ARTICLE 20:51

PHARMACISTS

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CHAPTER 20:51:01

REGISTRATION BY EXAMINATION

Section

- 20:51:01:01 Application for registration.
- 20:51:01:02 Experience required.

20:51:01:03	Application requirements.
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20:51:01:09	Approved colleges of pharmacy.
20:51:01:10	Application requirements for graduates from colleges of pharmacy located outside
	the United States.
20:51:01:11	NAPLEX score transfer form.
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20:51:01:12 Registration fee nonrefundable <u>Repealed</u>.

20:51:01:01. Application for registration. An applicant for registration as a pharmacist by examination shall apply on forms provided by the board and provide all requested information on or with the application. The completion of requirements in SDCL 36-11-16 and this chapter entitles the applicant to registration as pharmacist and qualifies the pharmacist for licensure.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-15, 36-11-16, 36-11-18.

Cross-Reference: Examination, § 20:51:01:04.

20:51:01:02. Experience required. An applicant meeting the requirements of SDCL 36-11-16 for a certificate of registration as a licentiate in pharmacy and who is examined after December 31, 2009, must have completed a pharmacy practice experience program which meets or exceeds the minimum pharmacy practice experience requirements of the board as defined in chapter 20:51:02.

Source: SL 1975, ch 16, § 1; 7 SDR 51, effective December 3, 1980; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996; 36 SDR 21, effective August 17, 2009

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-16.

Cross-References:

Goals and objectives of internship, § 20:51:02:01.01.

Required hours, § 20:51:02:13.

20:51:01:03. Application requirements. An applicant for registration by examination shall present the following to the secretary <u>board</u> with the application:

(1) The certificate of registration <u>nonrefundable</u> fee of \$35;

(2) A photo of the applicant that is at least 2¹/₄ by 3¹/₄ inches in size with the applicant's signature in ink on the back;

(3) A list of the applicant's practical experience on a form provided by or approved by the board;

(4) A transcript showing graduation from a college of pharmacy approved by the AmericanCouncil on Pharmaceutical Education; and

(5) A government-issued form of photo identification: and

(6) A criminal background check.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 8 SDR 144, effective May 4, 1982; 11 SDR 120, effective March 11, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 14 SDR 121, effective March 28, 1988; 15 SDR 20, effective August 9, 1988; 18 SDR 95, effective November 25, 1991; 22 SDR 133, effective April 25, 1996; 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1). Law Implemented: SDCL 36-11-16, <u>36-11-16.1</u>, 36-11-17.

Cross-Reference: Approved colleges of pharmacy, § 20:51:01:09.

20:51:01:09. Approved colleges of pharmacy. Approved colleges of pharmacy are those colleges of pharmacy which have demonstrated that the standards of their respective professional degree programs are at least equivalent to the minimum standards of accreditation established by the Accreditation Council for Pharmacy Education (ACPE), 20 North Clark Street, Suite 2500, 190 S. LaSalle St. Suite 2850, Chicago, IL 60602-5109-60603-3410; Phone: 312-664-3575; Web site: www.acpe-accredit.org.

Source: 9 SDR 171, effective July 12, 1983; 11 SDR 92, effective January 16, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 17 SDR 37, effective September 9, 1990; 18 SDR 95, effective November 25, 1991; 22 SDR 32, effective September 14, 1995; 22 SDR 133, effective April 25, 1996; 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-16.

20:51:01:11. NAPLEX score transfer form. An applicant meeting the requirements of this chapter who has taken the NAPLEX examination in another state may transfer scores on an official NAPLEX score transfer form furnished by through the National Association of Boards of Pharmacy. To be eligible for registration and initial licensure an applicant must complete the requirements of \$ 20:51:01:03 and receive a passing grade in the MPJE, South Dakota edition within one year from the date the scores are transferred by the National Association of Boards of Pharmacy to the board.

Source: 18 SDR 95, effective November 25, 1991; 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-16, 36-11-18.

Cross-Reference: Examination, § 20:51:01:04.

20:51:01:12. Registration fee nonrefundable. The certificate of registration fee is nonrefundable Repealed.

Source: 18 SDR 95, effective November 25, 1991; 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-16, 36-11-18.

CHAPTER 20:51:02

INTERNSHIP REQUIREMENTS

Section

- 20:51:02:01 Definitions.
- 20:51:02:01.01 Goal and objectives of internship.
- 20:51:02:02 Repealed.
- 20:51:02:03 Repealed.
- 20:51:02:04 Registration.
- 20:51:02:04.01 South Dakota State University College of Pharmacy practice experiences Repealed.
- 20:51:02:04.02 Identification.
- 20:51:02:05 Renewal of certificate registration.
- 20:51:02:06 Repealed.
- 20:51:02:07 Affidavit needed for each practical experience <u>Repealed</u>.
- 20:51:02:08 Report required at end of each practical experience.
- 20:51:02:09 Repealed.
- 20:51:02:10 Practical experience defined.
- 20:51:02:11 Supervising pharmacist requirements.
- 20:51:02:11.01 Number of interns.
- 20:51:02:12 Repealed.
- 20:51:02:12.01 Required hours.
- 20:51:02:13 Internship experiences from other states.
- 20:51:02:13.01 Foreign pharmacy graduates.

- 20:51:02:14 Credit given for military and research activities.
- 20:51:02:15 Badge and certificate required.
- 20:51:02:16 Denial of pharmacy intern registration.
- 20:51:02:17 Sanctions.

20:51:02:01. Definitions. Terms used in this chapter mean defined in SDCL 36-11-2 have the same meaning in this chapter. In addition, as used in this chapter:

- (1) "Board" or "board of pharmacy," as defined in SDCL 36-11-2(2);
- (2) "Pharmacist," as defined in SDCL 36-11-2(18);
- (3) "Pharmacy," as defined in SDCL 36-11-2(19);
- (4)"Pharmacy intern," <u>means</u> any one of the following:

(a) A person currently registered by the board to engage in the practice of pharmacy while under the supervision of a pharmacist and is enrolled in a professional degree program of a school or college of pharmacy, accredited by the Accreditation Council for Pharmacy Education that has been approved by the board and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;

(b) A graduate of an approved accredited professional degree program of a school or college of pharmacy or a graduate who has established educational equivalency by obtaining a Foreign Pharmacy Graduate Examination Committee (FPGEC) Certificate, who is currently registered by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(c) A qualified applicant awaiting examination for <u>licensure</u> <u>registration</u> or meeting board requirements for re-licensing; or

(d) A qualified applicant participating in a residency or fellowship program.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996; 31 SDR 35, effective September 19, 2004; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1), 36-11-25. **Law Implemented:** SDCL 36-11-11, 36-11-25.

Cross-Reference: Approved colleges of pharmacy, § 20:51:01:09.

20:51:02:04. Registration. The board shall grant a <u>certificate registration</u> as a pharmacy intern to any person enrolled in a college of pharmacy professional program who has completed one week of classes or has graduated from a college of pharmacy and who desires to secure credit for practical pharmacy experience by applying on a form provided by the board and accompanying the form with a fee of \$40. The board may not grant internship credit for experience obtained prior to the individual's registration as a pharmacy intern.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996; 31 SDR 35, effective September 19, 2004; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-10, 36-11-11(1), 36-11-25.

Law Implemented: SDCL 36-11-25.

20:51:02:04.01. South Dakota State University College of Pharmacy practice experiences. The board shall periodically review the Introductory Pharmacy Practice Experience and the Advanced Pharmacy Practice Experience programs of the college of pharmacy located in South Dakota. The board reserves the right to approve and set conditions relating to the practice site of such programs Repealed.

Source: 31 SDR 35, effective September 19, 2004; 36 SDR 21, effective August 17, 2009. General Authority: SDCL 36-11-10, 36-11-11(1), 36-11-25. Law Implemented: SDCL 36-11-25.

20:51:02:04.02. Identification. A pharmacy intern shall be designated as a pharmacy intern in the intern's professional relationship and may not hold himself or herself out, directly or by inference, as a pharmacist. The board shall issue to the pharmacy intern a certificate registration for the purposes of identification and verification of his or her role as a pharmacy intern.

Source: 36 SDR 21, effective August 17, 2009. General Authority: SDCL 36-11-11(1), 36-11-25. Law Implemented: SDCL 36-11-25.

20:51:02:05. Renewal of certificate registration. Each pharmacy intern shall apply for renewal of his or her certificate before October 1 each year. A pharmacy intern who desires to continue in the practice of pharmacy in South Dakota shall file with the board an application in such form and containing such facts as the board may require for renewal of the certificate. apply for renewal prior to October 1 each year, on forms provided by the board. The board shall issue a

certificate registration to the applicant if the board finds that the applicant has continued his or her pharmacy education in accordance with the rules of the board and is entitled to continue in the practice of pharmacy.

Source: SL 1975, chi 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1), 36-11-25.

Law Implemented: SDCL 36-11-25.

20:51:02:07. Affidavit needed for each practical experience Any pharmacy intern expecting to receive credit for practical experience as a qualification for registration as a licentiate shall submit a separate affidavit on a form provided by the board for each practical experience. The affidavit must be submitted to the board before the beginning of the practical experience; however, for good cause shown, the board may accept the affidavit at a later date <u>Repeal</u>.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11, 36-11-25.

Law Implemented: SDCL 36-11-25.

20:51:02:08. Report required at end of each practical experience. At the end of each practical experience, a registered intern shall submit a report to the Board of Pharmacy on a form supplied by the board. The form must be filed within five days after the ending of the experience; however, for good cause shown, the Board of Pharmacy may accept the form at a later date.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996.

General Authority: SDCL 36-11-11(1), 36-11-25.

Law Implemented: SDCL 36-11-25.

20:51:02:10. Practical experience defined. The term practical experience, as it relates to qualification for licensure, means performing the practice of pharmacy as defined in SDCL 36-11-2.2 and the functions authorized to registered pharmacists in SDCL 36-11-19.1, all of which must be performed under the immediate and personal supervision of a <u>registered licensed</u> pharmacist. The Board of Pharmacy may not accept practical experience of more than 48 hours a week <u>or less than eight hours a week</u>.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996.

General Authority: SDCL 36-11-11(1), 36-11-25. **Law Implemented:** SDCL 36-11-11(1), 36-11-25.

20:51:02:11. Supervising pharmacist requirements. A registered licensed pharmacist who agrees to supervise the practical experience of a registered pharmacy intern must certify this on a form provided by the board and agree to abide by the South Dakota pharmacy law and the rules of the South Dakota Board of Pharmacy. A pharmacist must be in continuous contact with and actually giving instructions to the intern during all professional activities of the entire internship, and actually giving instructions to the intern during all professional activities of the entire internship the intern. Interns may receive written or verbal prescriptions if the pharmacist reviews and makes the

necessary professional determinations about the medication order, including the name of the drug, its strength and dosage, directions for use, and the number of allowable refills.

A pharmacist must verify the accuracy of all information entered into the computer by the intern. The identity of the pharmacist must be included in the record.

The pharmacist must inspect the prepared prescription and verify the accuracy of the preparation, and its labeling, prior to dispensing the prescription to the patient or patient's representative.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996; 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-11(1), 36-11-25. **Law Implemented:** SDCL 36-11-25.

20:51:02:11.01. Number of interns. A pharmacist may not supervise more than one two pharmacy intern interns at a time in the pharmacy. The pharmacy intern does not count for purposes of the ratio of technicians supervised by the pharmacist.

Source: 31 SDR 35, effective September 19, 2004; 36 SDR 21, effective August 17, 2009.General Authority: SDCL 36-11-11(1), 36-11-25.Law Implemented: SDCL 36-11-25.

Cross-Reference: Ratio, § 20:51:29:19.

20:51:02:12. Notebook required. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, 22 SDR 133, effective April 25, 1996.

20:51:02:12.01. Required hours. An internship shall consist of a minimum of 2000 hours, of which 1740 hours may be a college-based pharmacy practical experience program approved or accepted by the board. A program shall be reviewed by the board and be structured to provide experience in community, institutional, and clinical pharmacy practices. The remaining 260 hours shall be acquired under the supervision of one or more preceptors in a board-licensed community or hospital pharmacy where the goal and objectives of a pharmacy internship as set forth in § 20:51:02:01.01 apply. Credit toward the 260 hours will be allowed, at a rate not to exceed 10 hours per week, for an internship served while the person is a full time student carrying, in a given school term, at least 75 percent of the average number of credit hours each term needed to graduate and receive an entry level degree in pharmacy. Internship hours during any recognized academic break, such as summer break, spring break and Christmas break, may be allowed at a rate of eight hours per day while the person is a full-time student. The competencies in § 20:51:02:01.01 shall not apply to college-based pharmacy practice experience programs.

Source: 36 SDR 21, effective August 17, 2009. General Authority: SDCL 36-11-11(1), 36-11-25. Law Implemented: SDCL 36-11-25. **20:51:02:14.** Credit given for military and research activities. The Board of Pharmacy may allow up to 400 hours of intern credit for suitable military and research activities in the field of pharmacy as part of the experience requirement.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(1), 36-11-25.

Law Implemented: SDCL 36-11-25.

20:51:02:15. Badge and certificate required. While on duty, a pharmacy intern registered under this chapter, must wear a badge identifying the intern as a pharmacy intern and must post the intern certificate in the location where the intern is practicing.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 133, effective April 25, 1996.

General Authority: SDCL 36-11-11(1), 36-11-25.

Law Implemented: SDCL 36-11-25.

20:51:02:16. Denial of pharmacy intern registration. The Board of Pharmacy may deny an application for registration as a pharmacy intern for any violation of law of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs (or for any violation of state pharmacy laws or rules).

Source: 31 SDR 35, effective September 19, 2004.

General Authority: SDCL 36-11-11(1), 36-11-25.

Law Implemented: SDCL 36-11-25.

20:51:02:17. Sanctions. The board may impose the following disciplinary sanctions on a pharmacy intern for any violations of this chapter:

- (1) Revoke a registration;
- (2) Suspend a registration until further order of the board or for a specified period; or

(3) Prohibit permanently, until further order of the board, or for a specified period, the engaging in specified procedures, methods, or acts pharmacy activities.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-25. Law Implemented: SDCL 36-11-25.

CHAPTER 20:51:04

REGISTRATION BY RECIPROCITY

Section

- 20:51:04:01 Application.
- 20:51:04:02 Qualifications for reciprocity.
- 20:51:04:03 Reciprocity requirements.
- 20:51:04:04 Application requirements.
- 20:51:04:05 Appearance before board.

20:51:04:06	Repealed.
20:51:04:07	Repealed.
20:51:04:08	Certificates of reciprocity identified by letter R.
20:51:04:09	Repealed.

20:51:04:02. Qualifications for reciprocity. The following qualifications are required for reciprocal registration in South Dakota:

(1) The applicant must be a registered <u>licensed</u> pharmacist by examination in the state from which the pharmacist will reciprocate;

(2) The applicant must be in good standing in that state at the time the pharmacist applies for reciprocity;

(3) The applicant must have engaged in the practice of pharmacy for a period of at least one year or have met the pharmacy practice experience requirements of this state within the one year period immediately prior to the date of such application; and

(4) For any applicant who obtained his or her original license after January 1, 1980, the <u>The</u> applicant must have passed the North American Pharmacist Licensure Examination (NAPLEX).

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-19.

20:51:04:04. Application requirements. Applicants must file their official National Association of Boards of Pharmacy reciprocal (NABP) license transfer application with the secretary of the board within 90 days from the date of issue. The application must be accompanied by with NABP at NABP.pharmacy. Prior to approval, the board must receive the following:

(1) The <u>A reciprocating pharmacist application with a nonrefundable</u> application fee of \$150;

(2) A recent photo of the applicant, in size not less than 2 1/4 by 3 1/4 inches, with the applicant's signature signed in ink on the back of the photo;

(3) A nonrefundable registration fee of \$35; and

(4) A criminal background check.

Source: SL 1975, ch 16, § 1; 3 SDR 45, effective December 18, 1976; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 29 SDR 37, effective September 26, 2002; 36 SDR 21, effective August 17, 2009.

General Authority: SDCL 36-11-11(1), 36-11-19.

Law Implemented: SDCL <u>36-11-16.1</u>, 36-11-19.

20:51:04:08. Certificates of reciprocity identified by letter R. Certificates of registration granted by reciprocity will be identified by the letter R next preceding the number of such certificates. The completion of requirements included in SDCL 36-11-16 and this chapter entitles the applicant to registration as a pharmacist and qualifies the pharmacist for licensure.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-19.

CHAPTER 20:51:05

RESTRICTED PROFESSIONAL PRACTICES

Section

- 20:51:05:00 Definitions.
- 20:51:05:01 Transferred.
- 20:51:05:02 Transferred.
- 20:51:05:03 Repealed.
- 20:51:05:04 Repealed.
- 20:51:05:05 Repealed.
- 20:51:05:06 Transferred.
- 20:51:05:07 Transferred.
- 20:51:05:08 Repealed.
- 20:51:05:09 Repealed.
- 20:51:05:10 Repealed.
- 20:51:05:11 Repealed.
- 20:51:05:12 Repealed.

- 20:51:05:13 Repealed.
- 20:51:05:14 No advertising permitted on prescription blanks furnished to doctors practitioners.
- 20:51:05:15 Controlled drug to be dispensed only by prescription.
- 20:51:05:15.1 Identification required for controlled drug prescription.
- 20:51:05:16 Prescription for Schedule II controlled drug requires date and signature of prescriber practitioner-- Not refillable.
- 20:51:05:17 Oral Verbal prescription permitted for Schedule II controlled drug in emergency.
- 20:51:05:18 Partial filling of prescription for Schedule II controlled drug.
- 20:51:05:19 Prescription required to dispense Schedule III or IV controlled drug -- Refill restricted.
- 20:51:05:20 Legend drug to be dispensed by prescription only -- Refill restricted.
- 20:51:05:21 Labeling of prescription container for controlled or noncontrolled legend drug.
- 20:51:05:22 Distribution of drugs to other practitioners or pharmacies.
- 20:51:05:23 Distribution of dialysate by manufacturer or the manufacturer's agent to a patient Exempt from pharmacy licensure.

20:51:05:00. Definitions. Words used in this chapter, unless the context plainly requires otherwise, mean <u>As used in this chapter</u>:

(1) "Controlled drug," <u>means</u> a substance as defined in SDCL 36-11-2(5) which is controlled under the provisions of SDCL chapter 34-20B and is listed in SDCL 34-20B-11 to 34-20B-26, inclusive.; (2) <u>"Dialysate," means a solution comprised of dextrose or icodextrin for use in peritoneal</u> <u>dialysis and approved by the federal Food and Drug Administration; and</u>

(3) "Legend drug," <u>means</u> a substance as defined in SDCL 34-20B-28.1(4)(3).

Source: 8 SDR 101, effective February 28, 1982; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:05:14. No advertising permitted on prescription blanks furnished to doctors practitioners. No prescription blank furnished a doctor to a practitioner shall carry any advertising or the name of any registered licensed pharmacy.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(1). Law Implemented: SDCL 36-11-11(1).

20:51:05:15. Controlled drug to be dispensed only by prescription. No pharmacist may dispense a controlled drug unless the controlled drug is dispensed pursuant to the prescription of a practitioner licensed to prescribe controlled drugs. A pharmacist shall exercise sound professional judgment with respect to the legitimacy of prescription orders. Any facsimile transmission of a Schedule II controlled drug prescription must comply with the requirements of § 44:58:08:18.03. A prescription must be dated and signed on the date issued. The prescription must bear the name and address of the patient and the name, strength, dosage form, quantity prescribed, directions for use,

and the name, address, and registration number of the practitioner. Where an oral <u>a</u> verbal prescription for a schedule II controlled drug is not permitted, a prescription order must be written in ink or typewritten and manually dated and signed by the practitioner or issued and signed electronically where permissible by law. <u>A prescription for a schedule II controlled drug shall not</u> be filled later than six months after date of issue.

Source: SL 1975, ch 16, § 1; transferred from § 20:51:05:01, 8 SDR 101, effective February 28, 1982; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 26 SDR 92, effective January 6, 2000; 40 SDR 40, effective September 16, 2013.

General Authority: SDCL 36-11-11(1), 34-20B-41. **Law Implemented:** SDCL 36-11-11(1), 34-20B-41.

20:51:05:15.01. Valid photographic identification or other verification required for controlled drug prescription release. A pharmacist or pharmacy staff, before releasing a controlled drug to any person not known to such dispenser, shall require the person purchasing, receiving, or otherwise acquiring the controlled drug to present a valid government issued photographic identification or other verification of his or her identity to the dispenser. If the person does not have proper identification, the dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system may be considered proper identification. This subsection does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted. The pharmacy shall post a notice to the public that states "No prescription for a controlled drug may be sold without verification of purchaser identify."

Source:

General Authority: SDCL 36-11-11(1)(6)

Law Implemented: SDCL 36-11-11(1), 34-20B

20:51:05:16. Prescription for Schedule II controlled drug requires date and signature of prescriber practitioner -- Not refillable. No pharmacist may dispense a Schedule II controlled drug for which a written prescription is required under federal or state law until a prescription bearing the date of issue and the written signature of the prescriber practitioner has been delivered to the pharmacy or issued and signed electronically where permissible by law. No pharmacist may refill a Schedule II controlled drug prescription.

Source: SL 1975, ch 16, § 1; transferred from § 20:51:05:02, 8 SDR 101, effective February 28, 1982; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 26 SDR 92, effective January 6, 2000; 40 SDR 40, effective September 16, 2013.

General Authority: SDCL 36-11-11(1). Law Implemented: SDCL 36-11-11(1).

20:51:05:17. Oral Verbal prescription permitted for Schedule II controlled drug in emergency. A pharmacist may in an emergency as defined in SDCL 22-42-2.2 dispense a Schedule II controlled drug prescription according to the procedure set out in § 44:58:08:13.

Source: 8 SDR 101, effective February 28, 1982; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:05:18. Partial filling of prescription for Schedule II controlled drug. A pharmacist may partially fill a prescription for a Schedule II controlled drug according to the procedure set out in §§ 44:58:08:18, and 44:58:08:18.01, <u>21 CFR §§ 1306.12</u>, and 1306.13, and 21 U.S.C. 829 § 702.

Source: 8 SDR 101, effective February 28, 1982; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:05:19. Prescription required to dispense Schedule III or IV controlled drug --**Refill restricted.** No pharmacist may dispense a Schedule III or IV controlled drug without a written, oral, or electronic prescription. A prescription by the <u>prescriber practitioner</u> may be delivered to a pharmacist <u>verbally or</u> by handwritten order, facsimile, or electronic equipment where permissible by law. A verbal prescription shall be reduced promptly to writing by the pharmacist or intern and the written record filed or electronically recorded in the same manner as though it was a written prescription. The pharmacist may refill the prescription, if so authorized on the prescription, up to five times within six months after the date of issue. The partial dispensing of refills may not exceed the total amount authorized on the prescription. Each refill shall be entered on the back of the prescription or captured electronically and shall indicate the quantity dispensed, date refilled, and the initials or name of the dispensing pharmacist. After six months or the dispensing of all authorized refills, whichever comes first, a new controlled drug prescription is required either orally, in writing, or electronically where permissible by law from the prescripter. Any prescription renewed by the prescriber shall be considered a new and separate prescription, assigned a new serial number, and subject to the restrictions in this section.

Electronic data processing equipment, when used to maintain patient files, must provide online retrieval of original prescription information for those prescription orders which are currently authorized for refilling. The original hard copy, facsimile, or electronic prescription must be stored in a file at the pharmacy and be maintained for a two-year period from the <u>last</u> dispensing date. The identity of the pharmacist dispensing a refill must be included in the record.

A pharmacist may not fill any expired prescription for a controlled drug prior to authorization from the prescriber.

Source: 8 SDR 101, effective February 28, 1982; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 26 SDR 92, effective January 6, 2000; 40 SDR 40, effective September 16, 2013.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:05:20. Legend drug to be dispensed by prescription only -- Refill restricted. A pharmacist may only dispense a legend drug or medicine pursuant to the written, oral verbal, or electronic prescription of a practitioner licensed to prescribe drugs and medicines. A prescription by a prescriber may be delivered to a pharmacist by handwritten order, facsimile, or electronic equipment where permissible by law. An oral <u>A verbal</u> prescription shall be reduced promptly to writing by the pharmacist and the written record filed or electronically recorded in the same manner as though it were a written prescription. No legend drug prescription may be refilled except as designated in the original prescription or as subsequently authorized by the prescriber. Each refill

shall be entered on the back of the original prescription or captured electronically and shall indicate the quantity dispensed, date refilled, and the initials or name of the dispensing pharmacist.

Electronic data processing equipment, when used to maintain patient files, must provide online retrieval of all original prescription information for those prescription orders which are currently authorized for refilling. The identity of the pharmacist refilling the prescription must be included in the record. The original hard copy, facsimile, or electronic version shall be filed and retained two years <u>from the last dispensing date</u>. Electronic records must contain daily back-up functionality to protect against record loss and be capable of printing the documentation of the record at the board's request.

A prescription renewed by the prescriber shall be considered a new and separate prescription, assigned a new serial number, and subject to the same restrictions in this section. A pharmacist may not fill any expired noncontrolled legend drug prescription prior to authorization from the prescriber.

Source: SL 1975, ch 16, § 1; transferred from §§ 20:51:05:06 and 20:51:05:07, 8 SDR 101, effective February 28, 1982; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 26 SDR 92, effective January 6, 2000; 40 SDR 40, effective September 16, 2013.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:05:21. Labeling of prescription container for controlled or noncontrolled legend **drug.** A pharmacist filling a prescription for a controlled or noncontrolled legend drug shall attach to the <u>each</u> container a label showing the date, the name, address, and telephone number of the pharmacy, the serial number of the prescription, the name of the prescriber, the name of the patient,

and the directions for use, precautions, if any, the name, strength, and quantity of the drug, <u>number</u> <u>of refills remaining</u>, and the initials of the dispensing pharmacist. The prescription label for controlled drugs must comply with the label requirements of § 44:58:08:20, including the transfer auxiliary label warning.

All medications ordered drugs dispensed for a specific nursing facility patients patient, including over-the-counter medications, are considered prescription medications and must be labeled as required in chapter 44:04:08 <u>44:73:08:04</u>.

Source: 8 SDR 101, effective February 28, 1982; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:05:22. Distribution of drugs to other practitioners or pharmacies. A registered licensed pharmacy is authorized to distribute up to five percent of its controlled drugs and legend drugs to a practitioner registered and licensed to prescribe, dispense, or distribute such drugs in the course of professional practice or to other registered licensed pharmacies to meet temporary inventory shortages. The pharmacy shall follow Title II of the Drug Quality Security Act (DQSA) and provide the mandatory information unless exempted by DQSA. The distribution shall be completed using invoices which shall include:

(1) Name, address, and DEA number, if required, of both locations involved in the transaction;

(2) Drug name, dosage form, and strength;

(3) Quantity of each drug sold; and

(4) Date of sale.

Schedule II drugs must have a completed DEA form 222 to accompany the invoice. The invoices shall be retained by both locations involved in the transaction for a period of two years from the date of the transaction.

Source: 11 SDR 92, effective January 16, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:05:23. Distribution of dialysate by the manufacturer or manufacturer's agent to patient – Exemption from pharmacy licensure. A manufacturer or agent of a manufacturer of dialysate may ship dialysate directly to a patient in this state, agent of the patient, or to a health care practitioner or institution for administration or delivery of dialysis therapy to a patient with chronic kidney failure without being licensed as a pharmacy in this state if the following criteria have been met:

(1) The manufacturer or manufacturer's agent shipping to the patient is licensed as a wholesaler or other drug distributor;

(2) The dialysate is stored and delivered in the original, sealed, and labeled packaging from the manufacturing facility.

Records for all sales and distribution of dialysate must be retained and readily available for inspection for a period of two years from the date of the transaction.

Source:

General Authority: SDCL 36-11-11(1)(10).

Law Implemented: SDCL 36-11-11(1)(10).

CHAPTER 20:51:06

PHARMACY PRACTICE AND REGISTRATION LICENSURE

Section

- 20:51:06:01 Application for pharmacy permit license Annual renewal required.
- 20:51:06:02 Ownership or control by pharmacist required.
- 20:51:06:02.01 Pharmacist-in-charge -- Defined, duties.
- 20:51:06:03 Renewal required each year <u>Initial application for pharmacy license</u>.
- 20:51:06:04 False application grounds for suspending or revoking.
- 20:51:06:05 Must be registered <u>licensed</u> in order to advertise pharmacy name.
- 20:51:06:06 Transfer of pharmacy registration <u>license</u>.
- 20:51:06:07 Changes in ownership or location must be reported to secretary board Patients

notified of cessation of pharmacy.

- 20:51:06:08 Valid permit <u>license</u> must be displayed.
- 20:51:06:09 Permit License expires 120 days after death of pharmacist.
- 20:51:06:10 Provisions for pharmacist temporary absence from pharmacy.

- 20:51:06:11 Pharmacy <u>structural</u> requirements for nonpharmacist owners.
- 20:51:06:12 Pharmacy requirements for pharmacist owners <u>Repealed</u>.
- 20:51:06:13 Repealed.

20:51:06:01. Application for pharmacy permit license – Annual renewal required. A registered licensed pharmacist actively conducting a pharmacy in the state of South Dakota must apply each year to the Board of Pharmacy board for a permit to conduct the pharmacy license for the fiscal year ending June thirtieth on forms provided by the board. Application blanks and affidavit forms may be secured by writing to the secretary of the Board of Pharmacy. The fee is \$200.

Source: SL 1975, ch 16, § 1; 2 SDR 56, effective February 11, 1976; 4 SDR 85, effective June 19, 1978; 11 SDR 151, effective May 15, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 24 SDR 160, effective May 26, 1998.

General Authority: SDCL 36-11-11(4)(3), 36-11-32.

Law Implemented: SDCL 36-11-32.

20:51:06:02. Ownership or control by pharmacist required. No permit to conduct a pharmacy license shall be issued to any pharmacist applicant unless such pharmacist the applicant is owner, or part owner, of the merchandise and fixtures of the place of business for which <u>a</u> pharmacy registration license is applied for, or unless application is made jointly with a registered licensed pharmacist owner, or unless the. In those instances of <u>a</u> non-pharmacist owner of the merchandise and fixtures of the place of business for which <u>a</u> pharmacy registration license is applied for, which <u>a</u> pharmacy registration license is applied for, which <u>a</u> pharmacy registration license is applied for, has made the non-pharmacist owner must make affidavit on a form prescribed by the state Board

of Pharmacy board delegating full and complete authority to the pharmacist applicant to be in active management of said the place of business for the fiscal year ending June 30.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(3).

Law Implemented: SDCL 36-11-32.

20:51:06:02.01. Pharmacist-in-charge -- Defined, duties. An application for a permit to conduct a pharmacy license as specified in § 20:51:06:02 shall indicate the pharmacist-in-charge. The term, pharmacist-in-charge, means a pharmacist manager or licensed pharmacist permittee duly licensed in South Dakota who has been so designated by the employer pharmacy owner.

The pharmacist-in-charge shall:

- (1) Be employed or contracted for pharmacy services at the <u>licensed</u> pharmacy so licensed;
- (2) Establish policy and procedure for the pharmacy;
- (3) Supervise all pharmacy employees; and

(4) Establish recordkeeping systems for the purchase, safekeeping, storage, compounding, sale, and return of drugs.

The pharmacist-in-charge shall notify the secretary of the Board of Pharmacy board immediately upon knowledge of termination of employment. A new pharmacist-in-charge shall be designated by the employer pharmacy owner within ten working days.

Source: 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-11(1)(4)(3).

Law Implemented: SDCL 36-11-11(1)(4)(3), 36-11-32.

20:51:06:03. Renewal required each year. Initial application for pharmacy license Application for the renewal of a permit to conduct a pharmacy shall be filed with the secretary of the Board of Pharmacy before July 1 each year. The fee set by the Board of Pharmacy shall accompany the application. Applications Initial applications for opening and conducting a new pharmacy license in South Dakota shall be filed with the secretary of the Board of Pharmacy board at least 30 days before the date when the new pharmacy is to be opened to the public. The owner must provide the board with a copy of the layout or blueprint of the pharmacy and building. The board may inspect the pharmacy prior to opening. If the applicant for a permit to open and conduct a new pharmacy in South Dakota will not be the owner of the merchandise and fixtures of the proposed new pharmacy to the extent that the applicant will be self employed, the place and space to be registered as a pharmacy shall not include any floor space where general merchandise is offered for sale at retail.

If the proposed new pharmacy is to include either a prescription department or the dispensing and sale of narcotics, or both, the space registered licensed as a pharmacy shall be separated from the remainder of the building in which it is located by walls extended from the floor to the <u>permanent</u> ceiling. The walls may contain doors to the interior of the building which shall be closed and locked whenever a registered licensed pharmacist is not on duty in and in charge of the pharmacy.

If the proposed new pharmacy will be for the exclusive sale of packaged drugs, medicines, and poisons other than those labeled "Caution: Federal law prohibits dispensing without prescription," the place and space to be registered as a pharmacy shall be designated as a packaged drug department. The space shall be separated from the remainder of the building in which it is located by solid walls at least eight feet high. The wall may contain doors to the interior of the building which shall be closed and locked whenever a registered pharmacist is not on duty in and in charge of the pharmacy.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(3).

Law Implemented: SDCL 36-11-32.

20:51:06:04. False application grounds for suspending or revoking. False representation made in an application for a permit to conduct a pharmacy license, or keeping a pharmacy open for the transaction of business without a pharmacist on duty in and in charge thereof, except as provided in § 20:51:06:10, shall be grounds for suspending or revoking such permit to conduct a the pharmacy license.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(3). Law Implemented: SDCL 36-11-44, 36-11-62.

20:51:06:05. Must be registered in order to advertise pharmacy name. Unless a place of business is a pharmacy duly authorized and registered by the state Board of Pharmacy licensed by the board, its owners shall not in any manner by advertisement, circular, poster, sign, symbol or insignia describe or refer to such place of business as a pharmacy, <u>or</u> drug store or packaged drug department.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(<u>3</u>). Law Implemented: SDCL 36-11-31.

20:51:06:06. Transfer of pharmacy registration license. Each permit to conduct a <u>A</u> pharmacy license may be transferred to another licensed pharmacist registered under the laws of this state, without payment of an additional fee; provided, an application for the transfer is made and the same is filed with the secretary of the Board of Pharmacy board no less than ten days before the transfer of such active management is made. Any application for transfer made at a later date than ten days before the transfer of such active management is made. Any application for transfer made at a later date than ten days before the transfer of such active management is made shall be accompanied accomplished by the fee as set by the Board of Pharmacy required pursuant to § 20:51:06:01 for permit to conduct a pharmacy license, and such The application for transfer shall be approved by the members of the Board of Pharmacy before permit to conduct a pharmacy is issued by the secretary of the Board of Pharmacy on such application board prior to issuing a license.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(3). Law Implemented: SDCL 36-11-37.

20:51:06:07. Changes in ownership or location must be reported to secretary <u>board</u> – <u>Patients notified of cessation of pharmacy</u>. Any change in the location <u>or ownership</u> of a pharmacy, or any change in the ownership of the merchandise and fixtures of a pharmacy, or the cessation of business as a pharmacy, shall be reported to the secretary of the Board of Pharmacy within <u>board</u> ten days of prior to such occurrence. The pharmacist permittee shall be held responsible

for reporting such changes to the Board of Pharmacy. When ownership changes, a new application must be submitted pursuant to § 20:51:06:01. If cessation of the business of pharmacy, patients must be notified at least 30 days prior to closure.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(3).

Law Implemented: SDCL 36-11-39.

20:51:06:08. Valid <u>permit license</u> must be displayed. A valid <u>permit to conduct a</u> pharmacy license shall be displayed in every pharmacy in this state at all times.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(3). Law Implemented: SDCL 36-11-36.

20:51:06:09. Permit License expires 120 days after death of pharmacist. Except in the event of the death of the licensed pharmacist permittee, a permit license to conduct operate a pharmacy is void when the license holder of the permit ceases to be in active management of the pharmacy. When a licensed pharmacist permittee dies, the pharmacy for which the pharmacist held a permit license to conduct operate may not be kept open for the transaction of business without a pharmacist on duty and in charge. A permit license to conduct operate a pharmacist who is deceased shall within 120 days after the death of the permit has been made within the 120-day period to a pharmacist owner or to an employee pharmacist manager

for whom an affidavit has been filed by a non_pharmacist owner or owners of the merchandise and fixtures of the pharmacy.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(3). Law Implemented: SDCL 36-11-38.

20:51:06:10. Provisions for pharmacist temporary absence from pharmacy. Where the place regularly registered as a pharmacy by the state Board of Pharmacy includes:

(1) A space or unrestricted floor area where general merchandise is sold, or offered for sale; and

(2) A restricted drug area where only packaged drugs, medicines and poisons are displayed and offered for sale; and

(3) A prescription department, and where facilities not less than eight feet high are maintained within such pharmacy for closing and isolating such restricted drug area and prescription department from the unrestricted floor area where general merchandise is sold.

It shall not be <u>considered in a</u> violation of <u>the state pharmacy law SDCL 36-11 or ARSD 20:51</u> if public entrances to <u>such the</u> general merchandise area are kept open for the transaction of business without a pharmacist on duty in <u>such the</u> pharmacy; provided, all entrances to the <u>restricted area and</u> the prescription department are closed for the transaction of business when no pharmacist is on duty within such pharmacy and a sign bearing the words "pharmacy services closed" has been posted at public entrances to such general merchandising area by the <u>licensed</u> pharmacist permittee before leaving the premises.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(3).

20:51:06:11. Pharmacy <u>structural</u> requirements. for nonpharmacist owners. If a pharmacist permittee has the authority to be in active management of a pharmacy by affidavit of nonpharmacist individuals or by affidavit of a nonpharmacist officer of a corporation and if the pharmacy regularly registered by the Board of Pharmacy on the renewal application of the pharmacist permittee includes:

(1)A space or unrestricted floor area where general merchandise is sold or offered for sale;

(2) A restricted floor area where only packaged drugs, medicines, and poisons are displayed and offered for sale_; and.

(3) A prescription department,

the pharmacist permittee shall require the nonpharmacist employer to maintain on the premises a prescription department and restricted floor area that is that is surrounded by a continuous partition or wall not less than 3/8 inch in thickness extending from the floor to the permanent ceiling, containing doors capable of being securely locked for closing and isolating the prescription department and restricting the drug area from any unrestricted floor area where general merchandise

is sold or offered for sale. The pharmacist permittee may not leave the pharmacy department in charge of the nonpharmacist employer until the pharmacist permittee has first closed and locked all entrances to the prescription department.

The prescription area must include sufficient security measures to protect the area from theft or access by unauthorized personnel.

If the licensed pharmacy is in a building which only houses the pharmacy department and a contiguous general merchandise area, the pharmacy department is not required to be separated from the general merchandise area by a barrier. If the pharmacy department is closed, except as outlined in 20:51:06:10, the entire business must be closed, locked, and secured to protect the area from theft or access by nonpharmacist personnel. However, if the general merchandise area remains open, except as outlined in 20:51:06:10, the pharmacy department must be separated by an appropriate barrier, not less than eight feet high. If the licensed pharmacy is in a building which includes multiple types of businesses or departments, the prescription area must be secured by a continuous partition or wall not less than 3/8 inch in thickness, extending from the floor to the permanent ceiling, with doors capable of being securely locked to isolate the prescription department. The licensed pharmacist must close and lock all entrances to the prescription department prior to leaving the building.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-11(4)(3).

20:51:06:12. Pharmacy requirements for pharmacist owners <u>repealed</u>. Facilities for closing and isolating any restricted drug area and prescription department from unrestricted floor areas where general merchandise is sold, or offered for sale, is not required in any pharmacy that is owned and managed by pharmacists registered under the laws of this state and within which a pharmacist is on duty and in charge at all times when the pharmacy is open to the public.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-11(4).

Law Implemented: SDCL 36-11-34.

CHAPTER 20:51:07

MINIMUM EQUIPMENT REQUIREMENTS

Section

- 20:51:07:01 Pharmacy must comply with all public health regulations.
- 20:51:07:02 Repealed.
- 20:51:07:03 Minimum equipment requirements.
- 20:51:07:04 Publication and reference library.

20:51:07:01. Pharmacy must comply with all public health regulations. The pharmacy shall comply with all public health regulations regarding sanitation and shall be maintained and operated in a clean and sanitary condition, free from unhealthful, foreign or injurious contamination and is subject to regular board inspections.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(4). Law Implemented: SDCL 36-11-42, 36-11-64.

20:51:07:03. Minimum equipment requirements. The following minimum equipment shall be maintained in every pharmacy in South Dakota unless the pharmacy offers limited professional services and does not use a specific item:

(1) A balance with a delicacy of not less than 1/10 grain;

(2) Prescription equipment of the kind and quality that will enable the pharmacist to meet all prescription requirements;

- (3) A poison register;
- (4) A supply of labels, including poison labels;
- (5) Permanent file for all prescriptions;
- (6) Locked space for narcotics and dangerous drugs;

(7) A supply of standard grade chemicals and pharmaceuticals adequate to meet the needs in the location; and

(8) Refrigerated storage space for biologicals and drugs affected by extreme temperatures.

A licensed pharmacy must maintain all equipment the pharmacist-in-charge determines to be necessary to perform professional pharmacy services provided to patients at that location. The equipment which requires certification, maintenance or calibration must be certified, maintained or calibrated according to the manufacturer and USP guidelines. All equipment failing to be in good working condition may not be used for pharmacy services.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(4). Law Implemented: SDCL 36-11-41.

20:51:07:04. Publication and reference library. Each pharmacy shall maintain <u>All</u> pharmacy staff must have access to the latest copy of South Dakota pharmacy laws and rules, federal laws and rules, all governing or regulatory agency documents needed to conduct pharmacy services and the telephone number of the nearest poison control center. Pharmaceutical reference publications may be printed or computer accessed online. At least one general pharmaceutical information reference must be a printed copy. Additional reference Reference material shall be maintained and shall include, at a minimum, one current <u>drug information reference the pharmacist-in-charge</u> determines to be necessary to perform professional pharmacy services provided to patients at that location. from three of the following categories, including access to period updates:

(1) Patient information references such as:

(a) USP-DI, Volume II (Advice for the Patient) by MicroMedex;

(b) Professional Guide to Patient Drug Facts by Facts and Comparisons;

- (2) References on drug interactions such as:
 - (a) Hansten and Horn's Drug Interaction;
 - (b) Drug Interactions Facts by Facts & Comparisons;
 - (c) Trissel's Handbook on Injectable Drugs, ASHP;
 - (d) Trissel's TM 2 Clinical Pharmaceutics Database;
- (3) General information reference such as:
 - (a) Facts and Comparisons;
 - (b) USP-DI, Volume I;
 - (c) Gold Standard;
 - (d) American Hospital Formulary Service;
 - (e) Lexi-Comp's Drug Information Handbook;
- (4) A drug equivalency reference such as:

(a) Approved Drug Products with Therapeutic Equivalence Evaluations (orange book);
 (b) USP Dispensing Information, Volume III;

(5) A reference on natural or herbal medicines such as:

(a) Natural Medicines - Comprehensive Database;

(b) The Review of Natural Products.

Each pharmacy shall have additional references as may be necessary for the pharmacist to adequately meet the needs of the patients served, such as the *Handbook of Nonprescription Drugs* by the American Pharmacists Association.

Source: 31 SDR 35, effective September 19, 2004.

General Authority: SDCL 36-11-11(+)(4).

Law Implemented: SDCL 36-11-41.

CHAPTER 20:51:13

SPECIAL RESTRICTIONS

Section

- 20:51:13:01 Repealed.
- 20:51:13:02 Return of unused drugs.
- 20:51:13:02.01 Return of unused unit dose <u>and unit of issue</u> drugs by patients in hospice programs, nursing facilities, or assisted living facilities.

20:51:13:02.02 Repealed.

- 20:51:13:02.03 Redispensing unit dose <u>and unit of issue</u> drugs returned from hospice programs, nursing facilities, or assisted living facilities.
- 20:51:13:02.04 Repackaging drugs from prescription container.
- 20:51:13:03 Free choice of pharmacies.

20:51:13:04 Splitting fees or rebates prohibited.

20:51:13:05 Medication disposal.

20:51:13:06 Remote prescription pickup sites.

20:51:13:02. Return of unused drugs. <u>Pharmacists</u> <u>Except as authorized by § 20:51:15:05</u>, <u>pharmacists</u> and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue, or resale any unused drugs, prescribed medications, poisons, sickroom supplies, or hygienic surgical appliances or garments. However, in a hospital with a licensed pharmacy, unused drugs, sickroom supplies, hygienic surgical appliances or garments, or other items dispensed for hospital inpatients may be returned to the pharmacy for credit and disposition by a pharmacist if the integrity of the products and packages is maintained.

Source: SL 1975, ch 16, § 1; 8 SDR 5, effective July 26, 1981; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:13:02.01. Return of unused unit dose and unit of issue drugs by patients in hospice programs, nursing facilities, or assisted living facilities. Only unused unit dose or unit of issue drugs from patients in a hospice program, a nursing facility, or an assisted living facility may be returned to the pharmacy that dispensed the drugs for credit and redispensing if the following requirements are met:

(1) The facility or hospice program consults with a licensed pharmacist to oversee the drug distribution to ensure that a person trained and knowledgeable in the storage, use, and administration of the drug has been in control of any <u>unit dose</u> drug being returned to the pharmacy and that the unit dose <u>or unit of issue</u> drug has not come into the physical possession of the person for whom it was prescribed;

(2) The pharmacy's manager has received written approval from the board of a protocol detailing the procedure used to repackage, label, transfer, restock, redispense, and credit any unit dose <u>or unit of issue</u> drugs returned to the pharmacy;

(3) The drugs are provided in the manufacturer's unit dose packaging or are repackaged by the pharmacy in a hermetically sealed single unit dose container that meets Class A or Class B standards on pages 1937 and 1938 of the United States Pharmacopeia in accordance with Chapter 20:51:21;

(4) The unit dose package is labeled by the manufacturer with the drug lot number and expiration date;

(5) If the drug is repackaged by the pharmacy, each single unit dose or <u>each unit of issue</u> prepackaged or repackaged container must be labeled in accordance with this regulation. Labeling must include the following:

(a) Name and strength of the medication;

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(b) A suitable expiration date which shall not be later than the expiration date on the manufacturer's container, or one year maximum from the date the drug is prepackaged or repackaged;

(c) The date the product was prepackaged or repackaged;

(d) The manufacturer's lot number, expiration date, and identity;

(e) The identity of the pharmacist responsible for prepackaging or repackaging;

If the requirements of subdivisions (d) and (e) are maintained in the internal records of the drug outlet, those requirements may be omitted from the labeling.

(6) The drug's packaging is tamper resistant and shows no evidence of contamination, such as an opened or stained container;

(7) The unit dose drugs have not reached the expiration date;

(8) The drugs have not been dispensed in packaging that intermingles different drugs in a single compartment; and

(9) The drugs are not controlled drugs.

Unused drugs that are returned under this section may be redispensed pursuant to § 20:51:13:02.03. Source: 10 SDR 38, effective October 27, 1983; 12 SDR 82, effective November 19, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002; SL 2004, ch 249, § 3, effective July 1, 2004.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1), 36-11-46.

Reference: Pages 1937 and 1938, The United States Pharmacopeia, Twenty-fourth Revision - The National Formulary, Nineteenth Edition, January 1, 2000, published by the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852. Photocopies of pages 11, 1937, and 1938 may be obtained without charge from the State Board of Pharmacy, 4305 South Louise Avenue, Suite 104, Sioux Falls, SD 57106.

Cross-Reference: Unit dose systems; definitions, 20:51:21:01.

20:51:13:02.03. Redispensing unit dose <u>or unit of issue</u> drugs returned from hospice programs, nursing facilities, or assisted living facilities. Unused unit dose <u>or unit of issue</u> drugs that are returned under § 20:51:13:02.01 may be redispensed under the following conditions:

(1) Drugs may not be removed and repackaged from the returned unit dose package prior to redispensing Drugs that have been repackaged by the pharmacy may only be redispensed one time. In order for a pharmacy to redispense the medication, the label or record must have the manufacturer expiration date and lot number; (2) Drugs in a manufacturer's unit dose package may be redispensed as often as necessary, if the integrity of the original product and package is maintained;

(3) Drugs which have been repackaged into a unit <u>dose of issue</u> package by the pharmacy may be redispensed into a unit <u>dose of issue</u> distribution system and mixed with drugs of a different lot number provided that all lot numbers and expiration dates are placed on the unit <u>dose of issue</u> package;

(4) Drugs may be removed from a unit dose <u>or unit of issue</u> package for dispensing in a traditional dispensing system as defined in § 20:51:21:01

Source: 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002.General Authority: SDCL 36-11-11(1).Law Implemented: SDCL 36-11-11(1), 36-11-46.

20:51:13:02.04. Repackaging drugs from prescription container. Drugs that have been dispensed as a prescription in a traditional dispensing system may not be repackaged into a unit dose <u>or unit of issue</u> package. However, drugs transferred directly from one pharmacy to another pharmacy may be repackaged into unit dose packaging if all the following information is obtained by the receiving pharmacy:

- (1) Date received;
- (2) Name of drug;
- (3) Strength;
- (4) Quantity;

- (5) Expiration date;
- (6) Lot number;
- (7) Manufacturer; and
- (8) National Drug Code (NDC).

Source: 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002.General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1), 36-11-46.

20:51:13:03. Free choice of pharmacies. The following notice provided by the South Dakota Board of Pharmacy board must be displayed conspicuously at all times in all licensed pharmacies:

"NOTICE TO THE PUBLIC

FREE CHOICE OF PHARMACIES

Any person has the right and privilege of having his prescription filled at the pharmacy of his choice. This regulation of the South Dakota Board of Pharmacy must be displayed conspicuously at all times in all licensed pharmacies."

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.
General Authority: SDCL 36-11-11(1).
Law Implemented: SDCL 36-11-11(1).

20:51:13:04. Splitting fees or rebates prohibited. The practice of splitting fees or making rebates for pharmaceutical services with other health practitioners or with health institutions providing patient care is contrary to the best interests of the patient and is therefore prohibited.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:13:05. Medication disposal. A pharmacy that has modified its DEA registration to a "collector" and has a proper disposal device pursuant to 21 CFR § 1317 may allow for patients to dispose of unused medications at the pharmacy location.

Source:

General Authority: SDCL 36-11-11(1). Law Implemented: SDCL 36-11-11(1).

Reference: 21 Code of Federal Regulations, Food and Drugs part 1317 -- Disposal, pages 41, 48, and 261-270. Published by U.S. Government Publishing Office, US Superintendent of Documents, Washington D.C. 20402-0001

20:51:13:06. Remote prescription pickup sites. A pharmacy may elect to have medications picked up by patients or caregivers at a certain unlicensed location away from the pharmacy for patient convenience. When electing to establish a pickup site, the pharmacy must have written board approval of the location before the pharmacy may use remote pickup site.

The location must have the following:

- (1) Locked cabinet, drawer, or kiosk;
- (2) <u>Limited access to the medications by only trained personnel;</u>
- (3) <u>Outer packaging should have the minimum amount of patient information to protect the</u> privacy of the patients. Patient name only should be sufficient to identify the person at a remote pickup site;
- (4) <u>All prescriptions picked up must be signed for by the person accepting the prescription;</u>

The dispensing pharmacy must provide:

(1) A pharmacy staff member to conduct and document quarterly visits at the remote

pickup site;

- (5) <u>A handout inside the outer package that explains that any questions need to be directed to</u> the pharmacy that includes the pharmacy name, phone number and hours of operation;
- (6) <u>Policies and procedures for the dispensing pharmacy and the remote pickup site, which</u> are reviewed at least annually, and must address the following:
 - (a) <u>Security;</u>
 - (b) <u>Staff training;</u>
 - (c) Patient counseling and the offer to counsel;
 - (d) <u>Delivery of medications;</u>
 - (e) <u>Pickup transaction;</u>
 - (f) Return of prescriptions to pharmacy; and
 - (g) <u>Records.</u>

Records for the remote pickup site shall be maintained in the pharmacy for two years. Remote pickup sites are an extension of the dispensing pharmacy and may be inspected by the board at any

time. Any issues, violations, or concerns will be directed to the pharmacist-in-charge for the pharmacy supplying the medications.

Source:

General Authority: SDCL 36-11-11(1)(3).

Law Implemented: SDCL 36-11-1, 36-11-11(1)(3).

CHAPTER 20:51:14

GENERAL ADMINISTRATION

Section

- 20:51:14:01 Annual certificate license renewal.
- 20:51:14:02 Repealed.
- 20:51:14:03 Repealed.
- 20:51:14:04 Equivalent drug products.

Annual certificate <u>license</u> renewal. The fee for annual <u>certificate license</u> renewal <u>for a</u> <u>pharmacist</u> is \$125. <u>Certificates Licenses</u> expire on September 30 following issuance and must be renewed annually by October 1.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 15 SDR 20, effective August 9, 1988; 23 SDR 26, 23 SDR 47, effective August 26, 1996; 28 SDR 24, effective September 2, 2001.

General Authority: SDCL 36-11-23.

Law Implemented: SDCL 36-11-23.

20:51:14:04. Equivalent drug products. An equivalent drug product is a drug product that is considered to be pharmaceutically equivalent to a drug product that contains the same active ingredient(s) as determined by the Food and Drug Administration in Approved Drug Products with Therapeutic Equivalence Evaluations, 19th Edition, 1999 (orange book). 39th Edition, 2019 (Orange Book), https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

If a pharmacist selects a pharmaceutically equivalent drug product for a prescribed product, the selected pharmaceutically equivalent drug product may not be rated less than AB as documented in **Approved Drug Products with Therapeutic Equivalence Evaluations** (orange book)(Orange Book).

Source: 13 SDR 179, effective June 2, 1987; 17 SDR 37, effective September 9, 1990; 18 SDR 95, effective November 25, 1991; 19 SDR 93, effective December 31, 1992; 20 SDR 28, effective August 30, 1993; 22 SDR 32, effective September 14, 1995; 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-2(12), 36-11-11(1), 36-11-46.1.

Law Implemented: SDCL 36-11-2(12).

CHAPTER 20:51:15

PHARMACIES IN HOSPITALS,

NURSING FACILITIES, OR RELATED FACILITIES

Section

- 20:51:15:01 Definition and general provisions.
- 20:51:15:02 Pharmaceutical services supervised by pharmacist.
- 20:51:15:03 Central area to be licensed as a pharmacy.
- 20:51:15:04 Dispensing limited to pharmacist.
- 20:51:15:05 Transferring drugs from original containers limited to pharmacists.
- 20:51:15:06 Removing a single dose from prescription container.
- 20:51:15:07 Preparing a solution.
- 20:51:15:08 Medication floor stocks.
- 20:51:15:09 Filling or refilling of nursing station containers limited to pharmacist <u>Repealed</u>.
- 20:51:15:10 **Registration** Licensure and renewal.
- 20:51:15:11 Schedule of attendance by pharmacist.
- 20:51:15:12 Supervision of drugs located in areas other than pharmacy.
- 20:51:15:13 Access to pharmacy -- Records.
- 20:51:15:14 Pharmacy must be in a separate room.
- 20:51:15:15 Pharmacist controls emergency drugs in health care facilities.
- 20:51:15:15.01 Pharmacist controls emergency kit in nursing facility.

20:51:15:17 Repealed.

20:51:15:01. Definition and general provisions. Definitions and general provisions <u>As</u> used in this chapter are as follows:

(1) The terms "part-time "Part-time," "limited," or "conditional" pharmacy, mean means the providing provision of pharmaceutical services by a registered licensed pharmacist under a pharmacy license issued by the South Dakota Board of Pharmacy board on less than a full-time operation basis, in hospitals, nursing facilities, and related facilities and where such pharmaceutical services are limited to inpatients;

(2) "Pharmacist," <u>means</u> a person licensed by the <u>South Dakota State Board of Pharmacy</u> <u>board</u>, to prepare, compound, and dispense <u>physicians'</u> practitioners' prescriptions, drugs, <u>and</u> medicines, <u>and poisons</u>, and whose license has not been revoked or suspended;

(3) The term "pharmaceutical "Pharmaceutical services," means and includes:

(a) The conduct, operation, management, or control of a pharmacy; or

(b) Preparing, compounding, processing, packaging, labeling, or dispensing one or more doses of medication either upon <u>a</u> prescription <u>or chart order</u> of an authorized practitioner for subsequent administration to, or use by, a patient; or

(c) Any other act, service, operation, or transaction incidental to or forming a part of any of the acts in the above subdivisions (1) and (2) subdivision (3) (a) and (b) requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training;

(4) "Compounding," <u>means</u> the taking of two or more measured ingredients, and by simple or complicated means, depending on the nature of the ingredients, fabricating them into a single preparation, usually referred to as a dosage form;

(5) "Dispensing," includes, but is not limited to, means issuing to a patient, or to a person acting on a patient's behalf one or more unit doses of medication in a suitable container with appropriate labeling. Dispensing affects one or many patients. Dispensing, while including compounding, also includes the act of packaging a drug or medication either from a bulk container, or as a result of compounding, in a container other than the original and labeling the new container with all required information;

(6) "Original container," <u>means</u> a container which has been packaged by a licensed manufacturer and which is labeled in compliance with federal and South Dakota law;

(7) "Hospice program," <u>means</u> a coordinated program of inpatient services providing palliative rather than curative care for a patient- <u>; and</u>

(8) "Chart order" means a lawful order entered on the chart or a medical record of a patient or resident of a licensed healthcare facility by a practitioner, or his or her designated agent, for a drug or device and shall be considered a prescription.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; SL 2004, ch 249, § 2, effective July 1, 2004.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-33.

20:51:15:02. Pharmaceutical services supervised by pharmacist. All pharmaceutical services shall be performed either by, or under the personal supervision of a registered licensed pharmacist.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(1). Law Implemented: SDCL 36-11-33.

20:51:15:03. Central area to be licensed as a pharmacy. The central area in a hospital, nursing facility, and related facilities where drugs are procured, stored, and issued, and where pharmaceutical services are performed shall be licensed as a pharmacy and by appropriate sign must be designated by that name and no other. The pharmacy must meet all requirements of South Dakota and federal law and the rules of the <u>South Dakota Board of Pharmacy board</u> and shall have a registered <u>licensed</u> pharmacist in charge of the pharmacy.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(1)(3).

Law Implemented: SDCL 36-11-33, <u>SDCL 36-11-1(3)</u>.

20:51:15:04. Dispensing limited to pharmacist. The act of dispensing is limited to a registered licensed pharmacist and may not be performed by any other person except under the personal supervision of a registered licensed pharmacist.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-33.

20:51:15:05. Transferring drugs from original containers limited to pharmacists. The act of transferring a drug or preparation from an original container to a new container is an act of dispensing which is restricted to a registered licensed pharmacist.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(1). Law Implemented: SDCL 36-11-33.

20:51:15:06. Removing a single dose from prescription container. Removing a single dose of medication from a prescription container which has been dispensed by a pharmacist to a medicine cup and placing this medicine cup on a tray with appropriate identification constitutes a step in administration of medication.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(1). Law Implemented: SDCL 36-11-33.

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20:51:15:07. Preparing a solution. The preparation of a solution by a licensed nurse licensed nurse pursuant to SDCL 36-9 for injection by a licensed nurse is considered a step in <u>the</u> administration of medication.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-33.

20:51:15:08. Medication floor stocks. Licensed hospitals and intensive care units having an organized medical staff, may maintain necessary floor stocks of medications at the nurses' station.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(1). Law Implemented: SDCL 36-11-33.

20:51:15:09. Filling or refilling of nursing station containers limited to pharmacists. The filling or refilling of a nursing station medication container, or container from other service areas where medications are stocked, with the drug called for, or the furnishing of a medication to such area, is dispensing and can be engaged in legally only by a licensed pharmacist under South Dakota pharmacy law <u>Repealed</u>.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11.

20:51:15:10. registration <u>Licensure</u> and renewal. The board may issue to a pharmacist in good standing a <u>permit license</u> to <u>conduct operate</u> a part-time, limited, or conditional pharmacy in a hospital, nursing facility, or related facility for the <u>fiscal</u> year ending June thirtieth if the pharmacist applies yearly on a form supplied by the board and pays a fee of \$160.

Source: SL 1975, ch 16, § 1; 2 SDR 56, effective February 11, 1976; 4 SDR 85, effective June 19, 1978; 11 SDR 151, effective May 15, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 24 SDR 160, effective May 26, 1998.

General Authority: SDCL 36-11-11(4)(3), 36-11-32.

Law Implemented: SDCL 36-11-33.

Cross-Reference: Pharmacy registration <u>licensure</u>, ch 20:51:06; Minimum equipment requirements, ch 20:51:07.

20:51:15:11. Schedule of attendance by pharmacist. A registered licensed pharmacist employed or otherwise engaged to supply pharmaceutical services may have a flexible schedule of attendance, but the pharmacist must be present for a sufficient number of hours weekly to maintain an adequate supply of medications at the several service areas from which medications are administered, to maintain all required records, to perform other services permitted or required by law, and to provide adequate control over all pharmaceutical services rendered by the hospital, nursing facility, or related facilities.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(1)(4).

20:51:15:12. Supervision of drugs located in areas other than pharmacy. Drugs, <u>and</u> medications <u>and poisons</u> located in areas of the facility other than in the pharmacy shall be under the general supervision of the <u>registered licensed</u> pharmacist employed or otherwise engaged.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-11(1)(4).

Law Implemented: SDCL 36-11-33.

20:51:15:13. Access to pharmacy -- Records. Only a registered licensed pharmacist may have access to the pharmacy stock of drugs in the hospital, nursing facility, or related facilities. However, when the pharmacist is absent from the hospital or other like facility, a registered nurse designated by the hospital may obtain from a hospital pharmacy stock of drugs a unit dose of a drug or medication necessary to administer to a bona fide patient in carrying out treatment and medication orders as prescribed by a licensed physician practitioner when the drug is not available in floor supplies or the emergency drug kit, to meet the immediate need in an emergency of the patient. This nurse shall leave in the pharmacy, on a suitable form, a record of any drugs removed, showing the name of the patient, the nurse shall leave with the record the container from which the emergency dose was taken for drug administration purposes in order that it may be properly checked by the pharmacist. Such records shall be kept for three-two years.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(1)(4).

20:51:15:14. Pharmacy must be in a separate room. The pharmacy must be in a separate room and locked at all times when the <u>registered licensed</u> pharmacist is not on duty.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(1)(4).

Law Implemented: SDCL 36-11-33.

20:51:15:15. Pharmacist controls emergency drugs in health care facilities. A pharmacist of a registered licensed pharmacy in a health care facility may provide, upon written request of the health care facility's physicians-practitioners, a defined supply of legend drugs in an emergency drug kit or crash cart. The emergency drugs shall meet the immediate therapeutic needs of a patient to prevent harm to the patient due to a delay in obtaining such drugs from the pharmacy. The emergency drugs shall remain the property of the registered pharmacy and shall be stored on-site in a suitable controlled location in the health care facility. The emergency drug supplies shall comply with the following requirements:

(1) The facility's registered licensed pharmacist controls the emergency drugs contained in an emergency kit or crash cart;

(2) Drug quantities are limited, properly labeled, and supplied in single dose packaging, if possible;

(3) All legend drugs used for an emergency shall be identified for replacement by a pharmacist;

(4) The pharmacist or the pharmacist's employee pharmacy staff shall inventory restock the contents of the emergency drug supply after each reported use or at least monthly.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-11(1)(4).

Law Implemented: SDCL 36-11-33.

20:51:15:15.01. Pharmacist controls emergency kit in nursing facility. A registered licensed pharmacist may provide to a nursing facility a limited quantity of controlled legend drugs pursuant to <u>§ 44:04:08:07.01 §§ 44:58:07:09 and 44:73:08:11</u> and a limited amount of noncontrolled legend drugs and nonprescription drugs, for emergency and supportive treatment, when requested in writing by the medical director The pharmacist shall retain control of all medications provided in emergency kits.

The provider pharmacist shall comply with the following requirements:

(1) The provider pharmacy shall provide to the Board of Pharmacy yearly the name of each nursing facility where emergency drugs are kept and stored;

(2) The medical director, director of nursing, and provider pharmacist shall jointly determine and prepare a limited list of emergency drugs by identity and quantity;

(3) Noncontrolled legend drugs in the emergency kit shall be limited to the extent possible with the following requirements:

(a) No more than 30 different noncontrolled legend drugs, up to a 24 hour supply shall be stocked, not counting oral antibiotics; and

(b) An unlimited number of oral antibiotics may be stocked;

(4) The provider pharmacist shall review all first dose antibiotic drug orders prior to administration to the patient from the emergency kit;

(5)(2) The provider pharmacist pharmacy shall be notified of any drug taken from the emergency kit;

(6)(3) The provider pharmacist or the pharmacist's employee pharmacy staff shall inventory and restock the contents of the emergency kit after reported use or at least monthly;

(7)(4) The emergency kit shall be stored in a suitable, controlled location in the nursing facility to prevent the unauthorized access and preservation of the drugs within it. The emergency kit exterior shall be labeled clearly, and unmistakably, that it is an emergency kit and is for emergency use only. The emergency kit shall contain the name, strength, quantity, and expiration date of drugs contained therein-;

(5) The pharmacy may utilize an automated medication distribution device to store, distribute, and record transactions as an emergency kit or for first dose medications. The pharmacy must also follow Chapter 20:51:17; and (6) The provider pharmacy must provide each facility where an emergency kit is placed with a contact number to a provider pharmacist 24 hours a day.

All other controlled and noncontrolled legend medications shall be obtained from a pharmacy licensed to distribute to patients pursuant to SDCL 34-12B-1 and 34-12B-2.

Source: 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-11(1)(4).

Law Implemented: SDCL 36-11-33.

<u>Cross-Reference: Automated Mechanical Distribution and Dispensing Devices; ch.</u> 20:51:17

20:51:15:16. Minimum standards for pharmacy service. Pharmacy service pursuant to <u>a</u> pharmacy permits issued under this section, shall be rendered in accordance with pages 119 to 128, inclusive, pharmaceutical services, of Accreditation Manual for Hospitals, 1985 edition, Joint Commission on Accreditation of Hospitals Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 86, effective November 27, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11.

Reference: Accreditation Manual for Hospitals, 1985 edition, 237 pages, is published by the Joint Commission on Accreditation of Hospitals, 875 North Michigan Avenue, Chicago, Illinois 60611. Current cost is \$40.

CHAPTER 20:51:16

RULES OF PROFESSIONAL CONDUCT

Section

- 20:51:16:01 Repealed.
- 20:51:16:02 Repealed.
- 20:51:16:03 The pharmacist's relation to the public.
- 20:51:16:04 The pharmacist's relations to other health professions.
- 20:51:16:05 The pharmacist's relations to fellow pharmacists.

20:51:16:03. The pharmacist's relation to the public. In relation to the public, the pharmacist:

(1) Upholds the approved legal standards of the U.S. Pharmacopeia and the National Formulary, and encourages the use of official drugs and preparations. The pharmacist purchases, compounds, and dispenses only drugs of good quality;

(2) Uses every precaution to safeguard the public when dispensing any drugs or preparations. Being legally entrusted with the dispensing and sale of these products, the pharmacist assumes responsibility by upholding and conforming to the laws and regulations governing the distribution of these substances;

(3) Seeks to enlist and to merit the confidence of the pharmacist's patrons. The pharmacist zealously guards this confidence. The pharmacist considers the knowledge and confidence which the pharmacist gains of the ailments of patrons as entrusted to the pharmacist's honor, and does not divulge such facts;

(4) Holds the health and safety of the pharmacist's patrons to be of first consideration; the pharmacist makes no attempt to prescribe for or treat diseases or to offer for sale any drug or medical device merely for profit;

(5) Keeps the pharmacy clean, neat, and sanitary, and well equipped with accurate measuring and weighing devices and other apparatus suitable for the proper performance of professional duties;

(6) Is a good citizen and upholds and defends the laws of the states and nation; the pharmacist keeps informed concerning pharmacy and drug laws and other laws pertaining to health and sanitation and cooperates with the enforcement authorities;

(7) Supports constructive efforts in behalf of the public health and welfare. The pharmacist seeks representation on public health committees and projects and offers to them full cooperation; and

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(8) At all times seeks only fair and honest remuneration for services.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-43. Law Implemented: SDCL 36-11-43.

20:51:16:04. The pharmacist's relations to other health professions. In the pharmacist's relations to other health professions, the pharmacist shall meet the following requirements:

(1) Willingly make available the pharmacist's expert knowledge of drugs to the other health professions;

(2) Refuse to prescribe or diagnose, but refer those needing such services to a licensed practitioner. In an emergency and pending the arrival of a qualified <u>healthcare</u> practitioner, the pharmacist may <u>apply first render</u> aid <u>treatment</u>;

(3) Compound and dispense prescriptions carefully and accurately, using correct pharmaceutical skill and procedure. If there is a question in the pharmacist's mind regarding the ingredients of a prescription, a possible error, or the safety of the directions, the pharmacist shall privately consult the practitioner before making any changes. The pharmacist shall exercise the best professional judgment following the prescriber's directions in the matter of refilling prescriptions, copying the formula upon the label, or giving a copy of the prescription to the patient. The pharmacist may add extra directions or caution on poison labels for the wishes of the prescriber and the safety of the patient; and

(4) Not have clandestine arrangements either directly or indirectly with a <u>licensed</u> practitioner of the health sciences or any person, partnership, or corporation by which fees are divided or in which secret or coded prescriptions are involved.

Source: SL 1975, ch 16, § 1; 12 SDR 86, effective November 27, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-43.

Law Implemented: SDCL 36-11-43.

CHAPTER 20:51:17

AUTOMATED MECHANICAL DISTRIBUTION AND DISPENSING DEVICES

Section

20:51:17:01 Definitions.

- 20:51:17:01.01 Approval for use of automated mechanical distribution device Repeal.
- 20:51:17:01.02 Pharmacist shall review first-dose prescription drug order -- Exception.
- 20:51:17:02 Procedure for distributing <u>or dispensing</u> drugs in automated mechanical distribution

device and automated prescription dispensing devices.

20:51:17:03 Stand-alone automated prescription dispensing device - license required.

20:51:17:01. Definitions. Terms <u>As</u> used in this chapter mean:

(1) "Automated mechanical distribution device," <u>means</u> a mechanical device that delivers a drug or drug device <u>located in a licensed health care facility</u>, other than by administration or dispensing and uses automated data processing technology to do the following:

(a) Limit access of stocked drugs or drug devices to only authorized personnel;

(b) Record identity of all personnel who have access to drugs or drug devices stocked within the device; and

(c) Document both stocking and removal transactions;

(2) "Automated prescription dispensing device," means a mechanical device that aids in the process of dispensing medication in a retail pharmacy or healthcare facility which may include storing, counting, and labeling medications;

(2)(3) "Health care facility," <u>means</u> any <u>state licensed</u>-hospital, nursing facility, or related facility-that offers supervised care-of the sick or injured <u>to inpatients.</u>

(3) "Health care facility pharmacist," a registered pharmacist who is practicing the profession of pharmacy in a licensed health care facility pharmacy;

(4) "Health care facility pharmacy," a place registered with the Board of Pharmacy where drugs are dispensed and pharmaceutical care is provided to the patients;

(5) "Pharmacist permittee," <u>means</u> the pharmacist named on the pharmacy permit <u>license</u> issued by the Board of Pharmacy <u>board</u> as the person who has been delegated complete responsibility for the operation of the health care facility pharmacy.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 32, effective September 14, 1995; 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-11(6)(5).

Law Implemented: SDCL 36-11-11(6)(5).

20:51:17:01.01. Approval for use of automated mechanical distribution device. Drugs may be distributed by an automated mechanical distribution device in a health care facility that has a registered pharmacy. Any pharmacist permittee seeking use of an automated mechanical distribution device in a health care facility shall register with the South Dakota Board of Pharmacy and file a notice of intent to use the device, the name of the manufacturer of the device, and the location in the health care facility. No such device may be used by a pharmacist in a health care facility until approval has been granted by the board <u>Repealed</u>.

Source: 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-11(6).

Law Implemented: SDCL 36-11-11(6).

20:51:17:01.02. Pharmacist shall review first-dose prescription drug order -- Exception. The pharmacist permittee may not allow the first dose of a prescription drug to be distributed may not be removed from an automated mechanical distribution device until the <u>a</u> pharmacist has reviewed the prescriber's orders. However, the medical staff may request in writing a defined number of drugs that may be removed without review by a pharmacist in an emergency situation.

Source: 26 SDR 92, effective January 6, 2000. General Authority: SDCL 36-11-11(6)(5). Law Implemented: SDCL 36-11-11(6)(5).

20:51:17:02. Procedures for distributing <u>or dispensing</u> drugs in automated mechanical distribution <u>and automated prescription dispensing</u> device <u>devices</u>. Drugs may be distributed <u>or</u> <u>dispensed</u> by an automated mechanical distribution device <u>or by an automated prescription</u> <u>dispensing device</u> under the following conditions:

(1) The automated mechanical distribution device is controlled by the pharmacist permittee pharmacist-in-charge. The pharmacist permittee pharmacist-in-charge shall develop policies and procedures to address all situations in which drugs are stocked, secured, removed, and accounted for;

(2) The automated mechanical distribution device shall be stocked with a limited supply of drugs only by a health care facility pharmacist or a person authorized by the pharmacist permittee pharmacist-in-charge. The health care facility pharmacist shall maintain electronic or written stocking, distribution, and dispensing records which contain the following information in the pharmacy for two years:

(a) The name of the person stocking the drug or medicine;

(b) The name, quantity, and strength of the drug or medicine; and

(c) The date of stocking.;

(3) The pharmacist permittee pharmacist-in-charge shall designate the person that persons who may have access to that portion, section, all or part of the automated mechanical distribution device in which the drugs or medicines are stored;

(4) All containers of drugs or medicines to be stored in the device must be correctly labeled.The label shall contain the following information:

- (a) The name of the drug;
- (b) The strength of the drug;
- (c) The lot or control number; and
- (d) The expiration date of the drug;

(5) The health care facility pharmacy shall maintain the electronic or written records for the drugs or medicines distributed from the device in the pharmacy for two years. The records shall contain the following information:

(a) The patient's name and the location within the hospital;

(b) The name of the person withdrawing the drug or medicine;

(c) The name, quantity, and strength of the drug or medicine; and

(d) The date of issue;

(6) When repackaging drug dosage forms from original manufacturers' containers, the new package must assure the stability of each drug and meet the storage and packaging standards on

pages 10, 11, 12, 13, 1786, and 1787 of the United States Pharmacopeia, Twenty-third Revision
- The National Formulary, Eighteenth Edition, January 1, 1995;

(7) When using automated mechanical or electronic devices as pharmaceutical tools, the health care facility pharmacy must arrange to provide pharmaceutical services if the device fails;

(8) The device may be used for the furnishing of drugs and medicines only to registered health care facility patients of the health care facility;

(9)(6) Notwithstanding any of the provisions in this section, the pharmacist permittee pharmacist-in-charge of the health care facility pharmacy is responsible for maintaining and enforcing written procedures that establish safeguards for distributing <u>or dispensing</u> drugs and medicines through the automated mechanical distribution <u>or dispensing</u> device.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 22 SDR 32, effective September 14, 1995; 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-11(6)(5).

Law Implemented: SDCL 36-11-11(6)(5).

Reference: Pages 10, 11, 12, 13, 1786, and 1787, **The United States Pharmacopeia**, **Twenty-third Revision - The National Formulary, Eighteenth Edition**, January 1, 1995, published by the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852. Photocopies of pages 10, 11, 12, 13, 1786, and 1787 may be obtained without charge from the State Board of Pharmacy, 4305 S. Louise Avenue, Suite 104, Sioux Falls, SD 57106. 20:51:17:03 Stand-alone automated prescription dispensing device - license required. A pharmacy that uses an automated prescription dispensing device to store, dispense, or track medications outside of the premises of the pharmacy license, shall apply to the board to license the automated device as a pharmacy.

<u>General Authority:</u> SDCL 36-11-11(<u>5</u>). <u>Law Implemented:</u> SDCL 36-11-11(<u>5</u>).

CHAPTER 20:51:19

CONTINUING EDUCATION

Section

- 20:51:19:01 Continuing professional education defined.
- 20:51:19:02 Active pharmacist defined Repealed.
- 20:51:19:03 Hours required.
- 20:51:19:03.01 Extension of time for good cause.
- 20:51:19:04 Hours defined.
- 20:51:19:05 Pharmacists keep own records.
- 20:51:19:05.01 Audit to verify hours earned.
- 20:51:19:06 Continuing education from other states.

20:51:19:07	Newly licensed registrants pharmacists.	
20:51:19:08	Different ways of obtaining accredited continuing education hours Repealed	
20:51:19:09	Sponsors defined.	
20:51:19:10	Program approval.	
20:51:19:11	Forms required for continuing education sponsors.	
20:51:19:12	Program changes.	
20:51:19:13	Frequency of participation.	
20:51:19:14	Attendance by board or council members.	
20:51:19:15	Sponsors' records.	
20:51:19:16	Sponsor to provide list of pharmacists and technicians attending program.	

20:51:19:01. Continuing professional education defined. As used in this chapter continuing professional education is means accredited, post registration post-license professional educational experience derived from participation in postgraduate studies, institutes, seminars, lectures, conferences, workshops, and such other forms of educational experiences designed to maintain the professional competency of the practice of pharmacy, improve professional skills, and preserve pharmaceutical standards for the purpose of the protection of the health and welfare of the citizens of the state of South Dakota.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-10, 36-11-11(1).

Law Implemented: SDCL 36-11-23.2.

20:51:19:02. Active pharmacist defined. An active pharmacist is a licensed pharmacist practicing pharmacy according to SDCL 36-11-2(1) <u>Repealed</u>.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-10, 36-11-11.

Law Implemented: SDCL 36-11-23.2.

20:51:19:03. Hours required. To qualify for relicensure licensure renewal or reinstatement, an active <u>a</u> pharmacist must successfully complete 12 hours of continuing education. The 12 hours of continuing education required each year for relicensure renewal must be completed within the 24 months before the pharmacist's certificate of registration license expires. When a pharmacist applies for yearly renewal of the pharmacist's certificate of registration license pursuant to SDCL 36-11-23, the pharmacist must report completed continuing education hours on a form supplied by the board have completed the required hours. If the pharmacist has a certification to administer immunizations, the pharmacist must have one hour of continuing education related to immunizations, which is not in addition to the 12 hours.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 16 SDR 98, effective December 3, 1989.

General Authority: SDCL 36-11-10, 36-11-11(1). Law Implemented: SDCL 36-11-23.2, 36-11-23.3. **20:51:19:04. Hours defined.** The hourly value is defined as the measurement of value applied to a particular accredited continuing pharmacy educational activity as assigned by the **Board** of Pharmacy board relative to maintaining the competency of a registrant licensee.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-10, 36-11-11(1).

Law Implemented: SDCL 36-11-23.2.

20:51:19:05. Pharmacists keep own records. Pharmacists are responsible for maintaining their own records of continuing education hours for three years from the program completion date.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 16 SDR 98, effective December 3, 1989.

General Authority: SDCL 36-11-10, 36-11-11(1).

Law Implemented: SDCL 36-11-23.2.

20:51:19:05.01. Audit to verify hours earned. The secretary of the Board of Pharmacy board shall audit five percent of the registered pharmacists at random annually after licensure to verify their continuing education.

Source: 9 SDR 171, effective July 12, 1983; 12 SDR 151, 12 SDR 155, effective July 1, 1986. General Authority: SDCL 36-11-23.2.

Law Implemented: SDCL 36-11-23.2.

20:51:19:06. Continuing education from other states. The Board of Pharmacy board may accept comparable continuing education hours <u>obtained in any state if</u> approved by other state boards of pharmacy. Accredited Council for Pharmacy Education, or the South Dakota Board of Pharmacy.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-10, 36-11-11(1).

Law Implemented: SDCL 36-11-23.2.

20:51:19:07. Newly licensed registrants pharmacists. Continuing education requirements for newly licensed pharmacists shall be calculated at the rate of one hour per month of continuing education credit from the date of registration licensure until relicensure license expiration.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-10, 36-11-11.

Law Implemented: SDCL 36-11-23.2.

20:51:19:08. Different ways of obtaining accredited continuing education hours. Accredited continuing education hours may be compiled in the following ways:

(1) Cassette and audio visual presentation;

(2) In company professional seminars;

(3) Accredited school of pharmacy continuing education programs;

(4) Post graduate courses in pharmaceutical sciences;

(5) Correspondence courses;

(6) Programs granted continuing education credit by other states;

(7) Continuing education television series;

(8) Programs sponsored by professional groups in public health provider services;

(9) Professional society and association sponsored programs;

(10) Study groups <u>Repealed</u>.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1,

1986.

General Authority: SDCL 36-11-10, 36-11-11.

Law Implemented: SDCL 36-11-23.2.

20:51:19:09. Sponsors defined. A sponsor shall be any person, school association, or corporation who wishes to develop a continuing education program.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-10, 36-11-11(1).

Law Implemented: SDCL 36-11-23.2.

20:51:19:10. Program approval. Each continuing education program must have the approval of the Board of Pharmacy <u>board</u>. Sponsors must apply for approval to the board, on forms furnished by the board, at least 30 days before the initiation of the course. The board shall send written notice of its approval or disapproval to sponsors.

The board shall give each approved program an identification number and an hourly value. The board's approval of a program expires at the end of two years.

Each program evaluated must be supported by back-up material, such as a brochure, a critique of material covered, a script, or a, cassette or book for a correspondence course and learning objectives.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 16 SDR 98, effective December 3, 1989.

General Authority: SDCL 36-11-10, 36-11-11(<u>1</u>). **Law Implemented:** SDCL 36-11-23.2.

20:51:19:11. Forms required for continuing education sponsors. The form for approval of continuing education programs may be obtained from the board office. The <u>A form which includes</u>

the following information shall be submitted to the board on the form:

- (1) Name of sponsor and address;
- (2) Name of person in charge;
- (3) Location of program;
- (4) Estimated number of pharmacists and technicians participating;
- (5) General title of program;
- (6) Type <u>of</u> program: Cassette, seminar, post graduate course, correspondence course, CETV program, programs sponsored by public health providers, professional society and association programs, programs granted continuing education credit by other states who reciprocate continuing education hours with South Dakota;

- (7) How program objectives will be met;
- (8) Estimated contact time;
- (9) How attendance or participation will be proven;
- (10) How certificates will be awarded;
- (11) Copy of examination, if utilized.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-10, 36-11-11(1).

Law Implemented: SDCL 36-11-23.2.

20:51:19:12. Program changes. Program changes shall be submitted to the board for approval prior to enactment by a sponsor. The board shall approve or disapprove program changes within 15 days.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 16 SDR 98, effective December 3, 1989.

General Authority: SDCL 36-11-10, 36-11-11(1).

Law Implemented: SDCL 36-11-23.2.

20:51:19:13. Frequency of participation. Continuing education credit will be given only once for a participant's successful completion of a program.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-10, 36-11-11(1).

Law Implemented: SDCL 36-11-23.2.

20:51:19:14. Attendance by board or council members. Any member of the South Dakota Board of Pharmacy or advisory council on continuing education board shall have the right to attend and supervise any continuing education program.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-10, 36-11-11(<u>1</u>).

Law Implemented: SDCL 36-11-23.2.

20:51:19:15. Sponsors' records. Sponsors shall retain a file of participants' program completion for four years.

Source: 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-10, 36-11-11(1).

Law Implemented: SDCL 36-11-23.2.

20:51:19:16. Sponsor to provide list of pharmacists <u>and technicians</u> attending program. The sponsor of a continuing education program shall provide to the <u>Board of Pharmacy board</u> a written <u>or electronic</u> list of the pharmacists <u>and technicians</u> attending within 45 <u>30</u> days after completion of the program or a licensed pharmacist may not use the hours or credits earned to qualify for continuing professional education.

Source: 9 SDR 171, effective July 12, 1983; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-23.2, <u>36-11-13</u>.

Law Implemented: SDCL 36-11-23.2, <u>36-11-13</u>.

CHAPTER 20:51:20

COMPUTER PHARMACY

Section

- 20:51:20:01 Input of drug information into <u>electronic data processing prescription software</u> <u>platform</u> to be by pharmacist or under supervision of pharmacist.
- 20:51:20:02 Requirements for storing prescription information.
- 20:51:20:03 Original prescription to be retained.
- 20:51:20:04 Use of common electronic data base shared prescription software platform.

20:51:20:01. Input of drug information into an electronic data processing prescription software platform to be by pharmacist or under supervision of pharmacist. When electronic data processing equipment a prescription software platform is employed by any pharmacy, input of drug prescription information shall be performed only by a pharmacist, under the immediate and personal supervision of a pharmacist technician, or intern. The pharmacist must certify the accuracy of the information to be entered and verify the prescription order at the time of entry. The identity of the pharmacist must be carried included in the record. Source: 5 SDR 77, effective March 20, 1979; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(12).

Law Implemented: SDCL 36-11-11(12).

20:51:20:02. Requirements for storing prescription information. Electronic data processing equipment <u>A prescription software platform</u>, when used to store prescription information, shall meet the following requirements:

(1) Guarantee the confidentiality of the information contained in the data bank platform;

(2) Be capable of producing a hard-copy daily summary of controlled substance transactions;

(3) Provide on-line retrieval of original prescription order information for those prescription orders which are currently authorized for refilling;

(4) Be capable of recording and carrying in the record all dates of refills of any prescription and the initials of the pharmacist. This shall meet the requirements of 20:51:05:0620;

(5) Be capable of producing a patient profile indicating all drugs being taken and the date of refills of these prescriptions; and

(6) Be capable of being reconstructed in the event of a computer malfunction or accident resulting in destruction of the data bank platform.

Source: 5 SDR 77, effective March 20, 1979; 12 SDR 151, 12 SDR 155, effective July 1, 1986.

General Authority: SDCL 36-11-11(12).

Law Implemented: SDCL 36-11-11(12).

20:51:20:03. Original prescription to be retained. The original prescription order shall be retained manually or electronically according to law. <u>To keep original prescriptions in electronic</u> format, the platform must be capable of producing a copy of the original prescription that was entered into the platform via scan or electronic record.

Source: 5 SDR 77, effective March 20, 1979; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 40 SDR 40, effective September 16, 2013.

General Authority: SDCL 36-11-11(12).

Law Implemented: SDCL 36-11-11(12).

20:51:20:04. Use of common electronic data base shared prescription software platform. Upon approval of the Board of Pharmacy, two Two or more affiliated pharmacies licensed by the board may utilize a common electronic data base shared prescription software platform to practice pharmacy as provided by SDCL 36-11-2.2. Prescriptions may be refilled at any of these pharmacies as long as each pharmacy is identified by a unique code that documents the location of each filling and provisions are made to assure that the number of authorized refills is not exceeded. Application for approval must be made on a form supplied by the Board of Pharmacy. A nonresident pharmacy not licensed by the board and sharing a common electronic data base prescription software platform with a pharmacy licensed by the board may not practice pharmacy in this state, but may refill a prescription if requested by the patient as long as the number of authorized refills is not exceeded Information must be verified and communicated orally between two licensed pharmacists at the time of refilling.

Licensed South Dakota pharmacies with a common electronic data base shared prescription software platform are exempt from chapter 20:51:23 if the requirements of this section are met.

Source: 16 SDR 98, effective December 3, 1989; 26 SDR 92, effective January 6, 2000. General Authority: SDCL 36-11-11(13)(12), 36-11-19.2. Law Implemented: SDCL 36-11-11(13)(12), 36-11-19.2.

CHAPTER 20:51:21

UNIT DOSE SYSTEMS

Section

- 20:51:21:01 Definitions.
- 20:51:21:01.01 Prepackaging and repackaging.
- 20:51:21:02 Transferred.
- 20:51:21:03 Pharmacist to interpret original order of practitioner <u>Repealed</u>.
- 20:51:21:04 Repealed.
- 20:51:21:05 Labeling of unit dose package -- Relabeling of unit dose system.

20:51:21:05.01 Recall of medication in unit dose package distribution system.

- 20:51:21:05.02 Manufacturer packaging.
- 20:51:21:06 Pharmacist to maintain drug profile.
- 20:51:21:07 Pharmacist to be responsible for delivery of medications to healthcare facility.

20:51:21:01. Definitions. Terms As used in this chapter mean:

(1) "Automated mechanical distribution device," <u>means the same as defined in</u> § 20:51:17:01 for definition and use;

(2) "Container," <u>means</u> that which holds the drug and is or may be in direct contact with the drug without interacting chemically or physically affecting the drug placed in it so as to alter the strength, quality, or purity of the drug beyond the official compendium requirements;

(3) "Customized patient medication package," <u>means</u> a package that contains two or more drugs per compartment;

(4) "Prepackage," <u>means</u> to prepare a drug in a container for dispensing, prior to the receipt of an order. Such packaging may be in a unit dose, single dose, or unit of issue package for use in a unit dose dispensing system, in a container suitable for a traditional dispensing system, or in a customized patient medication package; (5) "Repackage," <u>means</u> to prepare a unit dose, single dose, unit of issue package, customized patient medication package, or traditional dispensing system package for dispensing pursuant to an existing order;

(6) "Sealed unit dose container," <u>means</u> a container that holds the drug in a hermetically sealed compartment to reduce the drug's exposure to moisture, air, and tampering until the time of administration;

(7) "Traditional dispensing system," <u>means</u> a drug package system in which individual doses are not packaged in unit dose packages or unit of issue packages;

(8) "Unit dose," <u>means</u> a single dose of a drug in an individually sealed, labeled container ready for administration to a particular patient by the prescribed route at the prescribed time;

(9) "Unit dose distribution system," <u>means</u> a drug distribution system that is in a pharmacy outlet, hospital, or other healthcare facility and uses unit dose packages, or unit of issue packages, labeled in accordance with § 20:51:21:05 and preserves the identity of the drug until the time of administration;

(10) "Unit dose package," <u>means</u> an individual package that contains one single unit dose of a drug packaged by a manufacturer or a pharmacy and preserves the integrity and identity of the drug from the point of packaging to the point of administration; and

(11) "Unit of issue package," <u>means</u> a package that provides multiple units of the same drug doses, each separated in a medication card or other specifically designed container.

Source: 8 SDR 5, effective July 26, 1981; 12 SDR 151, 12 SDR 155, effective July 1, 1986; definition of "unit dose packaging" transferred from § 20:51:21:02, 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 34-12B-2, 36-11-11(1).

20:51:21:01.01. Prepackaging and repackaging. In a pharmacy prepackaging and repackaging may only be done by a pharmacist, an intern, or a support person technician with under direct supervision of a pharmacist. Such packaged drugs may only be dispensed or distributed from the premises where the medications are prepackaged or repackaged. Such drugs may only be distributed to a location which is under the same ownership as, or is affiliated with the premises where medications are prepackaged or repackaged. Any container used for prepackaging or repackaging must meet United States Pharmacopeia compendium requirements. Medication packaging must meet requirements of § 20:51:13:02.01 if medications are returned for credit or redispensing.

Source: 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 34-12B-2, 36-11-11(1).

20:51:21:03. Pharmacist to interpret original order of practitioner. A pharmacist in the pharmacy shall interpret the original order of a practitioner for a specific patient <u>Repealed</u>.

Source: 8 SDR 5, effective July 26, 1981; 12 SDR 151, 12 SDR 155, effective July 1, 1986;

18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 34-12B-2, 36-11-11(1).

20:51:21:05. Labeling of unit dose <u>and unit of issue</u> package -- Relabeling of unit dose <u>and unit of issue</u> system. Unit dose <u>and unit of issue</u> packages shall be labeled with the name of the drug and its strength. Labeling of the package with the drug lot number or expiration date is optional <u>according to § 20:51:13:02.01 (5)</u>.

After any change in dosage or administration schedule, the pharmacy shall relabel the unit dose <u>of issue system package</u> no later than the next medication exchange.

Source: 8 SDR 5, effective July 26, 1981; 9 SDR 14, effective August 8, 1982; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 34-12B-2, 36-11-11(1).

20:51:21:05.01. Recall of <u>medication in</u> unit dose <u>package</u> <u>distribution system</u>. If a specific drug is recalled, all doses labeled with the lot number of the recalled drug shall be removed from the unit dose <u>distribution</u> system. In addition, all doses of that drug not labeled with a lot number shall be removed from the unit dose <u>distribution</u> system.

Source: 9 SDR 14, effective August 8, 1982; 12 SDR 151, 12 SDR 155, effective July 1,

1986; 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 34-12B-2, 36-11-11(1).

20:51:21:06. Pharmacist to maintain drug profile. A pharmacist shall maintain a drug profile for each patient whose drugs are delivered in a unit dose <u>or unit of issue</u> system.

Source: 8 SDR 5, effective July 26, 1981; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 34-12B-2, 36-11-11(1).

20:51:21:07. Pharmacist to be responsible for delivery of medications to healthcare facility. A pharmacist is responsible for the delivery of medications packaged in a unit dose <u>or unit</u> <u>of issue</u> system to a healthcare facility before the time of administration to the patient.

Source: 8 SDR 5, effective July 26, 1981; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 34-12B-2, 36-11-11(1).

CHAPTER 20:51:22

SUPPORT PERSONNEL

Section

20:51:22:00	Repealed.
20:51:22:01	Repealed.
20:51:22:02	Repealed.
20:51:22:03	Repealed.
20:51:22:04	Repealed.
20:51:22:05	Support personnel.
20:51:22:06	Identification of pharmacy support per
20:51:22:07	Requirements to work in a pharmacy.

20:51:22:05. Support personnel. Support personnel are those persons other than a licensed pharmacist, a registered pharmacy intern, or a registered pharmacy technician, who may perform nontechnical duties assigned by the pharmacist under the pharmacist's supervision including the delivery, billing, cashier, <u>custodial, maintenance</u>, and clerical functions. Support personnel are expected to perform their duties outside the dispensing area of the pharmacy.

personnel

Appropriately trained pharmacy support personnel may perform the following nontechnical functions involving the handling of prescription medication, that have been delegated to the pharmacy support personnel by the supervising pharmacist:

 Perform the duties of a pharmacy clerk, including placing a prescription container into a bag or sack for delivery to the patient as part of the sales transaction after the accuracy of the prescription has been verified by the pharmacist;

- (2) <u>Open drug shipment and affix appropriate inventory or price stickers to drug stock bottles</u> or containers;
- (3) <u>Perform administrative duties, such as answering telephones, filing processed, hard-copy</u> prescriptions and other pharmacy records;
- (4) <u>Receive a patient's request for a prescription refill, excluding the processing of the refill</u> request.; and
- (5) Deliver drugs to patient care areas, long-term care facilities, patient residences, or patient employment locations, excluding the restocking of automated medication distribution system components.

Source: 31 SDR 35, effective September 19, 2004.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:22:06. Identification of pharmacy support personnel. A pharmacy support person shall wear a visible identification badge while on duty that clearly identifies the person as a pharmacy support person and includes the person's first name.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:22:07. Requirements to work in a pharmacy. Any person working in the pharmacy area must be at least 16 years of age or older and must be Health Information Privacy and Portability Act (HIPPA) trained.

Source:

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

CHAPTER 20:51:23

TRANSFER OF PRESCRIPTION INFORMATION

Section

- 20:51:23:01 Transfer of original prescription information permitted.
- 20:51:23:02 Requirements of transferring pharmacist <u>or intern</u>.
- 20:51:23:03 Requirements of receiving pharmacist <u>or intern</u>.
- 20:51:23:04 Additional requirements for controlled substances.
- 20:51:23:05 Pharmacies with electronic data processing equipment prescription software platforms.
- 20:51:23:06 Exemption for pharmacies using common electronic data base shared prescription software.
- 20:51:23:07 Prescription orders for patients discharged from hospitals <u>Repealed</u>.

20:51:23:01. Transfer of original prescription information permitted. For the purpose of dispensing refills of prescriptions, a pharmacy may transfer prescription information to another pharmacy, subject to the following requirements:

(1) The transfer is limited to the number of refills total quantity authorized on the original prescription;

(2) The transfer is communicated directly between two licensed pharmacists or registered interns; and

(3) Both the original and the transferred prescriptions are kept for two years from the date of the last refill.

Source: 17 SDR 170, effective May 16, 1991.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:23:02. Requirements of transferring pharmacist <u>or intern</u>. The pharmacist <u>or intern</u> transferring the prescription information shall:

(1) Record on the original prescription the following information:

- (a) The name and address of the pharmacy to which the prescription is transferred;
- (b) The name of the pharmacist <u>or intern</u> receiving the prescription information;
- (c) The name of the pharmacist <u>or intern</u> transferring the prescription information; and
- (d) The date of the transfer.

(2) Record the number of refills transferred. If all refills are transferred, the original prescription shall be marked "void".

Source: 17 SDR 170, effective May 16, 1991.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:23:03. Requirements of receiving pharmacist <u>or intern</u>. The pharmacist <u>or intern</u> receiving the transferred prescription information shall:

(1) Write the word "transfer" on the face of the transferred prescription; and

(2) Record on the transferred prescription the following information:

(a) The original date of issuance and the date of dispensing, if different from date of issuance;

(b) The original prescription number and the number of refills authorized on the original prescription;

(c) The number of valid refills remaining and the date of the last refill;

(d) The name and address of the pharmacy from which the prescription information is transferred; and

(e) The name of <u>both</u> the <u>transferring and receiving</u> pharmacist <u>or intern</u> transferring the <u>prescription information</u>.

Source: 17 SDR 170, effective May 16, 1991.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1).

20:51:23:04. Additional requirements for controlled substances. The following additional requirements apply to the transfer of controlled substances listed in SDCL 34-20B-18 to 34-20B-26, inclusive:

(1) The transfer of original prescription drug order information is permissible between pharmacies once, after which the original prescription is void;

(2) The transferring pharmacist shall write the word "void" on the face of the invalidated prescription drug order and record on the prescription the drug enforcement administration (DEA) registration number of the pharmacy to which the prescription is transferred; and

(3) The receiving pharmacist shall record the DEA registration number of the pharmacy from which the prescription was transferred.

Source: 17 SDR 170, effective May 16, 1991. General Authority: SDCL 36-11-11(1). Law Implemented: SDCL 36-11-11(1).

20:51:23:05. Pharmacies with electronic data processing equipment prescription software platforms. Pharmacies with electronic data processing equipment prescription software platform need not record information on the original prescription if the data processing system prescription software platform has the capacity to store all of the information required in §§ 20:51:23:02 to 20:51:23:04, inclusive, and the data processing system prescription software platform has a mechanism to prohibit the transfer or refilling of prescription drug orders for controlled substances which have been previously transferred.

Source: 17 SDR 170, effective May 16, 1991. General Authority: SDCL 36-11-11(1)(12). Law Implemented: SDCL 36-11-11(1)(12).

20:51:23:06. Exemption for pharmacies using common data processing system shared prescription software. Pharmacies electronically accessing the same prescription records on a common electronic data base shared prescription software are exempt from this chapter if the requirements of § 20:51:20:04 are met.

Source: 17 SDR 170, effective May 16, 1991. General Authority: SDCL 36-11-11(1)(12). Law Implemented: SDCL 36-11-11(1)(12).

20:51:23:07. Prescription orders for patients discharged from hospitals. If a patient is discharged from a hospital with an initial quantity of medication dispensed by the hospital pharmacy and the patient is authorized to receive additional quantities of medication, the hospital pharmacy may provide the original prescription to the patient under the following conditions:

(1) The hospital pharmacy retains a copy of the original prescription marked on the face "Original provided to patient — No refills authorized";

(2) The original prescription provided to the patient has marked on its face "initial quantity supplied by hospital" and has on its reverse the following information:

(a) The name and address of the hospital pharmacy;

- (b) The hospital prescription number;
- (c) The quantity dispensed;

(d) The date of dispensing; and

(e) The name of the pharmacist dispensing the medication Repealed.

Source: 17 SDR 170, effective May 16, 1991.

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

CHAPTER 20:51:24

PATIENT RECORD SYSTEM

Section

- 20:51:24:01 Transitory patient defined <u>Repealed</u>.
- 20:51:24:02 Patient record system.
- 20:51:24:03 Reasonable effort to obtain information.
- 20:51:24:04 Maintenance of records.

20:51:24:01. Transitory patient defined. A transitory patient is a patient that the pharmacist

determines will have prescription drug orders filled at the pharmacy on a one-time basis or no more

than once each year. If a pharmacist determines from information provided by a patient or caregiver that the patient is a transitory patient, the pharmacist may forego the requirement to record and maintain information <u>Repealed</u>.

Source: 19 SDR 93, effective December 31, 1992.

General Authority: SDCL 36-11-68.

Law Implemented: SDCL 36-11-68.

20:51:24:02. Patient record system. A pharmacy shall maintain a patient record system for patients for whom it dispenses prescription drug orders. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs or drug devices at the time a prescription drug order is presented for dispensing. The record shall include as much of the following information as the pharmacy is able to obtain:

- (1) The full <u>legal</u> name of the patient for whom the drug or drug device is intended;
- (2) The address and telephone number of the patient;
- (3) The patient's age or date of birth;
- (4) The patient's gender;

(5) A list of all prescription drugs or drug devices obtained by the patient at the pharmacy maintaining the patient record during the one-year period immediately preceding the most recent

entry, showing the prescription number, name and strength of the drug or drug device, the quantity and date received, and the name of the practitioner;

(6) Any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient;

(7) The identity of any other drugs, including over-the-counter drugs, or drug devices currently being used by the patient which may relate to prospective drug review; and

(8) Comments of the pharmacist relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug-; and

(9) If the patient is an animal, the profile must include the species and owner's name.

Source: 19 SDR 93, effective December 31, 1992. General Authority: SDCL 36-11-68. Law Implemented: SDCL 36-11-68.

20:51:24:04. Maintenance of records. A pharmacy shall maintain information in a patient record system for at least <u>one year</u> <u>two years</u> from the date of the last entry in the record. The information must be readily retrievable and may be maintained in an electronic data system or as a paper copy.

Source: 19 SDR 93, effective December 31, 1992.

General Authority: SDCL 36-11-68.

Law Implemented: SDCL 36-11-68.

CHAPTER 20:51:25

PATIENT COUNSELING

Section

- 20:51:25:01 Definitions.
- 20:51:25:02 Review of patient's record.
- 20:51:25:03 Elements of <u>patient</u> counseling.
- 20:51:25:04 Standards for counseling.
- 20:51:25:05 Alternative forms of patient information.
- 20:51:25:06 Record of counseling.

20:51:25:01. Definitions. Terms As used in this chapter mean:

(1) "Adverse medical result <u>drug reaction</u>," <u>means</u> a clinically significant undesirable effect experienced by a patient as a result of a course of drug therapy;

(2) "Caregiver," means a person who provides care for a friend, family member, or patient.

Source: 19 SDR 93, effective December 31, 1992.

General Authority: SDCL 36-11-68.

Law Implemented: SDCL 36-11-68.

20:51:25:02. Review of patient's record. A pharmacist shall review the patient's record at the time a prescription drug order or prescription refill request is presented for dispensing for the purpose of identifying any of the following conditions:

(1) Overutilization, use of a drug in quantities or for durations that put the patient at risk of an adverse medical result drug reaction;

(2) Underutilization, use of a drug by a patient in an insufficient quantity to achieve a desired therapeutic goal;

(3) Therapeutic duplication, use of two or more drugs from the same therapeutic class in such a way that the combined daily dose puts the patient at risk of an adverse medical result drug reaction;

(4) Drug-disease contraindications, the potential for or the occurrence of an undesirable alteration of the therapeutic effect of a given drug because of the presence of a disease condition in the patient or an adverse effect of the drug on the patient's disease condition;

(5) Adverse drug-drug interactions, the potential for or the occurrence of an adverse medical effect <u>drug reaction</u> as a result of the patient using two or more drugs together;

(6) Incorrect drug dosage, the dosage lies outside the daily dosage range specified predetermined standards listed in 42 C.F.R. § 456.703(f)(1), published in 57 Fed. Reg. 49,408 (November 2, 1992) as necessary to achieve therapeutic benefit. Dosage range is the strength multiplied by the quantity dispensed divided by days supply in the manufacturer's package insert for the drug;

(7) Incorrect duration of drug treatment, the number of days of prescribed therapy exceeds or falls short of the recommendations contained in predetermined standards listed in 42 C.F.R. § 456.703(f)(1), published in 57 Fed. Reg. 49,408 (November 2, 1992) the manufacturer's package insert for the drug;

(8) Drug-allergy interactions, the significant potential for or the occurrence of an allergic reaction as a result of drug therapy; or

(9) Clinical abuse or misuse.

The pharmacist shall attempt to avoid or resolve any problems identified during the review and may, if necessary, consult with the practitioner.

Source: 19 SDR 93, effective December 31, 1992. General Authority: SDCL 36-11-68. Law Implemented: SDCL 36-11-68.

20:51:25:03. Elements of <u>patient</u> counseling. Patient counseling must occur after review of the patient's record required in § 20:51:25:01. The counseling may include any of the following elements of patient counseling, as applicable:

- (1) The name and description of the drug;
- (2) The dosage form, dose, route of administration, and duration of drug therapy;
- (3) The intended use of the drug and its expected action;
- (4) Special directions and precautions for preparation, administration, and use by the patient;
- (5) Common severe side or adverse effects or interactions and therapeutic contraindications

that may be encountered, including their avoidance, and the action required if they occur;

- (6) Techniques for self-monitoring drug therapy;
- (7) Storage requirements;
- (8) Prescription refill information;
- (9) Action to be taken if a dose is missed; and
- (10) The pharmacist's comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

Source: 19 SDR 93, effective December 31, 1992.

General Authority: SDCL 36-11-68.

Law Implemented: SDCL 36-11-68.

CHAPTER 20:51:26

STERILE PRODUCTS FOR HOME CARE PATIENTS

(Repealed. 36 SDR 100, effective December 14, 2009)

CHAPTER 20:51:27 106

NONRESIDENT PHARMACY REGISTRATION LICENSURE

Section

20:51:27:01	Definitions.

- 20:51:27:02 Application form.
- 20:51:27:03 Application fee.
- 20:51:27:04 Report of change in ownership or location.

20:51:27:01. Definitions. In addition to terms defined by SDCL 36-11-2, terms as used in this chapter mean:

(1) "Home state," <u>means</u> the state in which the dispensing facilities of a nonresident pharmacy are located.

Source: 24 SDR 40, effective October 5, 1997.

General Authority: SDCL 36-11-11(4)(3).

Law Implemented: SDCL 36-11-19.3.

20:51:27:02. Application form. The application form for licensure of a nonresident pharmacy shall include the following information in addition to that required by SDCL 36-11-19.3:

(1) Evidence of licensure in good standing in the nonresident pharmacy's home state;

(2) A description of any disciplinary action against the nonresident pharmacy, the nonresident pharmacy, the nonresident pharmacy owner, or the pharmacist-in-charge in the home state or any other state within the last three four years and the resolution of any such action; and

(3) If the pharmacist in charge is not the sole owner or part owner of the merchandise and fixtures of the nonresident pharmacy, an affidavit as described in SDCL 36-11-34.

(4) A list of all others states currently licensed in; and

(5) A description of pharmacy services provided to patients located in the state of South Dakota.

Source: 24 SDR 40, effective October 5, 1997. General Authority: SDCL 36-11-11(4)(3), 36-11-19.3. Law Implemented: SDCL 36-11-19.3.

20:51:27:03. Application fee. The fee to accompany the initial application and each application for renewal is \$200.

Source: 24 SDR 40, effective October 5, 1997; 24 SDR 160, effective May 26, 1998.

General Authority: SDCL 36-11-11(4)(3), 36-11-19.3.

Law Implemented: SDCL 36-11-19.3, 36-11-19.5.

20:51:27:04. Report of change in ownership or location. 20:51:27:04. Report of change in ownership or location. The pharmacist in charge owner of a nonresident pharmacy or persons delegated by the owner of a nonresident pharmacy shall report any of the following changes to the board within the indicated timeframe. in the location of the nonresident pharmacy, any change in the ownership of the merchandise and fixtures of a nonresident pharmacy, or the cessation of business as a nonresident pharmacy to the secretary of the Board of Pharmacy within ten days after

the occurrence.

- (1) Change in pharmacist-in-charge within 10 days;
- (2) <u>Ownership change within 30 days post transaction.</u> The license of a nonresident pharmacy is not transferable to a new ownership. Any new <u>majority</u> ownership <u>change</u> of a nonresident pharmacy must apply for licensure pursuant to § 20:51:27:02;
- (3) <u>Change in location within 30 days post transaction. If location change is to a different state,</u> <u>a new application is required pursuant to § 20:51:27:02;</u>
- (4) <u>Cessation of business as a nonresident pharmacy at least 10 days prior to closure.</u>

Source: 24 SDR 40, effective October 5, 1997.

General Authority: 36-11-11(4)(3).

Law Implemented: 36-11-19.3.

CHAPTER 20:51:28

ADMINISTRATION OF INFLUENZA IMMUNIZATIONS

Section

20:51:28:01 Authority to administer influenza immunizations.

20:51:28:01.01. Authority to administer immunizations.

20:51:28:02 Qualifications for authorization to administer influenza immunizations.

20:51:28:02.01. Qualifications for authorization to administer immunizations for interns.

- 20:51:28:03 Standards for approval of influenza immunization training programs Repealed.
- 20:51:28:04 Training program requirements.
- 20:51:28:05 Record keeping and reporting requirements.
- 20:51:28:06 Confidentiality of records maintained.
- 20:51:28:07 Renewal of authorization to administer influenza immunizations.

20:51:28:01. Authority to administer influenza immunizations. A pharmacist may administer influenza immunizations to eligible patients <u>eighteen 18</u> years of age and older if the pharmacist has met the qualifications set forth by this chapter and has been granted authorization by the board. The board may issue a certificate authorizing this function to the pharmacist who meets the qualifications established in § 20:51:28:02. The authority to administer influenza immunizations is valid only for the pharmacist meeting this requirement and may not be delegated to any other pharmacist or employee.

Source: 29 SDR 37, effective September 26, 2002. General Authority: SDCL 36-11-11(1), 36-11-19.1. Law Implemented: SDCL 36-11-19.1. 20:51:28:01.01. Authority to administer immunizations. A pharmacist may administer immunizations by prescription drug order signed by a practitioner or by protocol signed by a physician if the pharmacist meets the criteria in § 20:51:28:02 and has been granted authorization by the board.

Source:

General Authority: SDCL 36-11-11(1), 36-11-19.1.

Law Implemented: SDCL 36-11-19.1.

20:51:28:02. Qualifications for authorization to administer influenza immunizations. The board may issue a certificate authorizing the administration of influenza immunizations an authorization to a pharmacist that meets the following qualifications:

- (1) Active licensure to practice pharmacy in this state;
- (2) Successful completion of an approved training program as outlined in this chapter; and
- (3) Active certification in basic cardiopulmonary resuscitation.

Source: 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11(1), 36-11-19.1.

Law Implemented: SDCL 36-11-19.1.

20:51:28:02.01. Qualifications for interns to administer immunizations. A pharmacy intern may administer immunizations in a pharmacy if the following criteria are met:

- (1) Active registration as a pharmacy intern in this state;
- (2)Successful completion of an approved training program;
- (3) Active certification in basic cardiopulmonary resuscitation; and
- (4)<u>Under the direct supervision of a pharmacist who has a current authorization to</u> administer immunizations in this state.

Source:

General Authority: SDCL 36-11-11(1), 36-11-19.1, 36-11-25 Law Implemented: SDCL 36-11-19.1, 36-11-25

20:51:28:03. Standards for approval of influenza immunization training programs. An institution desiring to offer a training program for administration of influenza immunizations must submit an application for approval to the board. The board may grant approval to an applicant training program upon proof that the training program meets the following requirements:

(1) The training program is based on the course requirements outlined in § 20:51:28:04;

(2) The training program is offered in an institution accredited by the American Council on Pharmaceutical Education;

(3) A completion certificate is awarded to a pharmacist who has successfully completed the training program. The certificate must include the name and location of the institution, the date of completion, the full name of the person who completed the program, the signature of the faculty member in charge of the course, and the date the certificate was awarded; and

(4) Records are maintained which include documentation of the following:

(a) Each person enrolled in the program, including documentation of performance and the date the person failed or completed the program;

(b) Each faculty member teaching the program, including qualifications;

(c) The course of study; and

(d) A list of graduates of the program who were awarded certificates and the date of the awards.

The applicant must submit an evaluation of the program standards for compliance with this section to the board every two years in order to maintain ongoing approval <u>Repealed</u>.

Source: 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11, 36-11-19.1.

Law Implemented: SDCL 36-11-19.1.

20:51:28:04. Training program requirements. The training program for administration of influenza immunizations must include the following course of study:

(1) Basic immunology and the human immune response;

(2) Mechanics of immunity, adverse effects, dose, and administration schedule of available vaccines;

(3) Response to an emergency situation as a result of the administration of an immunization;

(4) Administration of intramuscular-injections; and

(5) Record keeping and reporting requirements as set forth by § 20:51:28:05.

Any training program must be accredited by the Accreditation Council on Pharmaceutical Education and must provide a completion certificate to a pharmacist or intern who has successfully completed the training program.

Source: 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11(1), 36-11-19.1.

Law Implemented: SDCL 36-11-19.1.

20:51:28:05. Record keeping and reporting requirements. A pharmacist granted authorization under this chapter to administer influenza-immunizations shall maintain the following documentation in the pharmacy regarding each immunization administered for a minimum of five years:

(1) The name, address, and date of birth of the patient;

(2) The date of administration and site of injections injection;

(3) The name, dose, manufacturer's lot number, and expiration date of the vaccine;

(4) The name and address of the patient's primary health care practitioner, as identified by the patient;

(5) The name of the pharmacist person administering the immunization;

(6) The date that the written report was sent to the patient's primary health care provider;

(7) Consultation or other professional information provided to the patient; and

(8)(7) The name <u>and date</u> of the vaccine information sheet provided to the patient.

The pharmacist pharmacy must provide a written report all administrations of immunizations to the patient's primary health care provider of the above information South Dakota Immunization Information System (SDIIS) within 14 days of the immunization. The required records as set forth in this section are open to inspection by the board and must be made available upon the board's request.

Source: 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11(1), 36-11-19.1.

Law Implemented: SDCL 36-11-19.1.

20:51:28:06. Confidentiality of records maintained. The required records identified in § 20:51:28:05 that include specific patient information are confidential records. Nothing in this section affects the requirements of SDCL 36-11-69 relating to the release of confidential patient information.

Source: 29 SDR 37, effective September 26, 2002. General Authority: SDCL 36-11-11(1), 36-11-19.1. Law Implemented: SDCL 36-11-19.1, 36-11-69.

20:51:28:07. Renewal of authorization to administer influenza immunizations. The authorization to administer influenza immunizations must be renewed biennially annually by September 30. Any pharmacists desiring to renew the authorization shall provide attest to the following documentation to the board:

(1) Current certification in basic cardiopulmonary resuscitation; and

(2) Certificate of completion of a minimum of two hours <u>one hour</u> of continuing education related to immunizations.

The board may audit for compliance with the above renewal requirements.

Source: 29 SDR 37, effective September 26, 2002.

General Authority: SDCL 36-11-11(1), 36-11-19.1.

Law Implemented: SDCL 36-11-19.1.

CHAPTER 20:51:29

REGISTERED PHARMACY TECHNICIANS

Section	
20:51:29:00	Definitions.
20:51:29:01	Purpose of registration.
20:51:29:02	Registration required.
20:51:29:03	Original application.
20:51:29:04	College or vocational based training program.
20:51:29:05	Exemptions from registration.
20:51:29:06	Certification of pharmacy technicians.
20:51:29:07	Registration application form.

20:51:29:08 Declaration of current impairment or limitations.

20:51:29:09 Felony or misdemeanor crimes.

- 20:51:29:10 Sworn signature.
- 20:51:29:11 Registration renewal.
- 20:51:29:12 Registration fee.
- 20:51:29:13 Timeliness of initial application or renewal application.
- 20:51:29:14 Registration certification.
- 20:51:29:15 Notification to the board.
- 20:51:29:16 Training and utilization of pharmacy technicians.
- 20:51:29:17 Identification of pharmacy technicians.
- 20:51:29:18 Misrepresentation prohibited.
- 20:51:29:19 Ratio.
- 20:51:29:19.01 Repealed.
- 20:51:29:19.02 Exception to ratio for hospital, mail order, and long-term care pharmacy.
- 20:51:29:20 Delegation and supervision of technical functions.
- 20:51:29:21 Technical functions.
- 20:51:29:22 Tasks a pharmacy technician may not perform.
- 20:51:29:23 Misrepresentative deeds.
- 20:51:29:24 Confidentiality.
- 20:51:29:25 Illegal/unethical behavior.
- 20:51:29:26 Denial of registration.
- 20:51:29:27 Sanctions.

20:51:29:00. Definitions. Terms defined in SDCL 36-11-2 have the same meaning in this

chapter. In addition, as used in this chapter:

- (1) "Board" or "board of pharmacy," as defined in SDCL 36-11-2(2);
- (2) "Pharmacist," as defined in SDCL 36-11-2(18);
- (3) "Pharmacist intern," as defined in § 20:51:02:01;

(4) "Registered pharmacy technician," as defined in SDCL 36 11-2(22A);

(5)(2) "Pharmacy technician-in-training Technician-in-training," means an individual who is registered with the board to receive on-the-job training in a licensed pharmacy for in preparation for registration certification as a pharmacy technician. <u>A technician-in-training must become a certified</u> technician within two years of registration with the board.

(3) "Certified technician," means an individual defined in SDCL 36-11-2(22A) who has gained certification through training and examination pursuant to § 20:51:29:06.

(4) "Grandfathered technician," means an individual not requiring certification, who worked as a technician prior to July 1, 2014, and who has been continuously employed by a pharmacy without disruption.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:01. Purpose of registration. A registration program for <u>all</u> pharmacy technicians and pharmacy technicians in training is established for the primary purpose of assuring the competency of registered pharmacy technicians and for purposes of identification, tracking, and disciplinary actions.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:02. Registration required. Any person employed in South Dakota as a pharmacy technician or pharmacy technician-in-training shall obtain and maintain during such employment a current registration as a pharmacy technician or pharmacy technician-in-training pursuant to this chapter. Any person accepting employment as a pharmacy technician or pharmacy technician in-training in South Dakota who fails to register as a pharmacy technician or pharmacy technician-in-training as provided by rule may be subject to disciplinary sanction as provided by rule § 20:51:29:27.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:03. Original application. Any person initially applying for a certificate of registration as a pharmacy technician or pharmacy technician-in-training shall submit an application to the board within 30 days of accepting employment in a South Dakota pharmacy as a pharmacy technician or pharmacy technician-in-training.

Effective July 1, 2014, the board shall not issue an initial pharmacy technician registration or pharmacy technician-in-training registration to any individual who does not present the board with evidence of high school graduation or possession of a general educational development certificate equivalent. An individual who was registered by the board prior to July 1, 2011, may renew the individual's registration provided that all other requirements for renewal are met and provided that the individual maintains a pharmacy technician registration or national certification on an

uninterrupted basis. Any individual whose registration or national certification lapses for a period of one year must meet the registration requirements in effect at the time the individual applies for reinstatement of registration.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:04. College or vocational based training program. Any person who is enrolled in a college or vocational-based technician training program is required to obtain a pharmacy technician-in-training registration prior to beginning on-site practical experience. The length of technician-in-training program may not exceed a period of more than two years.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:05. Exemptions from registration. A registered pharmacy intern whose South Dakota registration is in good standing and who assists in the technician function of the practice of pharmacy is not required to register as a pharmacy technician.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13). **20:51:29:06.** Certification of pharmacy technicians. The national certification of pharmacy technicians is required. Effective July 1, 2014, the board shall not renew the registration of a pharmacy technician who was initially registered after July 1, 2011, unless the pharmacy technician is nationally certified and has passed a board-approved pharmacy technician certification examination that is accredited by the National Commission for Certifying Agencies (NCCA).

Pharmacy technician national certification does not supplant the need for a licensed pharmacist to exercise control over the performance of a delegated function nor does national certification exempt the pharmacy technician from registration pursuant to this chapter.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:07. Registration application form. The application form for registration as a pharmacy technician shall include the following:

 Information sufficient to identify the applicant including name, address, phone number, date of birth, gender, and social security number, and email address;

(2) Work experience; and

(3) Current and past places of employment.

Source: 31 SDR 35, effective September 19, 2004.

General Authority: SDCL 36-11-11(1), 36-11-11(14) (13).

Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:08. Declaration of current impairment or limitations. The applicant shall declare any current use of drugs, alcohol, or other chemical substances that in any way impairs or limits the applicant's ability to perform the duties of a pharmacy technician with reasonable skill and safety.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:09. Felony or misdemeanor crimes. The applicant shall declare any history of being charged, convicted, found guilty of or entering a plea of guilty or no contest to a felony or misdemeanor crime other than minor traffic violations with fines under \$100.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:10. Sworn signature. The applicant shall sign <u>or attest to the accuracy of</u> the application under penalty of perjury and shall submit it to the board.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13). **20:51:29:11. Registration renewal.** The registration of a pharmacy technician expires on October 31 each year following initial registration.

Effective July 1, 2014, the board shall not renew the registration of a pharmacy technician who was initially registered after July 1, 2011, or who was initially registered prior to that date but did not maintain continuous registration, unless the individual provides the board with evidence of completion of one of the following:

(1) A pharmacy technician training program offered by a board approved, accredited vocational/technical institution or college;

(2) A pharmacy technician training program accredited by a board approved, national organization that accredits pharmacy technician training programs;

(3) A pharmacy technician training program provided by a branch of the United States armed forces or Public Health Service; or

(4) An employer-based pharmacy technician training program that includes a minimum total of 480 hours in a one-year period to include both theoretical and practical instruction. An employer utilizing such a program must develop and regularly update a technician training manual that must be available for board inspection upon request. The employer must also supply a pharmacy technician who completes the training program with evidence of completion. The employer based pharmacy technician training program must include written guidelines, policies, and procedures that define the specific tasks the technician will be expected to perform. Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:12. Registration fee. The fee for initial registration is \$25. The renewal fee for the registration is \$25. Fees shall be paid at the time the new application or the renewal application is submitted. Fee payment shall be in the form of a personal check, certified or cashier check, or money order payable to the Board of Pharmacy.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:13. Timeliness of initial application or renewal application. An application for initial or renewal application may be denied if not received within the applicable period specified in § 20:51:29:03 for new applicants or by the expiration date of the renewal registration. Any registration not renewed before its expiration date is delinquent. An individual who continues employment as a pharmacy technician without a current registration may be subject to disciplinary sanctions as provided in § 20:51:29:27.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13). **20:51:29:14. Registration certification.** The pharmacy technician shall maintain the original certificate of registration as a pharmacy technician issued by the board. The pharmacist-in-charge (§ 20:51:06:02.01) of each pharmacy utilizing a pharmacy technician is responsible for verifying that any technician working in the pharmacy is registered and compliant with all rules of this chapter. Any violation by the technician may be grounds for disciplinary action against the pharmacist-in-charge.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(13) (14). Law Implemented: SDCL 36-11-11(13) (14).

20:51:29:15. Notification to the board. Within ten days of any change of the technician's name, address, or pharmacy employment status, a pharmacy technician shall report that change to the board.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:16. Training and utilization of pharmacy technicians. Notwithstanding the fact that a pharmacy technician has completed a training program as specified in § 20:51:29:11, it It is the responsibility of the pharmacist-in-charge of a pharmacy to ensure that a technician receives adequate training in the tasks performed by pharmacy technicians working at that pharmacy. Any pharmacy utilizing a pharmacy technician shall develop, implement, and periodically review written policies and procedures for training and utilizing pharmacy technicians appropriate to the practice

of pharmacy at that pharmacy. Each pharmacy shall specify in its policies the frequency of review. Each pharmacy shall document and maintain each technician's training for the duration of employment. The pharmacy shall make its policies and procedures and documentation of technician training available for inspection by the board.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:17. Identification of pharmacy technicians. A pharmacy technician shall wear a visible identification badge while on duty that clearly identifies the person as a pharmacy technician and includes the technician's first name.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:18. Misrepresentation prohibited. A pharmacy technician may not represent himself or herself in any manner as a pharmacist.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13). **20:51:29:19. Ratio.** The ratio of pharmacy technicians to pharmacists that may be on duty in a pharmacy at a given time is three technicians for every pharmacist. A pharmacy intern does not count in this ratio (§ 20:51:02:11.01).

Source: 31 SDR 35, effective September 19, 2004; 42 SDR 19, effective August 19, 2015. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:19.02. Exception to ratio for hospital, mail order, and long-term care pharmacy. The maximum ratio of pharmacy technicians to pharmacists that may be on duty in a hospital, mail order, and long-term care pharmacy will be determined by the pharmacist-in-charge pharmacist-in-charge. However, all of the following requirements must be met:

(1) Medication is dispensed pursuant to a legal prescription;

(2) The technology includes tablet or product imaging and or bar code scanning, or both, to <u>insure ensure</u> accuracy in the prescription filling process;

(3) A role-based access software automation system that places stop points within the prescription filling process is used, which requires a pharmacist's intervention before allowing the prescription to move to the next step in the prescription dispensing process;

(4) Pharmacy software that screens and detects drug allergies, identifies drug interactions, and checks age appropriate dosage ranges is used;

(5) A pharmacist reviews clinically significant computer warnings of drug interactions, therapy duplications, and contraindications;

(6) Electronic surveillance technology is used to control access or to provide continuous monitoring of all areas where drugs are stored or dispensed or both;

(7) All non-pharmacist personnel who input patient drug information into a computer or whose duties include receiving, packaging, shipping of drugs, or who have access to any areas where drugs are dispensed are registered as pharmacy technicians and meet the requirements in chapter 20:51:29;

(8) In hospital and long-term care pharmacies, nursing personnel in facilities served by the pharmacy have telephone access to a pharmacist 24 hours a day, 7 days a week. In mail order pharmacies, a patient has access to a pharmacist 24 hours a day, 7 days a week on a dedicated pharmacist staff line;

(9) Drug information, both electronic and hard copy, is readily available to pharmacists;

(10) A quality assurance program that identifies and evaluates dispensing errors, accompanied by a continuous quality improvement program that assures very high dispensing accuracy rates in place;

(11) There are written policies and procedures for all pharmacy functions -- clerical, supportive, technical, and clinical;

(12) There are written policies and procedures for training personnel, including on-going training programs for all personnel and documentation of that training for each employee;

(13) There is a strict monitoring program designed to prevent diversion of controlled substances. This includes perpetual inventory of all <u>schedule II scheduled</u> controlled drugs as well as selected high risk schedule III, IV, and V drugs. Routine audits are conducted to review purchases versus dispensing of controlled drugs to deter and detect diversion.

Source: 36 SDR 21, effective August 17, 2009; 42 SDR 19, effective August 19, 2015. General Authority: SDCL 36-11-11(1)(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:20. Delegation and supervision of technical functions. A pharmacist may delegate technical dispensing functions to a pharmacy technician, but only if the pharmacist is on site supervising the delegated functions performed. The pharmacist shall provide and document the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.

The physical presence requirement of the pharmacist does not apply when utilizing an automated <u>dispensing mechanical distribution</u> device approved by the board. After proper checking and verification with the <u>physician practitioners</u>' orders by the pharmacist, the technician may replace medications to the automated <u>dispensing mechanical distribution</u> device that have been checked by the pharmacist. The pharmacist is not required to accompany the technician when

placing medications into the automated <u>dispensing</u> <u>mechanical distribution</u> device. The automated <u>dispensing</u> <u>mechanical distribution</u> device must be capable of printing out a record of medications filled by the technician. The record shall be checked and verified by the pharmacist daily.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:21. Technical functions. At the discretion of the supervising pharmacist, technical functions which may be delegated to a pharmacy technician include the following:

(1) Performing packaging, manipulative, or repetitive tasks relating to the processing of a prescription or medication order in a licensed pharmacy;

(2) Accepting prescription refill authorization communicated to a pharmacy by a prescriber practitioner, or by the prescriber's practitioner's agent; Any changes other than number of refills on the prescription shall not be accepted by a technician and shall be accepted by a pharmacist or pharmacy intern;

(3) Contacting prescribers to obtain prescription refill authorization;

(4) Collecting pertinent patient information;

(5) Inspecting drug supplies provided and controlled by a South Dakota licensed pharmacy, including drug supplies maintained in an automated mechanical <u>dispensing</u> <u>distribution</u> device,

emergency medical room, ambulance vehicle, long-term care facility, a hospital nursing unit, or a hospice facility;

(6) Assisting the pharmacist with the preparation of medications for administration to the patient topically, by injection, or other approved methods.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:22. Tasks a pharmacy technician may not perform. A pharmacy technician may not:

(1) Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order;

(2) Conduct prospective drug use review or evaluate a patient's medication record for purposes identified in § 20:51:25:02;

(3) Provide final verification of automated dispensing medication fill records for accuracy and completeness;

(4) Make decisions that require a pharmacist's professional judgment such as interpreting new orders, applying information, or making product selection for drugs that are substitutable;

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(5) Accept new oral <u>verbal</u> prescription medication orders communicated to the pharmacy by a <u>prescriber practitioner</u>, or by the <u>prescriber's practitioner's</u> agent; or

(6) Open, keep open, or provide Provide pharmaceutical services from in a pharmacy without a pharmacist being present as provided in §§ 20:51:06:11, 20:51:15:02, and 20:51:15:04, except as provided in § 20:51:30:12.

A violation of this section constitutes illegal conduct or practice and may be grounds for disciplinary action as provided in § 20:51:29:27.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:23. Misrepresentative deeds. A pharmacy technician may not make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in a pharmacy or in the operation or conduct of a pharmacy.

Source: 31 SDR 35, effective September 19, 2004.

General Authority: SDCL 36-11-11(1), 36-11-11(14) (13).

Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:24. Confidentiality. In the absence of express written consent from the patient or written order or direction of a court, except where the best interests of the patient require, a pharmacy

technician may not divulge or reveal to any person other than the patient or the patient's authorized representative, the <u>prescriber practitioner</u> or other licensed practitioner then caring for the patient, a licensed pharmacist or a person duly authorized by law to receive such information, any of the following:

(1) The contents of any prescription drug order or medication or the therapeutic effect thereof or the nature of professional pharmaceutical services rendered to a patient;

(2) The nature, extent, or degree of illness suffered by any patient; or

(3) Any medical information furnished by the prescriber.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:25. Illegal/unethical behavior. A pharmacy technician may not exhibit illegal/unethical behavior in connection with the technician's pharmacy employment. Illegal/unethical behavior includes the following acts: verbal or physical abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, profanity, indecent or obscene conduct, and theft. A violation of this section may be grounds for disciplinary action as provided in § 20:51:29:27.

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13). **20:51:29:26. Denial of registration.** The board may deny an application for registration as a pharmacy technician for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs (or for any violation of this chapter).

Source: 31 SDR 35, effective September 19, 2004. General Authority: SDCL 36-11-11(1), 36-11-11(14) (13). Law Implemented: SDCL 36-11-11(14) (13).

20:51:29:27. Sanctions. The board may impose the following disciplinary sanctions for violations of this chapter:

(1) Revoke a pharmacy technician registration;

(2) Suspend a pharmacy technician registration until further order of the board or for a specified period;

(3) Not renew of a pharmacy technician registration;

(4) Prohibit permanently, until further order of the board, or for a specified period, the engaging in specified procedures, methods, or acts;

- (5) Impose a probationary period;
- (6) Order a physical or mental examination;
- (7) Issue a citation and warning.

Source: 31 SDR 35, effective September 19, 2004.

General Authority: SDCL 36-11-11(1), 36-11-11(14) (13).

Law Implemented: SDCL 36-11-11(14) (13).

CHAPTER 20:51:30

TELEPHARMACY

Section

- 20:51:30:01 Definitions.
- 20:51:30:02 Application for remote pharmacy site.
- 20:51:30:03 Ownership or control by pharmacist required.
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- 20:51:30:14 Prescription workload.
- 20:51:30:15 Requirements for prescription orders.
- 20:51:30:16 Requirements for operation.
- 20:51:30:17 Routine quality assurance required.
- 20:51:30:18 Use of automated mechanical prescription dispensing device.

20:51:30:01. Definitions. Terms used in this chapter mean: defined in SDCL 36-11-71 have the same meaning in this chapter.

(1) "Automated mechanical distribution device," as defined in § 20:51:17:01;
(2) "Central pharmacy," as defined in SDCL 36-11-71(1);
(3) "Remote pharmacy," as defined in SDCL 36-11-71(2);
(4) "Telepharmacy practice," as defined in SDCL 36-11-71(3)

Source: 35 SDR 183, effective February 2, 2009.

General Authority: SDCL 36-11-11(1).

Law Implemented: SDCL 36-11-11(1)(3)(4)(5), 36-11-71.

20:51:30:02. Application for remote pharmacy site. No remote pharmacy may be established, operated, or maintained unless the board issues a license. An application for licensure to establish, operate, or maintain a remote pharmacy shall be made on a form provided by the board. The applicant shall submit an initial license fee of \$200 and provide a set of blueprints and documentation showing that all requirements of this chapter have been met. The applicant shall demonstrate to the board that there is limited or no access to pharmacy services in the community. When considering whether to approve an application, the board shall consider the needs of the community. The board shall approve or disapprove an application within 60 days of receipt.

Source: 35 SDR 183, effective February 2, 2009.

General Authority: SDCL 36-11-11(1)(3), 36-11-72(1).

Law Implemented: SDCL 36-11-72(1).

20:51:30:03. Ownership or control by pharmacist required. The board may not issue a permit license to conduct operate a remote pharmacy to any pharmacist applicant unless such pharmacist applicant is an owner, or part owner, of the place of business from which the pharmacist will practice telepharmacy, or unless the non-pharmacist owner of the place of business from which the pharmacist will practice telepharmacy files an affidavit on a form prescribed by the board delegating full and complete authority to the pharmacist applicant to be in active management of the place of business for the license year ending June 30.

Source: 35 SDR 183, effective February 2, 2009. General Authority: SDCL 36-11-11(1)(3), 36-11-72(1). Law Implemented: SDCL 36-11-34, 36-11-72.

20:51:30:04. Board inspection. No remote pharmacy may provide pharmacy services until the board has inspected the remote pharmacy for minimum equipment, size, security, and sanitation standards as set forth in § 20:51:07:01 and found the remote pharmacy to be in compliance with such standards.

Source: 35 SDR 183, effective February 2, 2009. General Authority: SDCL 36-11-11(1)(3)(4), 36-11-72(1). Law Implemented: SDCL 36-11-71, 36-11-72. **20:51:30:07. Audiovisual link.** There must be a continuously accessible, two-way audiovisual link between the central pharmacy and the remote pharmacy. The transmission of information through the computer link must make information available to the central pharmacy and the remote pharmacy simultaneously. The video camera used for the certification of prescriptions must be of sufficient quality and resolution so that the certifying pharmacist can visually identify the markings on tablets and capsules. A second camera is required to meet security needs if the camera used to certify prescriptions is not able to monitor activities in other parts of the remote site.

Source: 35 SDR 183, effective February 2, 2009. General Authority: SDCL 36-11-11(1)(4), 36-11-72(2). Law Implemented: SDCL 36-11-72(2).

20:51:30:08. Remote pharmacy identification sign. Each remote site shall display a sign easily viewable by customers stating "This business is a remote pharmacy, supervised by a pharmacist located at (*insert name of pharmacy and address*)".

Source: 35 SDR 183, effective February 2, 2009. General Authority: SDCL 36-11-11(1)(4), 36-11-72(2),(5). Law Implemented: SDCL 36-11-72(2),(5).

20:51:30:09. Restricted area posted. The remote pharmacy dispensing area shall be posted as a restricted area. Only pharmacy technicians or pharmacy interns employed directly and involved in processing prescriptions are permitted in the dispensing area. There must be restricted access to the restricted area. The security system at the remote pharmacy must allow for tracking of each entry into the pharmacy. The pharmacist-in-charge shall review the log of entries at least weekly.

Source: 35 SDR 183, effective February 2, 2009.

General Authority: SDCL 36-11-11(1)(4), 36-11-72(2),(5).

Law Implemented: SDCL 36-11-72(2),(5).

20:51:30:10. Toll-free telephone number. The remote pharmacy shall provide a toll-free telephone number that patients and prescribers may use to contact the central pharmacy. The telephone number shall be printed on the label of each prescription container.

Source: 35 SDR 183, effective February 2, 2009. General Authority: SDCL 36-11-11(1)(4), 36-11-72(2),(5). Law Implemented: SDCL 36-11-72(2),(5).

20:51:30:11. Pharmacist staffing requirements. Any pharmacist performing services in support of a remote pharmacy, whether those services are performed at the central pharmacy or the remote pharmacy, must be licensed by the board. A copy of the pharmacist's license must be posted in any remote pharmacy to which the pharmacist provides services.

Source: 35 SDR 183, effective February 2, 2009.

General Authority: SDCL 36-11-11(1)(4), 36-11-13, 36-11-72(3).

Law Implemented: SDCL 36-11-72(3).

20:51:30:12. Technician and intern staffing requirements. Each remote pharmacy must be staffed with South Dakota registered pharmacy technicians or interns. A pharmacy technician working at a remote pharmacy shall have a minimum of 2000 hours of experience as a registered

pharmacy technician in accordance with chapter 20:51:29 and shall be certified-through one of the certification programs recognized by the board. An intern working at a remote pharmacy shall have a minimum of 500 hours of experience as a registered pharmacy intern in accordance with chapter 20:51:02.

Source: 35 SDR 183, effective February 2, 2009. General Authority: SDCL 36-11-11(1)(13), 36-11-72(3). Law Implemented: SDCL 36-11-72(3).

20:51:30:13. Pharmacist-to-technician ratio. The pharmacist on duty at a central pharmacy may supervise no more than the number of technicians <u>and interns as</u> allowed in accordance with § 20:51:29:19. The total number of allowed technicians <u>and interns</u> may be divided between the central pharmacy and the remote pharmacy in any manner. However, each remote pharmacy must have at least one pharmacy technician or pharmacy intern on duty when it is open.

Source: 35 SDR 183, effective February 2, 2009. General Authority: SDCL 36-11-11(1)(4)(13), 36-11-72(3). Law Implemented: SDCL 36-11-72(3).

20:51:30:15. Requirements for prescription orders. Only a registered licensed pharmacist or registered intern may take a verbal prescription order. A pharmacy technician at the remote pharmacy may not accept verbal orders for new prescriptions, but may accept written orders. A written order for a new prescription may be entered at the central pharmacy or the remote pharmacy. The pharmacist must approve or override all drug utilization review alerts.

Source: 35 SDR 183, effective February 2, 2009.

General Authority: SDCL 36-11-11(1), 36-11-72(5).

Law Implemented: SDCL 36-11-72(5).

20:51:30:16. Requirements for operation. The following requirements must be adhered to when operating a remote pharmacy:

(1) The remote pharmacy may only be open if a computer link, video link, and audio link with the central pharmacy are functioning properly. If any link is not functioning properly, the remote pharmacy must be closed unless a pharmacist is working at the remote pharmacy;

(2) No remote pharmacy may be open when the central pharmacy is closed, unless a licensed pharmacist is working at the remote pharmacy;

(3) Any prescription filled at the remote pharmacy must be profiled, reviewed, and interpretedby a pharmacist at the central pharmacy before the prescription is dispensed;

(4) Any remotely dispensed prescriptions must have a label properly prepared in accordance with § 20:51:05:21 attached to the final drug container before the pharmacist certifies verifies the dispensing process. This prescription certification verification process must be done in real time. All prescription certification verification must be documented in the computer record. The computer must be capable of carrying the initials of the technician preparing the prescription and the pharmacist verifying the prescription. Verification is required for both new prescriptions and refills;

(5) When the patient receives a prescription, the pharmacist must use audiovisual communication to counsel the patient regarding use of the prescription being dispensed. Counseling is required only for new prescriptions. The pharmacist must meet the counseling standards in accordance with § 20:51:25:04;

(6) The remote pharmacy must maintain a log, signed by the patient, that documents a patient's refusal for counseling by the pharmacist.

Source: 35 SDR 183, effective February 2, 2009. General Authority: SDCL 36-11-11(1)(4), 36-11-72(2),(3),(4),(5). Law Implemented: SDCL 36-11-72(2),(3),(4),(5).

20:51:30:17. Routine quality assurance required. The pharmacist-in-charge must adhere to the following procedures:

(1) An inspection of the remote pharmacy shall be conducted by a licensed pharmacist at weekly intervals or more if deemed necessary. Inspection must be documented and kept on file at the remote pharmacy and available upon request by the board;

(2) Implement and conduct a quality assurance plan that provides for on-going review of dispensing errors, with appropriate action taken, if necessary, to assure patient safety;

(3) Verify controlled substance prescriptions for both accuracy and legitimacy of the original prescription by the pharmacist-in-charge or a designated pharmacist during weekly inspection visits;

(4) Maintain records of all controlled substances stocked by the remote pharmacy through a daily perpetual inventory. Controlled substance perpetual inventory records must be available for inspection by the board's inspectors. A remote pharmacy stocking controlled drugs must be registered by the Drug Enforcement Administration and South Dakota Department of Health;

(5) Conduct an inventory of all controlled substances at least monthly to verify accuracy.

Source: 35 SDR 183, effective February 2, 2009. General Authority: SDCL 36-11-11(1)(4), 36-11-72(4),(5).

Law Implemented: SDCL 36-11-72(4),(5).

20:51:30:18. Use of automated mechanical prescription dispensing device. If the remote pharmacy uses an automated mechanical prescription dispensing device as defined in § 20:51:17:01, the stocking and loading of this device must either be checked by a pharmacist, prior to use, or employ a secure bar coding bar-coding system or its equivalent. Policies and procedures consistent with § 20:51:17:02 regarding the operation of the automated mechanical prescription dispensing system device must be developed and submitted to the board for consideration. After approval, these policies and procedures must be available at both the central pharmacy and the remote pharmacy.

Source: 35 SDR 183, effective February 2, 2009.

General Authority: SDCL 36-11-11(1),(6)(5), 36-11-72(6). **Law Implemented:** SDCL 36-11-11(6)(5), 36-11-72(6).

CHAPTER 20:51:35

CENTRAL FILL PHARMACIES

Section

20:51:35:01 Definitions.

20:51:35:02 License required.

20:51:35:03 Requirements for central fill.

20:51:35:04 Label requirements.

20:51:35:05 patient notification.

20:51:35:06 Patient requests.

20:51:35:01 Definitions. As used in this chapter:

- <u>"Central fill pharmacy," means a pharmacy under the same ownership or contracted</u> to provide prescription filling on behalf of an originating pharmacy; and
- (2) "Originating pharmacy," means a pharmacy that receives prescription drug orders
 from a patient, an agent of the patient, or a prescriber and outsources the filling or
 processing of the order to a central fill pharmacy and dispenses the prescription to the
 patient or agent of the patient.

Source:

General Authority: SDCL 36-11-11(1)(3) Law Implemented: SDCL 36-11-30 **20:51:35:02.** License required. Any pharmacy operating as a central fill pharmacy in this state must be licensed as a full-time pharmacy. Any pharmacy located outside the state of South Dakota operating as a central fill pharmacy must be licensed as a nonresident pharmacy.

Source:

General Authority: SDCL 36-11-11(1)(3)

Law Implemented: SDCL 36-11-30, 36-11-19.2

20:51:35:03. Requirements for central fill. For all pharmacies utilizing a central fill process, the originating pharmacy and central fill pharmacy must:

- (1) <u>Be under the same ownership or have a signed legal contract to provide central fill</u> <u>services;</u>
- (2) Share a prescription software platform system as defined in ARSD 20:51:20:04;
- (3) <u>Require a pharmacist from either the originating pharmacy or the central fill pharmacy to perform a prospective Drug Utilization Review (DUR) before dispensing any prescription. The identity of the pharmacist must be available to both pharmacies in the prescription record; and</u>
- (4) <u>Have a policy and procedure approved by both pharmacies on the process of the central</u> <u>fill procedure that outlines the expectations of both pharmacies and ensures patient safety</u> <u>and privacy.</u>

Source:

General Authority: SDCL 36-11-11(1)(3)(12)

Law Implemented: SDCL 36-11-30, 36-11-19.2

20:51:35:04. Label requirements. The prescription label for medications filled by a central fill pharmacy must meet the requirements in §§ 20:51:05:21 and 44:58:08:20, and must have wording indicating that the prescription was filled at a central fill pharmacy. The label must contain the name, address, and phone number of the originating pharmacy.

Source:

General Authority: SDCL 36-11-11(1)(3)

Law Implemented: SDCL 36-11-11(1)(3)

20:51:35:05. Patient notification. The originating pharmacy shall post a sign to notify patients that the pharmacy utilizes a central fill pharmacy process.

Source:

General Authority: SDCL 36-11-11(1)(3)

Law Implemented: SDCL 36-11-11(1)(3)

20:51:35:06. Patient requests. A patient may request the originating pharmacy not utilize the central fill pharmacy service. The pharmacy must comply with the request.

Source:

General Authority: SDCL 36-11-11(1)(3)

Law Implemented: SDCL 36-11-11(1)(3)