

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(c) Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;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, P.O. 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. WSR 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. WSR 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. WSR 82-06-042 (Order 165), § 360-21-020, filed 3/2/82.]