

WAC 246-945-590 Wholesaler—Policies and procedures. Wholesalers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and wholesale distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesalers shall include the following in their written policies and procedures:

(1) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the commission; or

(b) Any volunteer action by the manufacturer to remove defective or potentially defective drugs from the market.

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

(3) A procedure to ensure that any outdated drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated drugs.

(4) A procedure for the destruction of outdated drugs in accordance with federal and state laws.

(5) A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements.

(6) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies as required to the FDA, commission and/or appropriate federal or state agency upon discovery of such discrepancies.

(7) A procedure for reporting criminal or suspected criminal activities involving the inventory of drug(s) as required to the commission, FDA, and if applicable, DEA.

(8) Procedures addressing:

(a) The design and operation of the suspicious order monitoring and reporting system;

(b) Mandatory annual training for staff responsible for identifying and reporting suspicious orders and potential diversion activities. Such training must include the following:

(i) The wholesaler's suspicious order monitoring system;

(ii) The process to collect all relevant information on customers in accordance with WAC 246-960-330; and

(iii) The requirement and process for submission of suspicious order and information on customers who engage in potential diversion activities.

(9) A procedure for timely responding to customers who submit purchase orders for patients with emergent needs.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-590, filed 6/1/20, effective 7/1/20.]