warehouse's intra company pharmacy, to a patient or a person authorized to administer or dispense a prescription drug to a patient; or

(e) A manufacturer's authorized distributor of record, to a specialty wholesaler, to a pharmacy or a person authorized to administer or dispense a prescription drug to a patient; or

(f) A manufacturer's authorized distributor of record to a cooperative pharmacy warehouse, to a member of the affiliated group purchasing organization or pharmacy buying cooperative, to a patient or a person authorized to administer or dispense a prescription drug to a patient.

(17) "Pedigree" means a statement or record in a written or electronic form that accurately records each wholesale distribution of a prescription drug from the sale by a manufacturer through acquisition and sale by any wholesale distributor or repackager until final sale to a pharmacy or other person authorized to administer or dispense the drug. The pedigree must include, but not be limited to, the following information for each transaction:

(a) The source of the prescription drug, including the name and principal address of the seller;

(b) The proprietary and established name of the prescription drug, the National Drug Code number, the amount of the prescription drug, its dosage form and dosage strength, the date of the purchase, the sales invoice number or other unique shipping document number that identifies the transaction, container size, number of containers, expiration date, and lot number or control number of the prescription drug;

(c) The business name and address of each owner of the prescription drug and its shipping information, including the name and address of the facility of each person certifying delivery or receipt of the prescription drug.

(18) "Prescription Drug" means any drug required by law to be dispensed only by a prescription.

(19) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug excluding that completed by the pharmacist responsible for dispensing the product to a patient.

(20) "Specialty Wholesale Distributor" means an entity that exclusively distributes a limited product line of drugs to a specific group of pharmacies or registered practitioners as approved in writing by the Board. To be considered part of the Normal Chain of Distribution as defined in section (16) of this rule, a Specialty Wholesale Distributor must also be listed as an Authorized Distributor of Record for that manufacturer.

(21) "Third-Party Logistics Provider" means an entity that contracts with a manufacturer who is registered under these rules to provide or coordinate warehousing, distribution, or other services on behalf of the manufacturer, but does not take title to the drug or have general responsibility to direct the sale or disposition of the drug. To be considered part

of the Normal Chain of Distribution as defined in section (16) of this rule, a Third-Party Logistics Provider must also be listed as an Authorized Distributor of Record for that manufacturer.

(22) "Wholesale Distribution" means distribution of a drug to a person other than a consumer or patient, but does not include:

(a) Delivery by a retail pharmacy of a prescription drug to a patient or patient's agent pursuant to the lawful order of a licensed practitioner.

(b) The sale of minimal quantities of a prescription drug by retail pharmacies to licensed practitioners for office use.

(c) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons, including but not limited to transfer of a drug by a pharmacy to another pharmacy to alleviate a temporary shortage.

(d) Intra company transfer of drugs as defined in these rules.

(e) The lawful distribution of a drug sample by a manufacturer's or a distributor's representative.

(f) The sale of a drug by a charitable organization described under 501(c)(3) of the Internal Revenue Code to a non-profit affiliate of the organization to the extent permitted by law.

(g) The purchase or acquisition of a drug by a hospital or other health care entity that is a member of a group purchasing organization, for the hospital's or health care entity's own use, from the group purchasing organization or from other hospitals or health care entities that are members of the organization or under common control.

(h) The transfer of a prescription drug between pharmacies pursuant to a shared pharmacy service agreement as defined in OAR 855-006-0005.

(i) The distribution by a manufacturer, as part of a prescription assistance program, of a drug intended for a specific patient, to a person authorized to prescribe, administer or dispense prescription drugs.

(j) The sale, purchase, or trade of blood and blood components intended for transfusion.

(k) Drug returns, when conducted in accordance with state and federal laws and regulations. A drug return includes the sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned or recalled drugs to the original manufacturer, wholesale distributor, or to a third-party returns processor or reverse wholesaler, and the returns of saleable drugs to the original manufacturer or wholesaler.

(L) The transporting of a drug by common carrier where the common carrier does not take title to the drug and does not have responsibility to direct the drug's sale or distribution.

(m) The sale, transfer, merger or consolidation of all or part of the business of a pharmacy from or with another pharmacy.

(n) The distribution of drugs by a manufacturer registered under OAR 855-060-0001 of that manufacturer's own products to a person other than a patient.

(23) "Wholesale Distributor" means any entity engaged in the wholesale distribution of drugs, including any entity whose business name appears on any invoice or other type of shipping document indicating possession or title. The term "Wholesale Distributor" includes but is not limited to, ~~repackagers~~; own-label distributors; private-label distributors; ~~jobbers; brokers~~; warehouses, including manufacturers' and distributors' warehouses; drug wholesalers or distributors; independent wholesale drug traders; third-party logistics providers; cooperative pharmacy warehouses; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the Normal Chain of Distribution as defined in section (16) of this rule, a Wholesale Distributor must also be listed as an Authorized Distributor of Record for that manufacturer.

(24) "Wholesaler" means any wholesale distributor:

(a) "Class I Wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which prescription drugs, medicinal chemicals, or poisons are sold, dispensed, stocked, exposed or offered for sale at wholesale to a pharmacy or other legally licensed drug outlets or persons;

~~(b) "Class II Wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which nonprescription drugs are offered for sale at wholesale to a drug outlet legally authorized to resell.~~

**(b) "Class II Wholesaler" means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which any of the products in paragraphs (A) – (D) below are offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer. If any prescription drugs not included in paragraphs (B) and (D) below are offered for sale, the wholesaler must register as a Class I wholesaler:**

**(A) Non-prescription drugs;**

**(B) Veterinary products;**

**(C) Prescription or non-prescription devices that do not contain a prescription drug;**

**(D) Pharmaceutical products possessed by a state or local government agency or non-profit relief organization approved by the Board.**

Stat. Auth.: ORS 689.205

Stats.Implemented: ORS 689.155

## 855-065-0006

### Registration Requirements

(1) Every wholesale distributor, wherever located, that engages in wholesale distribution into, out of, or within Oregon must be registered with the Board in accordance with the laws and regulations of Oregon before engaging in wholesale distribution of drugs. Every applicant for registration or renewal of registration must pay the appropriate fee in accordance with OAR 855-110-0007 and 855-110-0010. **An applicant must register as a Class I Wholesaler or a Class II Wholesaler unless the applicant qualifies for registration as a Drug Distribution Agent under Division 62 of this chapter of rules.**

(2) Application for registration must be on a form approved by the Board and must include, but not be limited to, the following information:

(a) The name, business address, social security number and federal tax identification number of each owner, officer, and stockholder owning more than 10 per cent of the stock of the company, unless the stock of the company is publicly traded;

(b) All trade or business names used by the applicant including any businesses outside Oregon;

(c) The names, addresses and telephone numbers of the designated representatives for all facilities used by the applicant that engage in wholesale distribution into, out of, or within Oregon;

(d) The normal business hours for the applicant; and

(e) Any disciplinary action taken by any state or federal authority against the applicant or any other wholesale distributor under common ownership or control, or any owner, principal or designated representative of the applicant, in connection with the drug laws or regulations of any state or the federal government.

(3) The Board may require a criminal history and financial background check of each principal, owner, officer and designated representative of the applicant prior to initial registration and prior to any renewal. Any such checks shall be at the applicant's expense.

(4) The Board may require a physical inspection of each facility prior to initial registration and prior to any renewal.

(5) Any wholesale distributor located outside the boundaries of Oregon, applying for registration or re-registration, as a Class 1 Wholesaler, ~~after January 1, 2008~~ must provide evidence of one of the following:

(a) A current license or registration as a wholesale distributor in a state that has a license or registration procedure approved by the Board that included a physical inspection within the past three years; or

(b) A current accreditation by a process approved by the Board such as The National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) program or other nationally recognized accreditation program or contract inspection service.

(6) Any wholesale distributor located inside the boundaries of Oregon, applying for registration or re-registration, as a Class 1 Wholesaler, ~~after January 1, 2008~~ must provide evidence of one of the following:

(a) A current accreditation by a process approved by the Board such as The National Association of Boards of Pharmacy's Verified Accredited Wholesale Distributor (VAWD) program or other nationally recognized accreditation program or contract inspection service; or

(b) That it is a small business as defined in ORS 183.310(10); and

(A) The applicant has no affiliation with any out-of-state pharmaceutical company; and

(B) All owners and principals of the applicant are Oregon residents; and

(C) No owner or principal, or close family member of an owner or principal, has a controlling or business interest in any other pharmaceutical company; and

(D) Neither the applicant, nor any of its owners or principals, has ever been found to be in violation of any drug law or regulation in this or any other state.

(7) Notwithstanding the requirements of sections (5) and (6) of this rule, upon written request, the Board may waive any of the requirements of this rule if a waiver will further public health or safety. A waiver granted under this section shall only be effective when it is issued in writing.

(8) In addition to the above registration requirements, an applicant for registration as a Class 1 wholesaler under this rule, **that has not received VAWD accreditation**, must provide evidence that it has obtained a bond or equivalent means of security of at least \$100,000 that provides direct access to the Oregon Board of Pharmacy as a beneficiary to

secure payment of any administrative penalties that may be imposed by the Board and any fees and costs that may be incurred by the Board and that:

- (a) Are related to a registration held by the wholesale distributor; and
- (b) Are authorized under Oregon law; and
- (c) The wholesale distributor fails to pay less than thirty days after the penalties, fees, or costs become final.

(9) The Board may make a claim against a bond or security posted under section (8) of this rule within one year after the wholesale distributor's registration is no longer valid or sixty days after the conclusion of whichever occurs later:

- (a) An administrative or legal proceeding before or on behalf of the Board that involves the wholesale distributor and results in penalties, fees or costs; or
- (b) An appeal of such a proceeding.

(10) Where operations are conducted at more than one location by a single wholesale drug outlet, each such location that does business in Oregon must be registered by the Board.

(11) The registrant must notify the Board, within 15 days, of any substantial change to the information provided on the registration application. Substantial change shall include but not be limited to: change of ownership; change of business address; change of normal business hours; any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers, or designated representatives.

(12) The registration certificate is issued to a specific person and is non-transferable. Additions or deletions of an owner or partner shall be considered as a change of ownership.

(13) A new registration form is required for a change of ownership or location and must be submitted to the Board with the fees as specified in OAR 855-110-0007 within 15 days of the change.

(14) The registration fee cannot be prorated.

Stat. Auth.: ORS 689.205

Stats.Implemented: ORS 689.155