

**657—11.20 (124,147A,155A) Prescription drugs in service programs.** Prescription drugs maintained by a service program shall be owned by an Iowa-licensed pharmacy or the service program's medical director.

**11.20(1) Pharmacy-based service programs.** The pharmacist in charge, the medical director, and the service director shall jointly develop, consistent with the service program's protocol, a list of drugs to be maintained for administration by the service program. The pharmacy shall maintain a current list of all prescription drugs including controlled substances that the pharmacy maintains at the primary program site and at any program substation.

*a. Replenishment.* The responsible individual, the service director, or designee may request that replenishment supplies of drugs be maintained at the primary program site provided that the pharmacy has been supplied with administration records justifying the order. Records of the administration of Schedule III, IV, and V controlled substances and noncontrolled prescription drugs provided to and maintained at the pharmacy shall include, at a minimum: the patient's name; the name, strength, dosage form, and quantity of the drug administered; and the date of administration. Records of the administration of Schedule II controlled substances provided to and maintained at the pharmacy shall consist of a written prescription including all of the prescription information required pursuant to Iowa Code section 155A.27 or the patient care report if the patient care report includes the required prescription information, including an original signature of the authorizing prescriber. A pharmacist shall verify the accuracy of every drug to be disbursed to the primary program site. Documentation of this verification shall be maintained within the pharmacy records.

*b. Replenishment using automated medication distribution system (AMDS).* A pharmacy utilizing an automated medication distribution system (AMDS) may authorize replenishment of the service program's drug supplies from the AMDS provided that a pharmacist verifies the drugs stocked in the AMDS component before the drugs are removed from the pharmacy. Service program personnel authorized to remove drugs from the AMDS for restocking the service program's supplies shall be assigned a unique identification and access code for the purpose of accessing the AMDS. Access by authorized service program personnel shall be restricted to specific drug products authorized for use by the service program. A pharmacist shall, within 72 hours, review the access of and removal of drugs from the AMDS by service program personnel and shall maintain documentation of that review within the pharmacy records.

*c. Inspections.* The pharmacist in charge shall ensure the completion of a monthly inspection of all prescription drugs maintained by the pharmacy at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. All drugs removed from service program stock shall be returned to the pharmacy. Records of inspection shall be maintained for two years from the date of the inspection at the pharmacy. The pharmacist in charge may delegate the completion of the monthly inspection to another pharmacist, a pharmacist-intern, a certified pharmacy technician, or another designee of the pharmacist in charge.

**11.20(2) Medical director-based service programs.** The medical director and the service director shall jointly develop, consistent with the service program's protocol, a list of drugs to be maintained for administration by the service program. The medical director shall maintain a current list of all prescription drugs including controlled substances that the medical director maintains at the primary program site and at any program substation.

*a. Replenishment.* All drugs procured for administration in a medical director-based service program shall be obtained from an Iowa-licensed wholesaler, pharmacy, or authorized prescriber.

*b. Inspections.* The medical director shall ensure the completion of a monthly inspection of all prescription drugs maintained by the medical director at the primary program site and any program substation. Inspection shall include the removal of outdated or adulterated drugs. Records of inspection shall be maintained for two years from the date of the inspection at the primary program site or the program substation. The medical director may delegate the completion of the required inspections to the service director or other designee.

[ **ARC 9786B** , IAB 10/5/11, effective 11/9/11; **ARC 0342C** , IAB 10/3/12, effective 11/7/12; **ARC 1307C** , IAB 2/5/14, effective 3/12/14; **ARC 3101C** , IAB 6/7/17, effective 7/12/17]