

§ 106-145.9. Written procedures concerning prescription drugs and lists of responsible persons.

(a) Procedures. – A wholesale distributor shall establish, maintain, and adhere to written procedures for the receipt, security, storage, inventory, and distribution of prescription drugs. These shall include all of the following:

- (1) A procedure for identifying, recording, and reporting a loss or theft of a prescription drug.
- (2) A procedure for correcting all errors and inaccuracies in inventories of prescription drugs.
- (3) A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.
- (4) A procedure for handling recalls and withdrawals of prescription drugs that adequately addresses recalls and withdrawals due to any of the following:
 - a. An 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 Department.
 - b. Any voluntary action by the manufacturer to remove defective or potentially defective prescription drugs from the market.
 - c. Any action undertaken to promote public health and safety by replacing existing prescription drugs with an improved product or new package design.
- (5) A procedure to ensure that the wholesale distributor prepares for, protects against, and handles any crisis that affects security or operation of any facility in the event of a strike, a fire, flood, or other natural disaster, or another emergency.
- (6) A procedure to ensure that any outdated prescription drugs are segregated from other prescription drugs and either returned to the manufacturer or destroyed.

(b) Responsible Persons. – A wholesale distributor shall establish and maintain lists of officers, directors, managers, and other persons in charge of the distribution, storage, or handling of prescription drugs. The lists shall include a description of the duties of those on the list and a summary of their qualifications. (1991, c. 699, s. 2.)