

BOARD OF PHARMACY
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, shall 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 shall register as a manufacturer under OAR 855-060-0001.

(2) The following persons shall register as a Drug Distribution Agent under this division of rules:

(a) A broker;

(b) An import broker;

(c) An agent for a foreign manufacturer who is registered with the FDA as required by 21 USC 360(2)(i)(1);

(d) Sales and marketing office for a drug;

(e) A Drug Order Contractor

(f) 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) Any person who would otherwise be required to register as a wholesaler under OAR 855-065-0001 but who does not at any time have possession of a drug intended for distribution shall register as a Drug Distribution Agent under this division of rules.

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

(5) "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 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).

(6) “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;

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

Stat. Auth.: ORS 689.205

Stats.Implemented: ORS 689.155

855-062-0020

Registration

(1) Any person engaged in any part of the process of manufacture or wholesale distribution of a drug into, out of, or within Oregon must be registered with the Board. A person shall register as either:

(a) A manufacturer under OAR 855-060-0001 through 855-060-0035; or

(b) A wholesaler under OAR 855-065-0001 through 855-065-0013; or

(c) A Drug Distribution Agent under this Division of Rules.

(2) A person that is required to register as a Drug Distribution Agent must be registered before commencing business in Oregon and before any drug for which they provide a manufacturing, marketing or distribution service, may be sold, distributed, dispensed or administered in Oregon.

(3) A person that is required to register as a Drug Distribution Agent must apply for registration on a form provided by the Board and must provide information required by the Board that shall include but is not limited to:

(a) The name, business address, social security number or 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) Every trade or business name used by the applicant;

(c) Any disciplinary action taken by any state or federal authority against the applicant or any other 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.

(4) An applicant for renewal must complete the form provided by the Board and submit it to the Board with the appropriate fee by August 31 annually.

(5) An applicant that provides a manufacturing or distribution service in respect of a controlled substance as defined in Division 80 of this chapter of rules must also complete and submit the Controlled Substance registration form provided by the Board, with the appropriate fee.

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

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

(8) Each separate business entity and each location that does business in Oregon must be separately registered by the Board.

(9) 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 is not limited to:

(a) Change of ownership;

(b) Change of business address;

(c) Any disciplinary action taken or pending by any state or federal authority against the registrant, or any of its principals, owners, directors, officers.

(10) The registration certificate is issued to a specific person and is non-transferable. Any addition or deletion of an owner or partner constitutes a change of ownership.

(11) The Board may waive any requirement of this rule if, in the Board's judgment, a waiver will further public health or safety. A waiver granted under this section shall only be effective when issued in writing.

Stat. Auth.: ORS 689.205

Stats.Implemented: ORS 689.155

855-062-0030

Minimum Qualifications

The Board may deny an application for registration or renewal of registration as a Drug Distribution Agent on any of the following grounds:

(1) The applicant has been found by the Board or by a court to have violated the pharmacy or drug laws or rules of this state or of any other state, or of the federal government;

(2) The applicant has a history of non-compliance with state or federal rules or laws regulating the manufacture, distribution, or dispensing of drugs;

(3) The applicant has made a material misrepresentation to the Board in the course of applying for an initial or renewal of registration;

(4) Disciplinary action has been taken by the federal government or by any state, or local government regarding any license or registration currently or previously held by the applicant for the manufacture, distribution or dispensing of any drugs;

(5) The applicant has engaged in any conduct involving moral turpitude;

(6) The Board determines that granting the registration is not consistent with the public health or safety or is otherwise not in the public interest.

Stat. Auth.: ORS 689.205

Stats.Implemented: ORS 689.155

855-062-0040

Record Keeping

(1) A Drug Distribution Agent must establish and maintain records of all transactions regarding the distribution or other disposition of a drug. These records must comply with all federal drug laws and regulations and must include the following information:

(a) The source of the drug, including the name and physical address of the seller or transferor and any broker or other person involved in the transaction, the address of the location from which the drug was shipped and the address of the location to which the drug was shipped;

(b) The name, dose and quantity of the drug distributed;

(c) The date of distribution or other disposition of the drug;

(2) Records required by this rule must be made available for inspection and copying by any authorized official of the Drug Enforcement Agency, the Food and Drug Administration, the Department of Agriculture, authorized law enforcement agencies, and this Board.

(3) Records required under these rules must be maintained for three years.

(4) Records required under these rules that are less than 13 months old must be kept at the address of record or be immediately retrievable by computer or other electronic means, and must be immediately available for inspection. All other records required by these rules must be made available for inspection within three business days of a request.

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) Facilitating the distribution of a drug that was previously dispensed by a retail pharmacy or a practitioner.

(o) 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