§ 106-145.7. Storage, handling, and records of prescription drugs.

(a) Facilities. – All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed for wholesale distribution shall meet the following requirements:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations.

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions.

(3) Have a quarantine area for the storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.

(4) Be maintained in a clean and orderly condition.

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security. – All facilities used for wholesale distribution shall be secure from unauthorized entry. Access from outside the premises shall be kept to a minimum and be well-controlled. The outside perimeter of the premises shall be well-lighted. Entry into areas where prescription drugs are held shall be limited to authorized personnel. The facilities shall be equipped with the following:

(1) An alarm system to detect entry after hours.

(2) A security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage. – All prescription drugs for wholesale distribution shall be stored at appropriate temperatures and under appropriate conditions in accordance with any requirements stated in the labeling of the prescription drugs or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF). If the labeling of a prescription drug or a compendium do not establish storage requirements 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.

(d) Examination of Materials. – A wholesale distributor shall visually examine each outside shipping container upon receipt for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. The examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents. A wholesale distributor shall carefully inspect each outgoing shipment for identity of the prescription drugs and to ensure that no prescription drugs that have been damaged in storage or held under improper conditions are delivered.

(e) Returned, Damaged, and Outdated Prescription Drugs. – A wholesale distributor shall quarantine and physically separate prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated from other prescription drugs until their destruction or their return to their supplier. A prescription drug whose immediate or sealed outer or sealed secondary container has been opened or used shall be identified as having been opened or used and shall be treated in the same manner as outdated prescription drugs.

If the conditions under which a prescription drug has been returned to a wholesale distributor cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed or returned to its 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 prescription drug has been returned cast

doubt on the drug's safety, identity, strength, quality, or purity, the wholesale 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. (1991, c. 699, s. 2.)