

CHAPTER 44:04:08

MEDICATION CONTROL

Section

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44:04:08:01. Medication control in hospitals and nursing facilities. Hospitals and nursing facilities must comply with §§ 44:04:08:02 to 44:04:08:05, inclusive, in regard to medication control.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:02. Policies and procedures. Methods and written policies and procedures must be established to include the manner of issuance, proper storage, control, accountability, and administration of medications or drugs in each hospital or nursing facility. If any patient or resident is permitted to self-administer medications, the facility's policies and procedures related to self-administered drugs must include a description of the responsibilities of the patient or resident, the patient's or resident's family members, and the facility staff. The facility must provide written educational material explaining to the patient or resident and the patient's or resident's family the patient's or resident's rights and responsibilities associated with self-administration. Each nursing facility must keep a list of the following in the drug storage area for reference:

- (1) Generic and trade names for drugs substituted within the facility;
- (2) Drugs with unique requirements for administration, used within the facility, including enteric coatings, sublingual, buccal, and sustained release dosage forms; and
- (3) Drugs controlled under SDCL 34-20B that are used within the facility.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; 28 SDR 83, effective December 16, 2001; 29 SDR 81, effective December 11, 2002.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:03. Written orders for medication required. All medications or drugs administered to patients or residents must be ordered in writing and signed by the prescribing practitioner. Telephone orders for medications or drugs may be taken only when there is an urgent need to initiate or change an order and accepted only by a pharmacist or licensed nurse in both hospitals and nursing facilities. The practitioner shall sign or initial the orders for nursing facility residents on the next visit to the facility. The practitioner shall sign or initial the orders for hospital patients as soon as possible. In hospitals a policy on stop orders for antibiotics, anticoagulants, and controlled drugs must be established based on recommendations of the medical staff. In nursing facilities, a policy on stop orders for anticoagulants, antibiotics, narcotics, sedatives, hypnotics, and central nervous system stimulants must be established.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; 26 SDR 96, effective January 23, 2000; 30 SDR 84, effective December 4, 2003.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:03.01. Drug therapy reviewed monthly. The pharmaceutical service must be under the supervision of a licensed pharmacist who is responsible to the administrator for developing, coordinating, and supervising medication control. The pharmacist must review the drug regimen of each nursing facility resident or swing bed patient at least monthly. In an assisted living center with approval for medication administration, the pharmacist must review the drug regimen at least monthly of only those residents who require administration of medications. The pharmacist must review, at a minimum, the resident's or patient's diagnosis, the drug regimen, and any pertinent laboratory findings and dietary considerations. The pharmacist must report potential drug therapy irregularities and make recommendations for improving the drug therapy of the residents or patients to the attending physician and the administrator. The pharmacist must document the review by preparing a monthly report of the potential irregularities and recommendations. The administrator must retain the report in the nursing facility, assisted living center with approval for medication administration, or hospital.

Source: 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 28 SDR 83, effective December 16, 2001.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:04. Storage and labeling of medications and drugs. All drugs or medications must be stored in a well illuminated, locked storage area which is well ventilated, maintained at a temperature appropriate for drug storage, and inaccessible to patients, residents, or visitors at all times. Medications suitable for storage at room temperature must be maintained between 59 and 86 degrees Fahrenheit (15 and 30 degrees centigrade). Medications that require refrigeration must be maintained between 36 and 46 degrees Fahrenheit (2 and 8 degrees centigrade). Poisons and

medications prescribed for external use must be stored separately from internal medications, locked and made inaccessible to patients or residents.

In hospitals, locked storage does not apply to drugs and medications needed for emergency use in intensive care, emergency room, neonatal intensive care, pediatric intensive care, or coronary care units. Drugs and medications utilized in these care units must be in a storage area which is readily available to the professional staff but inaccessible to patients or visitors.

The medications or drugs of each patient or resident for whom medications are facility-administered must be stored in the containers in which they were originally received and may not be transferred to another container. Special modification of this requirement may be made when single dose packaging is used. Each prescription drug container, including manufacturer's complimentary samples, must be labeled with the patient's or resident's name, practitioner's name, drug name and strength, directions for use, and prescription date. Containers with contents that will not be used within 30 days of issue or with contents that expire in less than 30 days of issue must bear an expiration date. If a single dose system is used, the drug name and strength, expiration date, and a control number must be on the unit dose packet. A nursing facility, a co-located nursing facility and assisted living center, a co-located hospital and assisted living center, or an assisted living center with 24 hour per day licensed nursing staff may procure and stock, including in bulk form, nonlegend medications and administer them in accordance with written policies and procedures that provide for oversight by qualified personnel.

If a stock bottle system is used in a hospital or a nursing facility with a licensed pharmacy, the container must be labeled with the drug name and strength, expiration date, and a control number. Any container with a worn, illegible, or missing label must be destroyed pursuant to § 44:04:08:04.02. Licensed pharmacists are responsible for the labeling, relabeling, or altering of labels on medication containers.

Source: SL 1975, ch 16, § 1; 4 SDR 14, effective September 14, 1977; 5 SDR 29, effective October 22, 1978; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 27 SDR 59, effective December 17, 2000; 28 SDR 83, effective December 16, 2001.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:04.01. Control and accountability of medications and drugs. Medications brought from home may be used if ordered by the attending physician and, if prior to administration, is identified as the prescribed drug. Medications prescribed for one patient or resident may not be administered to another. Patients or residents in licensed health care facilities may not keep medications on their person or in their room without a physician's order allowing self-administration. Written authorization by the attending physician must be secured for the release of any medication to a patient or resident upon discharge, transfer, or temporary leave from the facility. The release of medication must be documented in the patient's or resident's record, indicating quantity, drug name, and strength.

Source: 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; 26 SDR 96, effective January 23, 2000; 28 SDR 83, effective December 16, 2001.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:04.02. Documentation of drug disposal. If a hospital or nursing facility has a licensed pharmacy, outdated or discontinued medications must be returned to the pharmacy for disposition. In the absence of a licensed pharmacy, the method of disposition of outdated or discontinued medications must be handled and recorded in the patient's or resident's medical record as follows:

(1) Legend drugs not controlled under SDCL 34-20B must be destroyed by a professional nurse and another witness;

(2) Medications controlled under SDCL 34-20B must be destroyed in the facility by a pharmacist and a registered nurse; and

(3) Medications, excluding controlled substances listed in SDCL chapter 34-20B, in unit dose packaging which meets packaging standards in § 20:51:13:02.01 may be returned to the pharmacy pursuant to § 20:51:13:02.01.

Source: 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:05. Administration of medications and drugs. Medication administration records must be used and regularly checked against the physician's orders. Except in hospitals having admixtures programs, a person may not administer medications that have been prepared by another person. Nursing facilities must obtain solid dosage forms of medications from pharmacists in the specific dosage needed by the residents of the facility.

Each medication administered must be recorded in the patient's or resident's medical record and signed by the individual responsible. Medication errors and drug reactions must be reported to the patient's or resident's physician and an entry made in the patient's or resident's medical record. Orders involving abbreviations and chemical symbols may be carried out only if the facility has a standard list of abbreviations and symbols approved by the medical staff or, in the absence of an organized medical staff, by the medical director and the list is available to the nursing staff. In hospitals and nursing facilities all medications must be administered to patients by personnel acting under delegation of a licensed nurse, or licensed to administer medications.

In an assisted living center approved for medication administration, a resident with the cognitive ability to understand may self-administer medications. At least every three months, the supervising nurse or the physician must evaluate and record the continued appropriateness of the resident's ability to self-administer medications.

Source: SL 1975, ch 16, § 1; 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; 28 SDR 83, effective December 16, 2001; 31 SDR 62, effective November 7, 2004.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:06. Administration of hospital or nursing facility pharmacy. The pharmaceutical service of each hospital or nursing facility with a licensed full or part-time pharmacy must be directed by a licensed pharmacist accountable to the administration of the hospital or nursing facility. Only prepackaged drugs or a single dose unit may be removed from the pharmacy when the pharmacist is not available. These drugs may be removed only by a designated registered nurse or physician in amounts sufficient only for immediate therapeutic needs. A record of such withdrawals must be made by the designated nurse or the physician making the withdrawal.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:07. Stock of legend drugs prohibited in nursing facilities -- Exception. Legend drugs or medications may not be stocked in bulk form in nursing facilities except in nursing facilities which employ a licensed pharmacist full or part time to supervise, within the facility, the procurement, storage, and dispensing of such drugs and medications. Nursing facilities without a pharmacy shall use the emergency drug box kept on the premises pursuant to § 44:04:08:07.01 or obtain emergency medications from a pharmacy licensed to distribute to outpatients.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:07.01. Controlled drugs kept for emergency use. In nursing facilities, controlled drugs may be kept for emergency use under the following circumstances:

(1) The pharmacist supplying the controlled drugs maintains ownership and responsibility for the drugs, including a monthly physical inventory;

(2) The controlled drugs are stored in a manner that allows only those individuals authorized to administer the drugs access to them;

(3) The controlled drugs are stored in a sealed emergency box or in a separate locked cabinet, with a complete and accurate record kept of the drugs in the box or cabinet and of their disposition;

(4) The facility notifies the pharmacist within 36 hours after the withdrawal of a Schedule II drug and within 72 hours after the withdrawal of Schedule III and IV drugs and the pharmacist replaces the drugs within 72 hours after notification; and

(5) No more than 5 different controlled drugs are stored in the emergency box, which may contain no more than 6 doses of any Schedule II controlled drug, no more than 6 doses of any

Schedule III or IV injectable controlled drug, and no more than 12 doses of any oral Schedule III or IV controlled drug.

Source: 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:08:08. Assisted living center medication control. Each assisted living center must establish and practice methods and procedures for medication control which include the following:

(1) A requirement that each resident's prescribing practitioner provide to the center written signed orders for any medications taken by the resident;

(2) Provision for proper storage of prescribed medications which is inaccessible to residents or visitors. Residents may not keep medications or drugs on their persons or in their rooms except with written orders from their prescribing practitioner;

(3) Provisions for the separate storage of poisons, topical medications, and oral medications;

(4) A requirement that each resident's medication be stored in the container in which it was originally received and not transferred to another container;

(5) A requirement that the medication prescribed for one resident not be administered to any other resident;

(6) A requirement that self-administration of medications be accomplished with the supervision of a designated employee of the center;

(7) If any resident of the facility cannot assume responsibility for medication self-administration or self-directed assistance with medication administration or if the assisted living center is approved to provide services to cognitively impaired residents as noted in subdivision 44:04:04:12.01(3), the facility must also be approved by the department to provide medication administration;

(8) If medication administration is provided, it must comply with §§ 44:04:08:02 to 44:04:08:05, inclusive, and with the requirements for training in §§ 20:48:04.01:14 and 20:48:04.01:15 and supervision in § 20:48:04.01:02 . The supervising nurse shall provide an orientation to the unlicensed assistive personnel who will administer medications. The orientation must be specific to the facility and relevant to the residents receiving administered medications; and

(9) A written procedure for the proper disposition of medicines which are discontinued because of the discharge or death of the resident, because the drug is outdated, or because the prescription is no longer appropriate to the care of the resident.

Each original prescription drug container including any manufacturer's complimentary sample must be labeled with patient or resident name, drug name and strength, practitioner's name, directions for use, and prescription date. Any container with contents that will not be used within

30 days after issue or with contents that expire in less than 30 days after issue must bear an expiration date. When a single-dose system is used, the drug name and strength, expiration date, and a control number must be on the unit dose packet. Any container with a worn, illegible, or missing label must be destroyed. The labeling, relabeling, or altering of labels on medication containers must be done by licensed pharmacists.

Source: SL 1975, ch 16, § 1; 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; 26 SDR 96, effective January 23, 2000; 27 SDR 59, effective December 17, 2000; 28 SDR 83, effective December 16, 2001.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

Cross-Reference: Documentation of drug disposal, § 44:04:08:04.02.

44:04:08:09. Qualifications of medication aide. Repealed.

Source: 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; repealed, 23 SDR 195, effective May 26, 1997.

44:04:08:10. Length of medication aide training. Repealed.

Source: 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; repealed, 23 SDR 195, effective May 26, 1997.

44:04:08:11. Course content for medication aides. Repealed.

Source: 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; repealed, 23 SDR 195, effective May 26, 1997.

44:04:08:12. Restrictions in course content. Repealed.

Source: 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; repealed, 23 SDR 195, effective May 26, 1997.

44:04:08:13. Medication aide proficiency review. Repealed.

Source: 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; repealed, 23 SDR 195, effective May 26, 1997.

44:04:08:14. Authority and responsibility. Repealed.

Source: 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; repealed, 23 SDR 195, effective May 26, 1997.

44:04:08:15. Continuing education. Repealed.

Source: 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; repealed, 23 SDR 195, effective May 26, 1997.

44:04:08:16. Transfer between facilities. Repealed.

Source: 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; repealed, 23 SDR 195, effective May 26, 1997.