

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 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.

(2) Any person **who is a Third-Party Logistics Provider as defined in Division 62 or whose sole purpose is the marketing, brokering or arranging the distribution of drugs manufactured by a manufacturer** 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 a Drug Distribution Agent in accordance with Division 62 of this eChapter of rules, ~~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) "Affiliate" means a business entity that has a relationship, or is an authorized trading partner, with a second business entity if, directly or indirectly:

(a) One business entity controls, or has the power to control, the other business entity; or

(b) A third party controls, or has the power to control, both of the business entities.

~~(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) (7) "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)~~ **(8)** "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.

(9) "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.

~~(13)~~ **(10)** "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)~~ **(11)** "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.

~~(15) "Manufacturer's Exclusive Distributor" means an entity, including a manufacturer's wholly owned distributor, that contracts with a manufacturer who is registered under 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; or 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)~~ **(12)** "Pedigree" **for the purpose of this Division consists of:** 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.~~

(a) "Transaction History," which 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," which 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," which is a statement, in paper or electronic form, that the entity transferring ownership in a transaction is compliant with Food and Drug Administration (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.

~~(18)~~ **(13)** "Prescription Drug" means any drug required by law to be dispensed only by a prescription.

(14) "Quarantine" means the storage or identification of a product, to prevent distribution or transfer of the product, in a physically separate area clearly identified for such use or through other procedures.

~~(19)~~ **(15)** "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.

(16) “Repackager” means a person who owns or operates an establishment that repacks and relabels a product or package for:

(a) Further sale; or

(b) Distribution without a further transaction.

(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.

(17) “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.

(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.

(18) “Trading Partner” means:

(a) A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or

(b) A third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

(19) “Validate” means to verify that each transaction listed on the pedigree and other accompanying documentation has occurred and is accurately recorded.

~~(22)~~ **(20)** "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 **or institutional** 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.~~ **The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug which may include:**

(A) Emergency medical reasons;

(B) Drug or devices used during a federal or state declared emergency; or

(C) The 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 **distribution** of a drug **or an offer to distribute 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 **dispenser,** 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)~~ **(l)** The sale, transfer, merger or consolidation of all or part of the business of a pharmacy from or with another pharmacy.

~~(n)~~ **(m)** The distribution of drugs by a manufacturer registered under Division 60 of this chapter of rules of its own products to a person other than a patient.

~~(23)~~ **(21)** "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, own-label distributors; private-label distributors; 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)~~ **(22)** "Wholesaler" means any wholesale distributor:

(a) "Class I Wholesaler" **for the purpose of these rules** means any person operating or maintaining a wholesale distribution center, wholesale business or any other business in which prescription drugs; **including controlled drugs, devices containing 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 **and is required to comply with all pedigree requirements;**

(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 **non-prescription drugs** ~~products in paragraphs (A)-(E) below~~ are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer.;

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

~~(B) Drugs distributed exclusively for veterinary use. If any prescription drugs not intended for veterinary use are offered for sale, the wholesaler must register as a Class I wholesaler;~~

~~(C) Prescription devices that do not contain a prescription drug;—~~

~~(D) Drugs or devices possessed by a state or local government agency, or non-profit relief organization approved by the Board.~~

(E) Oxygen USP and medical gases.

(c) “Class III 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)-(F) below are stored, or offered for sale or distribution at wholesale to a drug outlet or practitioner legally authorized to resell, distribute, dispense or administer and is exempted from Federal recordkeeping requirements:

(A) Drugs distributed exclusively for veterinary use. If any prescription drugs not intended for veterinary use are offered for sale, the wholesaler must register as a Class I wholesaler;

(B) Prescription devices that do not contain a prescription drug;

(C) Drugs or devices possessed by a state or local government agency, or non-profit relief organization approved by the Board;

(D) Oxygen USP and medical gases;

(E) Intravenous drugs; by which formulation, are intended for the replenishment of fluids, electrolytes or calories;

(F) Medical convenience kits which includes any non controlled drug product or biological product, assembled in kit form.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155

855-065-0010

Minimum Requirements for Record Keeping and Inventory Management

(1) A Wholesale distributor must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs. These records must comply with all federal drug laws and regulations **unless exempted.** ~~and must include the following information:~~

~~(a) The source of the drugs, 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 drugs were shipped and the address of the location the drugs were shipped to;~~

~~(b) The identity and quantity of the drugs received and distributed or disposed of;~~

~~(c) The dates of receipt and distribution or other disposition of the drugs; and~~

~~(d) A pedigree as defined in OAR 855-065-0005(17) for any prescription drug that leaves the normal chain of distribution as defined by OAR 855-065-0005(16). All pedigrees initiated after~~

~~January 1, 2009 must be in electronic form except that the Board may extend this date if it appears that the necessary technology is not adequately deployed across the pharmaceutical supply chain.~~

(2) Inventories and 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, law enforcement agencies, and this Board.

(3) Inventories and records required under these rules must be maintained for **a minimum of** three years following disposition of the drugs.

(4) Records described in this section that are less than 13 months old must be kept at the inspection site or be immediately retrievable by computer or other electronic means, and must be immediately available for inspection. All other records required by this rule must be made available for inspection within three business days of a request.

(5) A wholesale distributor must establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, transport, shipping and distribution of drugs, including policies and procedures for identifying, recording, and reporting any loss, theft, counterfeiting or diversion of any drug and for correcting all errors and inaccuracies in inventories. A wholesale distributor must include in its written policies and procedures the following:

(a) A procedure whereby the oldest approved stock of a drug is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

(b) A procedure to be followed for handling a recall or withdrawal of a drug. Such procedure must be adequate to deal with a recall or withdrawal due to:

(A) Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the Board;

(B) Any voluntary action by the manufacturer to remove a defective or potentially defective drug from the market; or

(C) Any action undertaken to promote public health and safety by replacing an existing drug with an improved product or new package design.

(c) A procedure to prepare for, protect against, and handle any crisis that affects the security or operation of the facility in the event of strike, fire, flood, or other natural disaster, or other local, state, or national emergencies.

(d) A procedure to ensure that any outdated drug is segregated from other drugs and either returned to the manufacturer or destroyed. This procedure must provide for written documentation of the disposition of an outdated drug. This documentation must be maintained for three years after disposition of the outdated drug.

(e) Disposition and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging are not used in counterfeiting activities, including necessary documentation and witnessing in accordance with state and federal law.

(f) Investigation of discrepancies in the inventory involving counterfeit, suspected counterfeit, contraband, or suspected contraband drugs and reporting of discrepancies within three business days to the Board and any other appropriate state or federal agency.

(g) Reporting of criminal or suspected criminal activities involving the inventory of drugs to the Board within three business days.

(h) Conducting for cause authentication as required under section (7) of this rule.

(i) Procedures for accurately documenting the temperature and humidity conditions of the storage facility.

(6) A wholesale distributor must maintain and adhere to written policies and procedures for all incoming and outgoing product shipments, including but not limited to the following:

(a) Upon receipt, visual examination of each shipping container sufficient to identify the drugs in the container and to determine whether the drugs may be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution.

(b) Upon receipt, review of records for accuracy and completeness, considering the:

(A) Total facts and circumstances surrounding each transaction involving the drugs; and

(B) Wholesale distributors involved.

(c) Quarantine of a drug considered to be outdated, adulterated, misbranded, contaminated, contraband, counterfeit, damaged, or otherwise unfit for distribution until:

(A) Examination and a determination is made that the drug is fit for distribution; or

(B) The drug is destroyed or returned to the manufacturer or wholesale distributor from which the drug was acquired.

(d) If the wholesale distributor **identifies a suspect product**, ~~determines that a drug is adulterated, misbranded, counterfeit,~~ the wholesale distributor must **quarantine the product and promptly conduct an investigation to determine whether the suspect product is illegitimate. If it is determined to be an illegitimate product the wholesale distributor must** provide notice ~~of the adulteration, misbranding or counterfeiting~~ to the Board, the Food and Drug Administration, and the ~~manufacturer or wholesale drug distributor from which the drug was acquired,~~ **trading partners involved in the transaction**, within **24 hours** ~~three business days~~.

(e) If the immediate or sealed outer or secondary container or labeling of a drug is adulterated, misbranded, counterfeit, or suspected counterfeit, the wholesale distributor must:

(A) Quarantine the drug until the drug is destroyed or returned to the manufacturer or wholesale distributor from which the drug was acquired; and

(B) Provide notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting to the Board, the Food and Drug Administration, and the manufacturer or wholesale distributor from which the drug was acquired, within ~~three business days~~ **24 hours**.

(f) A drug that is not adulterated, misbranded, counterfeit, or suspected counterfeit, but has been opened or used, is identified as such and quarantined until the drug is destroyed or returned to the manufacturer or wholesale distributor from which the drug was acquired.

(g) A drug that will be returned to a manufacturer or wholesale distributor is stored, handled and transported under proper conditions before the return, and documentation showing that proper conditions were maintained must be provided to the manufacturer or wholesale distributor to which the drug is returned.

(h) Inspection of each outgoing shipment to verify the identity of each drug and to ensure that each drug has not been damaged in storage or held under improper conditions.

(i) Contraband, counterfeit, or suspected counterfeit drugs, other evidence of criminal activity, and accompanying documentation are retained until a disposition is authorized by the Board or the Food and Drug Administration.

(j) Any sealed outer or secondary shipping container or labeling, and accompanying documentation, for a drug that is suspected to be counterfeit or fraudulent, is retained until a disposition is authorized by the Board and the Food and Drug Administration.

(k) Operations comply with all state and federal laws, rules and regulations applicable to wholesale drug distribution.

(l) All confidential information is stored in an area with restricted access and in such a way as to protect the integrity and confidentiality of the information.

~~(7) A wholesale distributor that has reason to suspect that a drug may be adulterated, misbranded, contaminated, contraband, counterfeit or otherwise unfit for distribution must conduct a "for cause" authentication of each distribution of the drug back to the manufacturer.~~

~~(8) A wholesale distributor that has engaged in the distribution of a drug for which a purchasing wholesale distributor conducts a "for cause" authentication must provide, upon request, detailed information regarding the distribution of the drug, including:~~

~~(a) The date of purchase of the prescription drug;~~

~~(b) The lot number of the prescription drug;~~

~~(c) The sales invoice number of the prescription drug; and~~

~~(d) Contact information, including name, address, telephone number, and electronic mail address of the wholesale distributor that sold the prescription drug.~~

~~(9) A wholesale distributor that purchases prescription drugs from another wholesale distributor must conduct a random authentication of at least 10 per cent of the pedigrees required under section (1)(d) of this rule, at least annually.~~

~~(10) (7) If A wholesale distributor conducts an authentication of a drug pedigree, the wholesale distributor must maintain such **pedigree** records for **a minimum of** three years and must produce the records for the Board and the Food and Drug Administration upon request.~~

~~(11) If a wholesale distributor conducts an authentication and is unable to authenticate each distribution of the prescription drug, the wholesale distributor must immediately quarantine the prescription drug and report the circumstances to the Board, and the Food and Drug Administration if applicable, not more than 10 business days after completing the attempted authentication.~~

~~(12) (8) If the wholesale distributor is involved in the distribution of controlled substances, the distributor must register with the Drug Enforcement Administration and the Board, and comply with all laws related to the storage, handling, transport, shipment, and distribution of controlled substances including, but not limited to, the isolation of controlled substances from non-controlled substances and storage of the controlled substances in a secure area in accordance with Drug Enforcement Administration security requirements and standards.~~

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155, 689.315, 689.325 & 689.765 527

855-065-0013

Prohibited Practices

(1) The following practices are expressly prohibited:

(a) A wholesale distributor may not purchase drugs from a closed-door pharmacy.

(b) A wholesale distributor may not sell, distribute or transfer a drug to a person who is required by the laws and rules of Oregon to be registered with the Oregon Board of Pharmacy and who is not appropriately registered by the Board. Before furnishing a drug to any person not known to the wholesale distributor, the wholesale distributor must verify that the person is legally authorized to receive the drug.

(c) A wholesale distributor may not purchase any drug from a person who is required by the laws and rules of Oregon to be registered with the Oregon Board of Pharmacy and who is not appropriately registered by the Board. Before purchasing a drug from any person not known to the wholesale distributor, the wholesale distributor must verify that the person is legally authorized to sell the drug.

~~(d) A Class 1 wholesaler may not purchase any prescription drug from outside the normal chain of distribution, as defined by section 855-065-0005(16) without receiving an accompanying pedigree.~~

~~(e) A Class 1 wholesaler may not sell, distribute or transfer a prescription drug to another wholesale distributor, outside the normal chain of distribution as defined by section 855-065-0005(16), without providing a complete pedigree for the prescription drug.~~

~~(f)~~ **(d)** A Class 1 ~~w~~**Wholesaler** who is classified as a "Specialty Wholesaler Distributor" as defined in OAR 855-065-005(20) may not:

(A) Sell, distribute or transfer a prescription drug to a pharmacy or to a practitioner who is licensed to prescribe the prescription drug, without providing a complete pedigree for the prescription drug, unless the prescription drug was purchased directly from the manufacturer or from the manufacturer's authorized distributor of record.

(B) Sell, distribute or transfer a prescription drug to a wholesale distributor, without providing a complete pedigree for the prescription drug.

(2) A wholesaler 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 **intentional** receipt of a drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected counterfeit **product**, 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 without the authorization of the manufacturer.

(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) Obtaining or attempting to obtain a drug by fraud, deceit, misrepresentation, or engaging in fraud, deceit, or misrepresentation in the distribution of a drug.
- (l) Failing to ~~obtain, authenticate, or provide a required~~ **maintain required** pedigree **records.** ~~for a prescription drug.~~
- (m) Receiving a prescription drug through wholesale distribution without receiving a required pedigree attested to as accurate and complete by the wholesale distributor.
- (n) Distributing 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 855.065 to the appropriate state or federal authorities.

Stat. Auth.: ORS 689.205

Stats. Implemented: ORS 689.155, 689.305, 689.315 & 689.765-**527**