

Chapter 246-879 WAC

PHARMACEUTICAL WHOLESALERS

WAC

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WAC 246-879-010 Definitions. (1) "Full line wholesaler" means any wholesaler authorized by the board to possess and sell legend drugs, controlled substances (additional registration required see WAC 246-879-080) and nonprescription drugs (over-the-counter - OTC see WAC 246-879-070) to a licensed pharmacy or other legally licensed or authorized person.

(2) "Over-the-counter only wholesaler" means any wholesaler authorized by the board to possess and sell nonprescription (OTC) drugs to any outlets licensed for resale.

(3) "Controlled substances wholesaler" means a licensed wholesaler authorized by the board to possess and sell controlled substances to a licensed pharmacy or other legally licensed or authorized person.

(4) "Export wholesaler" means any wholesaler authorized by the board to export legend drugs and nonprescription (OTC) drugs to foreign countries.

(5) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.

(6) "Blood component" means that part of the blood separated by physical or mechanical means.

(7) "Drug sample" means a unit of prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(8) "Manufacturer" means anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a drug, provided that a pharmacist compounding drugs to be dispensed from the pharmacy in which the drugs are compounded pursuant to prescriptions for individual patients shall not be considered a manufacturer.

(9) "Prescription drug" means any drug required by state or federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

(10) "Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a) The sale, purchase, or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;

(b) The lawful distribution of drug samples by manufacturers' representatives or distributors' representatives; or

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

(d) Intracompany sales, being defined as any transaction or transfer between any division, subsidiary, parent and/or affiliated or related company under the common ownership and control of a corporate entity, unless such transfer occurs between a wholesale distributor and a health care entity or practitioner.

(e) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons; for purposes of this section, "emergency medical reasons" includes transfers of prescription drugs by retail pharmacy to another retail pharmacy or practitioner to alleviate a temporary shortage, except that the gross dollar value of such transfers shall not exceed five percent of the total prescription drug sale revenue of either the transferor or transferee pharmacy during any twelve consecutive month period.

(11) "Wholesale distributor" means anyone engaged in wholesale distribution of drugs, including but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses; including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

[Statutory Authority: RCW 18.64.005. 92-15-069 (Order 289B), § 246-879-010, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-879-010, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-010, filed 3/2/82.]

WAC 246-879-020 Minimum standards for wholesalers. The following shall constitute minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees:

(1) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded,

or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(d) Be maintained in a clean and orderly condition; and

(e) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Storage. All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs or with the requirements in the 22nd edition of the United States Pharmacopeia/National Formulary (USP/NF). United States Pharmacopeia/National Formulary (USP/NF) is available for public inspection at the Office of the State Board of Pharmacy, 1300 Quince St SE, PO Box 47863, Olympia WA 98504-7863.

(a) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

(3) Examination of materials.

(a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to contents.

(b) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(4) Returned, damaged, and outdated prescription drugs.

(a) Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

(b) Any drug whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other drugs until they are either destroyed or returned to the supplier.

(c) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(5) Written policies and procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription

drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies:

(a) A procedure whereby the oldest approved stock of a drug product 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 recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(i) Any action initiated at the request of the Food and Drug Administration or other federal, state, or local law enforcement or other governmental agency, including the board of pharmacy;

(ii) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

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

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

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

(6) Responsible persons. Wholesale drug distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

[Statutory Authority: RCW 18.64.005, 92-15-069 (Order 289B), § 246-879-020, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW, 91-18-057 (Order 191B), recodified as § 246-879-020, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075, 82-06-042 (Order 165), § 360-21-020, filed 3/2/82.]

WAC 246-879-030 Inspections. (1) Inspections shall be performed by representatives of the board of pharmacy to ensure compliance with chapter 246-879 WAC. The following items shall be included in these inspections:

(a) Housekeeping, sanitation, recordkeeping, accountability, security, types of outlets sold to and sources of drugs purchased.

(b) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(2) Wholesale drug distributors shall permit the board's authorized personnel and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law. Such officials shall be required to show appropriate identification prior to being

permitted access to wholesale drug distributors' premises and delivery vehicles.

[Statutory Authority: RCW 18.64.005. 92-15-069 (Order 289B), § 246-879-030, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-879-030, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-030, filed 3/2/82.]

WAC 246-879-040 Records. (1) Recordkeeping. Wholesale drug distributors shall establish and maintain inventories and records of transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:

(a) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

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

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

(2) Inventories and records shall be made available for inspection and photocopying by an authorized official of any governmental agency charged with enforcement of these rules for a period of two years following disposition of the drugs.

(3) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of any governmental agency charged with enforcement of these rules.

[Statutory Authority: RCW 18.64.005. 92-15-069 (Order 289B), § 246-879-040, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-879-040, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-040, filed 3/2/82.]

WAC 246-879-050 Security. (1) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(2) Access from outside the premises shall be kept to a minimum and be well-controlled.

(3) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(4) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

(5) Drug storage areas shall be constructed in such a manner as to prevent illegal entry.

(6) Adequate lighting shall be provided at the outside perimeter of the premises to reduce the possibility of illegal entry.

(7) All applicants for a license as a controlled substances wholesaler must comply with the security requirements as

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found in 21 CFR 1301.02, 1301.71 through 1301.74 and 1301.90 through 1301.92.

[Statutory Authority: RCW 18.64.005. 92-15-069 (Order 289B), § 246-879-050, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-879-050, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-050, filed 3/2/82.]

WAC 246-879-060 Unauthorized sales. No wholesaler distributor shall sell or distribute any prescription drugs or devices except to an individual, corporation, or entity who is authorized by law or regulation to possess such drugs or devices. No wholesaler shall sell any prescription drugs or devices to an ultimate consumer.

[Statutory Authority: RCW 18.64.005. 92-15-069 (Order 289B), § 246-879-060, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-879-060, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-060, filed 3/2/82.]

WAC 246-879-070 Application for full line wholesaler license and over-the-counter only wholesaler license.

(1) All applications for licensure of a new or relocated wholesaler shall be accompanied by the required fee as set forth in chapter 246-907 WAC.

(2) All license renewal applications shall be accompanied by the annual fee and contain the same information required in subsection (6) of this section.

(3) A change of ownership or location requires a new license.

(4) The license is issued to a person or firm and is non-transferable. Additions or deletions of a partner/partners shall be considered as a change of ownership.

(5) The license fee cannot be prorated.

(6) Every wholesale distributor, wherever located, who engages in wholesale distribution into, out of, or within this state must be licensed by the board in accordance with the laws and regulations of this state before engaging in wholesale distribution of prescription drugs.

(a) Minimum required information for licensure. The board requires the following from each wholesale drug distributor as part of the initial licensing procedure and as part of any renewal of such license.

(i) The name, full business address, and telephone number of the licensee;

(ii) All trade or business names used by the licensee;

(iii) Addresses, telephone numbers, and the names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;

(iv) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

(v) The name(s) of the owner and/or operator of the licensee, including:

(A) If a person, the name of the person;

(B) If a partnership, the name of each partner, and the name of the partnership;

(C) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation, and the name of the parent company, if any;

(D) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

(vi) When operations are conducted at more than one location by a single wholesale distributor, each such location shall be licensed by the board.

(vii) Change in any information required by this section shall be submitted to the board within thirty days after such change.

(b) Minimum qualifications. The board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the state:

(i) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale, or retail drug distribution, or distribution of controlled substances;

(ii) Any felony convictions of the applicant under federal, state, or local laws;

(iii) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;

(iv) Any false or fraudulent material furnished by the applicant in any application made in connection with drug manufacturing or distribution;

(v) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(vi) Compliance with licensing requirements under previously granted licenses, if any;

(vii) Compliance with requirements to maintain and/or make available to the board, federal, state, or local enforcement officials those records required to be maintained by wholesale drug distributors; and

(viii) Any other factors or qualifications the board considers relevant to and consistent with public health and safety.

(c) The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest. Public interest considerations shall be based on factors and qualifications that are directly related to the protection of the public health and safety.

(d) Personnel. As a condition for receiving and retaining a wholesale drug distributor license, the licensee shall require each person employed in any prescription drug wholesale distribution activity to have education, training, and experience, or any combination thereof, sufficient for that person to perform the assigned functions in such a manner as to provide assurance that the drug product quality, safety and security will at all times be maintained as required by law.

[Statutory Authority: RCW 43.70.280. 98-05-060, § 246-879-070, filed 2/13/98, effective 3/16/98. Statutory Authority: RCW 18.64.005. 92-15-069 (Order 289B), § 246-879-070, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-879-070, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-070, filed 3/2/82.]

WAC 246-879-080 Application for controlled substance wholesaler license. Wholesale drug distributors that deal in controlled substances shall register with the board and

with the Drug Enforcement Administration (DEA), and shall comply with applicable state, local, and DEA regulations.

(1) He/she must be licensed as a full line wholesaler.

(2) He/she must meet all security requirements as set forth in WAC 246-879-050.

(3) He/she must meet additional requirements for registration and fees as set forth in chapter 246-907 WAC.

[Statutory Authority: RCW 18.64.005. 92-15-069 (Order 289B), § 246-879-080, filed 7/14/92, effective 8/14/92. Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-879-080, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-080, filed 3/2/82.]

WAC 246-879-090 Export wholesaler. (1) Upon application the board may issue a wholesaler license for the primary business of exporting drugs to foreign countries.

(2) Such license authorizes the holder to export non-controlled drugs to persons in a foreign jurisdiction that have legitimate reasons to possess such drugs.

(3) Letters from consulate of the country to which drugs are exported should verify consignee receiving such drugs is legally entitled in that country to receive them, if applicable. These letters shall be made available to the board upon its request.

(4) Records to be kept by export wholesaler:

(a) Complete description of drug, including, name, quantity, strength, and dosage unit.

(b) Name and address of purchaser.

(c) Name and address of consignee in the country of destination.

(d) Name and address of forwarding agent.

(e) Proposed export date.

(f) Shippers involved and methods of shipment.

(5) The issuance of an export wholesaler license does not authorize delivery of drugs in the United States.

[Statutory Authority: RCW 18.64.005 and chapter 18.64A RCW. 91-18-057 (Order 191B), recodified as § 246-879-090, filed 8/30/91, effective 9/30/91. Statutory Authority: RCW 18.64.005(11) and 69.41.075. 82-06-042 (Order 165), § 360-21-090, filed 3/2/82.]

WAC 246-879-100 Salvaging and reprocessing companies. Wholesale drug distributors shall be subject to the provisions of any applicable federal, state, or local laws or rules that relate to prescription drug product salvaging or reprocessing, including this chapter.

[Statutory Authority: RCW 18.64.005. 92-15-069 (Order 289B), § 246-879-100, filed 7/14/92, effective 8/14/92.]

WAC 246-879-110 Violations and penalties. The board shall have the authority to suspend or revoke any licenses granted under this chapter upon conviction of violations of the federal, state, or local drug laws or rules. Before any license may be suspended or revoked, a wholesale distributor shall have a right to prior notice and a hearing pursuant to the Administrative Procedure Act, chapter 34.05 RCW.

[Statutory Authority: RCW 18.64.005. 92-15-069 (Order 289B), § 246-879-110, filed 7/14/92, effective 8/14/92.]

WAC 246-879-120 Reciprocity. A wholesale distributor licensed in another state may be licensed in this state upon submission of the fee required in chapter 246-907 WAC and

submission of information compiled by the National Association of Boards of Pharmacy (NABP) Clearinghouse demonstrating that the license is not, and has not been, the subject of adverse license action.

[Statutory Authority: RCW 18.64.005. 92-15-069 (Order 289B), § 246-879-120, filed 7/14/92, effective 8/14/92.]