

657—17.15(155A) Returned, damaged, and outdated prescription drugs.

17.15(1) *Quarantine required.* Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.

17.15(2) *Seal opened.* Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

17.15(3) *Drug safety, purity uncertain.* Unless examination, testing, or other investigation proves that a drug meets appropriate standards of safety, identity, strength, quality, and purity, a prescription drug that has been returned under conditions that cast doubt on the drug's safety, identity, strength, quality, or purity shall be destroyed or returned to the supplier. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesaler shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling as a result of storage or shipping.

17.15(4) *Exception.* The requirements of this rule do not apply to reverse distribution operations.