657—9.10 (147,155A) Quality assurance and performance improvement. The goal of any AMDS is the accurate dispensing of drugs. In all dispensing activities, the pharmacy shall strive for 100 percent accuracy. Quality assurance data shall be utilized to monitor and improve systems.

9.10(1) *AMDS.* Pharmacies utilizing an AMDS shall have a written quality assurance and monitoring plan pursuant to rule 657—9.3(147,155A) prior to implementation of the AMDS. The quality assurance plan shall target the preparation, delivery, and verification of AMDS unit contents during fill and refill processes and shall include, but not be limited to, the following:

a. Requiring continuous monitoring of the system.

b. Establishing mechanisms and procedures to test the accuracy of the system.

c. Establishing a protocol for measuring the effectiveness of the system.

d. Requiring the pharmacy to report to the board each recurring error of the system.

9.10(2) *Telepharmacy.* In addition to the requirements of subrule 9.10(1), a managing pharmacy that provides telepharmacy services at a remote dispensing site shall operate according to a written program for quality assurance that includes, but is not limited to, the following:

a. Requiring continuous supervision of the remote dispensing site at all times when the remote site is open to provide telepharmacy services.

b. Requiring a pharmacist at the managing pharmacy to be accessible to respond to inquiries or requests pertaining to drugs that are dispensed by utilizing the automated pharmacy system located at the remote dispensing site.

c. Establishing procedures to test the operation of all aspects of the automated pharmacy system, including all electronic audio and video communication components, at a minimum of every six months and whenever any upgrade or change is made to the system, and to document the testing of each system.

d. Establishing a written plan for recovery from a failure of the automated pharmacy system or any component of the system pursuant to subrule 9.10(3).

9.10(3) *Recovery from failure of the automated pharmacy system.* The written plan for recovery from an event that interrupts the ability of a pharmacist to electronically supervise the automated pharmacy system and the dispensing of drugs at the remote dispensing site shall include, at a minimum, the following:

a. A statement that drugs shall not be dispensed at the remote dispensing site if a pharmacist is not available or able to electronically supervise such dispensing, including the utilization of audio and video communication, or if a pharmacist is not on site at the remote dispensing site to personally dispense the drugs.

b. Procedures for response when the automated pharmacy system is experiencing downtime.

c. Procedures for the maintenance and testing of the written plan for recovery.

d. Procedures for notifying the board and other appropriate agencies or organizations of a disaster affecting the ability of the pharmacy to provide services for an extended period of time, including the date on which the pharmacy expects to recommence services.

9.10(4) *Records.* All records and documentation of quality assurance and monitoring, performance improvement projects, and recovery from system failure shall be maintained by the managing pharmacy and be available for inspection and copying by the board or its representative for a minimum of two years from the date of the record.

[**ARC 1961C**, IAB 4/15/15, effective 5/20/15]