

**657—17.8(124,155A) Written policies and procedures.** Wholesale distributors shall establish, maintain, and adhere to written policies and procedures that are in compliance with federal law 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 distributors shall also include in their written policies and procedures the following:

**17.8(1) *Recalls and market withdrawals.*** A procedure to be followed for handling recalls and withdrawals of prescription drugs.

*a.* The procedure shall be adequate to deal with recalls and withdrawals due to:

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

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

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

*b.* The requirement of this subrule shall not apply to a returns processor.

**17.8(2) *Emergency and disaster plan.*** A procedure to ensure that wholesale 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.

**17.8(3) *Outdated drugs.*** A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. The requirement of this subrule shall not apply to a returns processor.

**17.8(4) *Security and storage.*** A procedure to ensure adequate security in accordance with rule 657—17.10(124,155A) and proper storage conditions in accordance with rule 657—17.11(155A). The requirement for proper storage conditions shall not apply to a returns processor.

**17.8(5) *Drugs supplied to salesperson/representative.*** If supplying drugs to wholesale distributor salespersons, a procedure directing that the security, storage, and record-keeping requirements contained in these rules shall be maintained by those salespersons.

**17.8(6) *Personnel.*** A procedure to ensure the wholesale distributor employs personnel with the education and experience appropriate to the responsibilities of the position held by the individual. Licensed wholesale 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.

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