

481—63.16(135C) Drugs.**63.16(1) Drug storage.**

a. Residents who have been certified in writing by their primary care provider as capable of taking their own medications may retain these medications in their bedroom, but locked storage must be provided, with staff and the resident having access, and the drug storage shall be kept locked when not in use. Monitoring of the storage, administration, and documentation by the resident shall be carried out by a person who meets the requirements of subrule 63.16(3) and is responsible for administering medications. (II, III)

b. Drug storage for residents who are unable to take their own medications and require supervision shall meet the following requirements:

- (1) Locked storage for drugs, solutions, and prescriptions shall be provided. (III)
- (2) A bathroom shall not be used for drug storage. (III)
- (3) The drug storage shall be kept locked when not in use. (III)
- (4) The drug storage key shall be secured and available only to those employees charged with the responsibility of administering medications. (II, III)
- (5) Schedule II drugs, as defined by Iowa Code chapter 124, shall be kept in a locked box within the locked drug storage. (II, III)
- (6) Medications requiring refrigeration shall be kept locked in a refrigerator and separated from food and other items. (II, III)
- (7) Drugs for external use shall be stored separately from drugs for internal use. (II, III)
- (8) All potent, poisonous, or caustic materials shall be stored separately from drugs, shall be plainly labeled and stored in a specific, well-illuminated cabinet, closet, or storeroom, and shall be made accessible only to authorized persons. (I, II)
- (9) Inspection of drug storage shall be made by the administrator or designee and a registered pharmacist not less than once every three months. The inspection shall be verified by a report signed by the administrator and the pharmacist and filed with the administrator. The report shall include, but not be limited to, certification of the absence of the following: expired drugs, deteriorated drugs, improper labeling, drugs for which there is no current primary care provider's order, and drugs improperly stored. (III)
- (10) Bulk supplies of prescription drugs for multiresident use shall not be kept in a residential care facility. (III)

63.16(2) Drug safeguards.

a. All prescribed medications shall be clearly labeled indicating the resident's full name, primary care provider's name, prescription number, name and strength of drug, dosage, directions for use, date of issue, and name and address and telephone number of pharmacy or primary care provider issuing the drug. Where unit dose is used, prescribed medications shall, at a minimum, indicate the resident's full name, primary care provider's name, name and strength of drug, and directions for use. Standard containers shall be utilized for dispensing drugs. (III)

b. Sample medications provided by the resident's primary care provider shall clearly identify to whom the medications belong. (III)

c. Medication containers having soiled, damaged, illegible, or makeshift labels shall be returned to the issuing pharmacist, pharmacy, or primary care provider for relabeling or disposal. (III)

d. The medication for each resident shall be kept or stored in the original containers unless the resident is participating in an individualized medication program. (II, III)

e. Unused prescription drugs shall be destroyed by the person in charge, in the presence of a witness, and with a notation made on the resident's record or shall be returned to the supplying pharmacist. (III)

f. Prescriptions shall be refilled only with the permission of the resident's primary care provider. (II, III)

g. Medications prescribed for one resident shall not be administered to or allowed in the possession of another resident. (I, II)

h. Instructions shall be requested from the Iowa board of pharmacy concerning disposal of unused Schedule II drugs prescribed for a resident who has died or for whom the Schedule II drug was discontinued. (III)

i. Discontinued medications shall be destroyed within a specified time by a responsible person, in the presence of a witness, and with a notation made to that effect or shall be returned to the pharmacist for destruction. Drugs listed under the Schedule II drugs shall be destroyed in accordance with the requirements established by the Iowa board of pharmacy. (II, III)

j. All medication orders which do not specifically indicate the number of doses to be administered or the length of time the drug is to be administered shall be stopped automatically after a given time period. The automatic-stop order may vary for different types of drugs. The resident's primary care provider, in conjunction with the pharmacist, shall institute these policies and provide procedures for review and endorsement. (II, III)

k. No resident shall be allowed to possess any medications unless the primary care provider has certified in writing on the resident's medical record that the resident is mentally and physically capable of doing so. (II)

l. No medications or prescription drugs shall be administered to a resident without a written order signed by the primary care provider. (II)

m. The facility shall establish a policy to govern the distribution of prescribed medications to residents who are on leave from the facility. (II, III)

(1) Medications may be issued to residents who will be on leave from a facility for less than 24 hours. Only those medications needed for the time period that the resident will be on leave from the facility may be issued. Non-child-resistant containers may be used. Instructions shall be provided and include the date, the resident's name, the name of the facility, and the name of the medication, its strength, dose and time of administration. (II, III)

(2) Medication for residents on leave from a facility for longer than 24 hours shall be obtained in accordance with requirements established by the Iowa board of pharmacy. (II, III)

(3) Medication for residents on leave from a facility may be issued only by facility personnel responsible for administering medication. (II, III)

63.16(3) Drug administration—authorized personnel.

a. A properly trained person shall be charged with the responsibility of administering medications as ordered by a primary care provider. (II, III)

b. The person shall have knowledge of the purpose of the drugs and their dangers and contraindications. (II, III)

c. The person shall be a licensed nurse or primary care provider or an individual who has completed the state-approved training course in medication administration, including a medication manager or certified medication aide. (II, III)

d. Prior to taking a department-approved medication aide course, the person shall have a letter of recommendation for admission to the medication aide course from the employing facility. (III)

e. A person who is a nursing student or a graduate nurse may take the medication aide challenge examination in place of taking a course. The person shall do all of the following before taking the challenge examination:

(1) Complete a clinical or nursing theory course within six months before taking the challenge examination; (III)

(2) Successfully complete a nursing program pharmacology course within one year before taking the challenge examination; (III)

(3) Provide to the community college a written statement from the nursing program's pharmacology or clinical instructor indicating that the person is competent in medication administration. (III)

f. A person who has written documentation of certification as a medication aide in another state may become a medication aide in Iowa by successfully completing a department-approved nurse aide competency examination and a medication aide challenge examination. The requirements of paragraph 63.16(3) "d" do not apply to this person. (III)

63.16(4) Drug administration.

a. Unless the unit dose system is used, the person assigned the responsibility of medication administration must complete the procedure by personally preparing the dose, observing the actual act of swallowing the oral medication, and charting the medication. In facilities where the unit dose system is used, the person assigned the responsibility of medication administration must complete the procedure by observing the actual act of swallowing the oral medication and by charting the medication. Medications shall be prepared on the same shift of the same day that they are administered unless the unit dose system is used. (II)

b. Injectable medications shall be administered as permitted by Iowa law by a registered nurse, licensed practical nurse, primary care provider or pharmacist. For purposes of this subrule, “injectable medications” does not include an epinephrine autoinjector, e.g., an EpiPen. (II, III)

c. A resident certified by the resident’s primary care provider as capable of injecting the resident’s own insulin may do so. Insulin may be administered pursuant to paragraph 63.16(4) “*b*” or as otherwise authorized by the resident’s primary care provider. (II, III) Authorization shall:

- (1) Be in writing,
- (2) Be maintained in the resident’s record,
- (3) Be renewed quarterly,
- (4) Include the name of the person authorized to administer the insulin,
- (5) Include documentation by the primary care provider that the authorized person is qualified to administer insulin to that resident. (II, III)

d. A resident may participate in the administration of the resident’s own medication if the primary care provider has certified in writing in the resident’s medical record that the resident is mentally and physically capable of participating and has explained in writing in the resident’s medical record what the resident’s participation may include.

e. An individual inventory record shall be maintained for each Schedule II drug prescribed for each resident, with an accurate count and authorized signatures at every shift. (II)

f. The facility may use a unit dose system.

g. Medication aides and medication managers may administer PRN medications without contacting a licensed nurse or primary care provider if all of the following apply: (I, II, III)

(1) A written order from the resident’s primary care provider specifies the purpose of the PRN medication and the frequency, dosage and strength of the PRN medication.

(2) The resident’s primary care provider provides in writing specific criteria for administering PRN medications.

(3) The pharmacist assesses the resident’s use of PRN medications when conducting the inspection of drug storage as required by subparagraph 63.16(1) “*b*”(9).

h. The pharmacist shall assess the use of PRN medications when conducting the inspection of drug storage as required by subparagraph 63.16(1) “*b*”(9). (II, III)

i. Medications administered by an employee of the facility shall be recorded on a medication record by the individual who administers the medication. (I, II, III)

[ARC 3740C, IAB 4/11/18, effective 5/16/18; ARC 4577C, IAB 7/31/19, effective 9/4/19]