

657—9.3 (147,155A) Responsibilities.

9.3(1) AMDS. In any pharmacy utilizing an AMDS, the following responsibilities, which are in addition to the responsibilities required by all applicable federal and state laws, rules and regulations and the responsibilities described in rule 657—8.3(155A), shall be assigned as follows:

a. The pharmacy and the pharmacist in charge shall share responsibility for establishing, the pharmacist in charge shall be responsible for implementing, and the pharmacist in charge and staff pharmacists shall share responsibility for utilizing an ongoing quality assurance program the purpose of which is to monitor and improve performance of each AMDS as provided in rule 657—9.10(147,155A).

b. The pharmacist in charge shall be responsible for assigning, discontinuing, or changing drug and information access to the AMDS.

c. The pharmacist in charge and staff pharmacists shall share responsibility for:

(1) Ensuring that drug access, including access to controlled substances, is in compliance with state and federal laws, rules and regulations.

(2) Ensuring that each AMDS component is filled or stocked accurately and in accordance with established, written policies and procedures.

(3) Ensuring that each AMDS component is in good working order and performs its designated tasks, including ensuring the correct strength, dosage form, and quantity of the prescribed drug.

(4) Ensuring that confidentiality of patient-specific information is maintained.

(5) Ensuring that all personnel utilizing or accessing the AMDS or any component of the AMDS have been appropriately trained.

d. The pharmacist in charge, staff pharmacists, and the pharmacy, by and through its owner or license holder, shall share responsibility for ensuring that the AMDS has adequate security safeguards regarding drug and information access.

e. The pharmacy shall provide the board with written notice at least 30 days prior to an installation, removal, or upgrade that significantly changes the operation of an AMDS. The notice shall include:

(1) The name, address, and license number of the pharmacy;

(2) The location of the automated equipment;

(3) Identification of the pharmacist in charge;

(4) The name, manufacturer, and model of the system;

(5) A description of the change or upgrade, if applicable, and a description of the intended use of the equipment; and

(6) If a new or significantly changed AMDS will be installed or upgraded, a copy of the quality assurance plan.

9.3(2) Telepharmacy. The pharmacist in charge of the managing pharmacy shall also serve as the pharmacist in charge of the remote dispensing site. In addition to other responsibilities assigned under federal and state laws and regulations, including the responsibilities identified in rule 657—6.2(155A), the pharmacist in charge shall be responsible for, at a minimum, the following:

a. Submitting for board approval the operational plan for the telepharmacy service, including identification of the managing pharmacy; identification of the remote dispensing site; the names and titles of key personnel at both locations; the quality assurance and improvement plan; policies and procedures as provided in rule 9.11(147,155A); identification of the AMDS as provided in subrule 9.3(1), paragraph “j”; justification of the need for the telepharmacy service as provided in subrule 9.5(2); and a copy of the proposed contract between the managing pharmacy and the remote dispensing site.

b. Maintaining all licenses and registrations required of the managing pharmacy and of the remote dispensing site.

c. Ensuring that the practice of telepharmacy performed at a remote dispensing site, including the utilization of an automated pharmacy system and the supervision of one or more qualified certified pharmacy technicians, complies with these rules and other applicable rules of the board.

d. Ensuring that the managing pharmacy and the remote dispensing site have entered into a written contract as provided by subrule 9.5(6).

e. Ensuring that the automated pharmacy system is in good working order and that the AMDS accurately dispenses the correct strength, dosage form, and quantity of the prescribed drug and accurately prints the prescription label, while maintaining appropriate record-keeping and security safeguards.

f. Ensuring that all pharmacists, pharmacist-interns, and pharmacy technicians authorized to engage in telepharmacy services at the managing pharmacy or the remote site maintain current licensure or registration with the board and are trained in the operation of the automated pharmacy system and familiar with policies and procedures relating to the telepharmacy practice.

g. Ensuring that a pharmacist completes and documents monthly inspections of each remote site pursuant to subrule 9.5(8).

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