

657—17.8 (124,155A) Written policies and procedures. Wholesalers shall establish, maintain, and adhere to written policies and procedures 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. Wholesalers shall also include in their written policies and procedures the following:

17.8(1) *Oldest stock distributed first.* A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

17.8(2) *Recalls and market withdrawals.* 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:

a. 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;

b. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

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

17.8(3) *Emergency and disaster plan.* 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 strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

17.8(4) *Outdated drugs.* A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs.

17.8(5) *Exception.* The procedure required by subrule 17.8(1) does not apply to reverse distribution operations. All other procedures addressed in this rule are required of reverse distribution operations.

17.8(6) *Drugs supplied to salesperson/representative.* If supplying drugs to wholesale salespersons or manufacturers' representatives, a procedure directing that the security, storage, and record-keeping requirements contained in these rules shall be maintained by those wholesale salespersons or manufacturers' representatives.