

**481—58.21(135C) Drugs, storage, and handling.**

**58.21(1)** Drug storage for residents who are unable to take their own medications and require supervision shall meet the following requirements:

- a.* A cabinet with a lock, convenient to nursing service, shall be provided and used for storage of all drugs, solutions, and prescriptions; (III)
- b.* The drug storage cabinet shall be kept locked when not in use; (III)
- c.* The medication cabinet key shall be in the possession of the person directly responsible for issuing medications; (II, III)
- d.* Double-locked storage of Schedule II drugs shall not be required under single unit package drug distribution systems in which the quantity stored does not exceed a three-day supply and a missing dose can be readily detected. (II)

**58.21(2)** Drugs for external use shall be stored separately from drugs for internal use. (III)

**58.21(3)** Medications requiring refrigeration shall be kept in a refrigerator and separated from food and other items. A method for locking these medications shall be provided. (III)

**58.21(4)** All potent, poisonous, or caustic materials shall be stored separately from drugs. They shall be plainly labeled and stored in a specific, well-illuminated cabinet, closet, or storeroom and made accessible only to authorized persons. (I, II)

**58.21(5)** All flammable materials shall be specially stored and handled in accordance with applicable local and state fire regulations. (II)

**58.21(6)** A properly trained person shall be charged with the responsibility of administering nonparenteral medications.

*a.* The individual shall have knowledge of the purpose of the drugs, their dangers, and contraindications.

*b.* This person shall be a licensed nurse or physician or shall have successfully completed a department-approved medication aide course or passed a department-approved medication aide challenge examination administered by an area community college.

*c.* Prior to taking a department-approved medication aide course, the individual shall:

(1) Successfully complete an approved nurse aide course, nurse aide training and testing program or nurse aide competency examination.

(2) Be employed in the same facility and work at least 480 hours prior to the start of the medication aide course.

(3) Have a letter of recommendation for admission to the medication aide course from the employing facility.

*d.* A person who is a nursing student may take the challenge examination in place of taking a medication aide course. This individual shall do all of the following before taking the medication aide challenge examination:

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

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

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

(4) Successfully complete a department-approved nurse aide competency evaluation.

*e.* 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 "c" of this subrule do not apply to this individual.

**58.21(7)** 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. (II) In facilities where the unit dose system is used, the person assigned the responsibility must complete the procedure by observing the actual act of

swallowing the medication and charting the medication. Medications shall be prepared on the same shift of the same day that they are administered, (II) unless the unit dose system is used.

**58.21(8)** An accurate written record of medications administered shall be made by the individual administering the medication. (III)

**58.21(9)** Records shall be kept of all medications received and dispensed in accordance with 42 CFR 483.45(b)(2) and federal interpretive guidelines. (III)

**58.21(10)** Any unusual resident reaction shall be reported to the physician at once. (II)

**58.21(11)** A policy shall be established by the facility in conjunction with a licensed pharmacist to govern the distribution of prescribed medications to residents who are on leave from the facility. (III)

*a.* Medication may be issued to residents who will be on leave from a facility for less than 24 hours. Notwithstanding the prohibition against paper envelopes in 58.21(14) “*a*,” non-child-resistant containers may be used. Each container may hold only one medication. A label on each container shall indicate the date, the resident’s name, the facility, the medication, its strength, dose, and time of administration.

*b.* Medication for residents on leave from a facility longer than 24 hours shall be obtained in accordance with requirements established by the Iowa board of pharmacy.

*c.* Medication distributed as above may be issued only by a nurse responsible for administering medication. (I, II, III)

**58.21(12)** Emergency medications. A nursing facility shall provide emergency medications pursuant to the following requirements: (III)

*a.* Prescription drugs as well as nonprescription items must be prescribed or approved by the physician, in consultation with the pharmacist, who provides emergency service to the facility; (III)

*b.* The emergency medications shall be stored in an accessible place; (III)

*c.* A list of the emergency medications and quantities of each item shall be maintained by the facility; (III)

*d.* The container holding the emergency medications shall be closed with a seal which may be broken when drugs are required in an emergency or for inspection; (III)

*e.* Any item removed from the emergency medications shall be replaced within 48 hours; (III)

*f.* A permanent record shall be kept of each time the emergency medications are used; (III)

*g.* The emergency medications shall be inspected by a pharmacist at least once every three months to determine the stability of items. (III)

**58.21(13)** Drug handling.

*a.* Bulk supplies of prescription drugs shall not be kept in a nursing facility unless a licensed pharmacy is established in the facility under the direct supervision and control of a pharmacist or the prescription drugs are stored in an automated medication distribution system (AMDS) in compliance with standards established by the Iowa board of pharmacy. (III)

*b.* Inspection of drug storage condition shall be made by the health service supervisor and a registered pharmacist not less than once every three months. The inspection shall be verified by a report signed by the nurse and pharmacist and filed with the administrator. The report shall include, but not be limited to, certifying absence of the following: expired drugs, deteriorated drugs, improper labeling, drugs for which there is no current physician’s order, and drugs improperly stored. (III)

*c.* If the facility permits licensed nurses to dilute or reconstitute drugs at the nursing station, distinctive supplementary labels shall be available for the purpose. The notation on the label shall be so made as to be indelible. (III)

*d.* Dilution and reconstitution of drugs and their labeling shall be done by the pharmacist whenever possible. If not possible, the following shall be carried out only by the licensed nurse:

(1) Specific directions for dilution or reconstitution and expiration date should accompany the drug; (III)

(2) A distinctive supplementary label shall be affixed to the drug container when diluted or reconstituted by the nurse for other than immediate use. (III) The label shall bear the following: resident’s name, dosage and strength per unit/volume, nurse’s name, expiration date, and date and time of dilution. (III)

**58.21(14)** Drug safeguards.

- a.* All prescribed medications shall be clearly labeled indicating the resident's full name, physician'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 physician issuing the drug. Where unit dose is used, prescribed medications shall, as a minimum, indicate the resident's full name, physician's name, name and strength of drug, and directions for use. Standard containers shall be utilized for dispensing drugs. Paper envelopes shall not be considered standard containers. Prescription medications distributed from an AMDS shall follow any labeling standards established by the Iowa board of pharmacy. (III)
- b.* Medication containers having soiled, damaged, illegible or makeshift labels, or medication samples shall be returned to the issuing pharmacist, pharmacy, or physician for relabeling or disposal. (III)
- c.* There shall be no medications or any solution in unlabeled containers. (II, III)
- d.* The medications of each resident shall be kept or stored in the originally received containers. (II, III)
- e.* Labels on containers shall be clearly legible and firmly affixed. No label shall be superimposed on another label of a drug container. (II, III)
- f.* When a resident is discharged or leaves the facility, the unused prescription shall be sent with the resident or with a legal representative only upon the written order of a physician. (III)
- g.* Unused prescription drugs prescribed for residents who are deceased shall be returned to the supplying pharmacist. (III)
- h.* Prescriptions shall be refilled only with the permission of the attending physician. (II, III)
- i.* No medications prescribed for one resident may be administered to or allowed in the possession of another resident. (II)
- j.* Instructions shall be requested of the Iowa board of pharmacy concerning disposal of unused Schedule II drugs prescribed for residents who have died or for whom the Schedule II drug was discontinued. (III)
- k.* There shall be a formal routine for the proper disposal of discontinued medications within a reasonable but specified time. These medications shall not be retained with the resident's current medications. Discontinued drugs shall be destroyed by the responsible nurse with a witness and a notation made to that effect or returned to the pharmacist for destruction or resident credit. Drugs listed under the Schedule II drugs shall be disposed of in accordance with the provisions of the Iowa board of pharmacy. (II, III)
- l.* 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 physician, in consultation with the pharmacist serving the home, shall institute policies and provide procedures for review and endorsement of stop orders on drugs. This policy shall be conveniently located for personnel administering medications. (II, III)
- m.* No resident shall be allowed to keep possession of any medications unless the attending physician has certified in writing on the resident's medical record that the resident is mentally and physically capable of doing so. (II)
- n.* Residents who have been certified in writing by the physician as capable of taking their own medications may retain these medications in their bedroom, but locked storage must be provided. (II)
- o.* No medications or prescription drugs shall be administered to a resident without a written order signed by the attending physician. (II)
- p.* A qualified nurse shall:
- (1) Establish a medication schedule system which identifies the time and dosage of each medication prescribed for each resident, is based on the resident's desired routine, and is approved by the resident's physician. (II, III)
  - (2) Establish a medication record containing the information specified above needed to monitor each resident's drug regimen. (II, III)
- q.* Telephone orders shall be taken by a qualified nurse. Orders shall be written into the resident's record and signed by the person receiving the order. Telephone orders shall be submitted to the physician for signature within 48 hours. (III)

*r.* A pharmacy operating in connection with a nursing facility shall comply with the provisions of the pharmacy law requiring registration of pharmacies and the regulations of the Iowa board of pharmacy. (III)

*s.* In a nursing facility with a pharmacy or drug supply, service shall be under the personal supervision of a pharmacist licensed to practice in the state of Iowa. (III)

**58.21(15)** Drug administration.

*a.* Injectable medications shall be administered as permitted by Iowa law by a qualified nurse, physician, pharmacist, or physician assistant (PA). In the case of a resident who has been certified by the resident's physician or physician assistant (PA) as capable of taking the resident's own insulin, the resident may inject the resident's own insulin. (II)

*b.* An individual inventory record shall be maintained for each Schedule II drug prescribed for each resident. (II)

*c.* The health service supervisor shall be responsible for the supervision and direction of all personnel administering medications. (II)

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