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PHARMACISTS

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ARTICLE 20:51

PHARMACISTS

CHAPTER 20:51:01

REGISTRATION BY EXAMINATION

1 Requested emergency waivers for COVID-19 emergency April 2, 2020

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.

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. In COVID-19 emergency, Board may waive 200 hours of experience required for licensure and may offer temporary licensure for issues of not being able to test, due to emergency test center closure.

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 with the application:

(1) The certificate of registration fee of $35;

(2) A photo of the applicant that is at least 2¼ by 3¼ 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 American Council on Pharmaceutical Education; and

(5) A government-issued form of photo identification.

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, 36-11-17.

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

20:51:01:04. Examination. An applicant for registration by examination shall successfully complete the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Jurisprudence Examination (MPJE), South Dakota edition. A total scaled score of not less than 75 is required to pass each examination. As in § 20:51.02, a temporary license may be provided by the Board in order to provide pharmacists needed in practice sites.

Source: SL 1975, ch 16, § 1; 10 SDR 117, effective May 8, 1984; 12 SDR 178, effective May 11, 1986; 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 36-11-16, 36-11-18.

20:51:01:05. Practical experience mandatory. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

20:51:01:06. Passing grade for National Association of Boards of Pharmacy examination. Repealed.

Source: SL 1975, ch 16, § 1; 10 SDR 117, effective May 8, 1984; 12 SDR 178, effective May 11, 1986; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 13 SDR 179, effective June 2, 1987; 18 SDR 95, effective November 25, 1991; repealed, 36 SDR 21, effective August 17, 2009.

20:51:01:06.01. Passing grades for examination in practical-jurisprudence. Repealed.

Source: 10 SDR 117, effective May 8, 1984; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; repealed, 36 SDR 21, effective August 17, 2009.

20:51:01:07. Reexamination requirements. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 178, effective May 11, 1986.

20:51:01:08. Experience not concurrent with college attendance. 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.

20:51:01:09. 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, 20 North Clark Street, Suite 2500, Chicago, IL 60602-5109; 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.

20:51:01:10. Application requirements for graduates from colleges of pharmacy located outside the United States. Any applicant who is a graduate of a school or college of pharmacy located outside of the United States must submit the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification awarded by the National Association of Boards of Pharmacy (NABP). The FPGEC certification includes the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English (TSE), or the Internet-based TOEFL iBT as a prerequisite to taking the licensure examinations.

A foreign pharmacy graduate applicant shall also be required to obtain internship experience in one or more board-licensed community or hospital pharmacies.

Source: 9 SDR 171, effective July 12, 1983; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 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, 36-11-18.

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 the National Association of Boards of Pharmacy. To be eligible for 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.

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. Terms used in this chapter mean:

(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," 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 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 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 licensure 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.

20:51:02:01.01. Goal and objectives of internship. A pharmacy internship shall provide the pharmacy intern with the opportunity, over a period of time, to attain and build upon the intern's knowledge, skills, and ability to safely, efficiently, and effectively practice pharmacy under the laws and rules of the state.

The objectives of an internship are to provide each intern with the following responsibilities:

(1) To manage drug therapy to optimize patient outcomes. The pharmacy intern shall evaluate the patient and patient information to determine the presence of a disease or medical condition to determine the need for treatment or referral and to identify patient-specific factors that affect the patient's health to ensure the appropriateness of the patient's specific pharmacotherapeutic agents, dosing regimens, dosage forms, routes of administration, and delivery systems; and monitor the patient and patient information and manage the drug regimen to promote health and ensure safe and effective pharmacotherapy;

(2) To perform calculations required to compound, dispense, and administer medications; to select and dispense drugs and devices; and to prepare and compound extemporaneous preparations and sterile products;

(3) To assess, evaluate, and apply information to promote optimal healthcare and to educate patients and other healthcare professionals regarding prescription drugs, nonprescription drugs, and medical devices; and

(4) To develop a general understanding of the business procedures of a pharmacy and develop knowledge concerning the employment and supervision of pharmacy employees.

While performing these responsibilities, the pharmacy intern shall adhere to the professional, legal, moral, and ethical standards relative to the practice of pharmacy.

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

20:51:02:02. Experience required. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 8 SDR 5, effective July 26, 1981.

20:51:02:03. Experience not concurrent with college attendance. 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.

20:51:02:04. Registration. The board shall grant a certificate 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.

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 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, 36-11-25.
Law Implemented: SDCL 36-11-25.

20:51:02:05. Renewal of certificate. 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. The board shall issue a certificate 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, 36-11-25.
Law Implemented: SDCL 36-11-25.

20:51:02:06. Intern certificates void when employment ceases. 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.

20:51:02:07. 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.

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, 36-11-25.
Law Implemented: SDCL 36-11-25.

20:51:02:09. Supervisor notifies board at beginning and end of employment. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

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 registered pharmacist. The Board of Pharmacy may not accept practical experience of more than 48 hours a week or less than eight hours a week.

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, 36-11-25.
Law Implemented: SDCL 36-11-11, 36-11-25.

20:51:02:11. Supervising pharmacist requirements. A registered 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. 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 pharmacy intern at a time in the pharmacy. The pharmacy intern does not count for purposes of the ratio of technicians supervised by the pharmacist. Due to COVID-19 emergency situations, a pharmacist may supervise more than one intern as needed.

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.

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. In the COVID-19 emergency period, the board may waive 1740 hours down to 1600 hours of IPPE and APPE combined for licensure.

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

20:51:02:13. Internship experiences from other states. The South Dakota Board of Pharmacy may give credit for practical experience obtained in a state other than South Dakota if the credit for the experience has been certified by the Board of Pharmacy of the other state.

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

20:51:02:13.01. Foreign pharmacy graduate internship. A graduate of a foreign school of pharmacy who is a candidate for licensure in South Dakota and who has met the requirements of § 20:51:01:10 must obtain a minimum of 1500 hours of internship in a licensed pharmacy or other board-approved location before receiving a South Dakota pharmacist license.

Source: 31 SDR 35, effective September 19, 2004.
General Authority: SDCL 36-11-11(1), 36-11-16, 36-11-25.
Law Implemented: SDCL 36-11-16, 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, 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, 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.

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 20:51:03

INTERNS IN CLINICAL PROJECTS

(Repealed. 22 SDR 133, effective April 25, 1996)

CHAPTER 20:51:04

REGISTRATION BY RECIPROCITY

Section

20:51:04:01. Application. An application to the board shall consist of the official application for license transfer prepared by the National Association of Boards of Pharmacy (NABP) pursuant to the NABP license transfer program.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 12 SDR 86, effective November 27, 1985; 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.

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

(1) The applicant must be a registered 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 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.

20:51:04:03. Reciprocity requirements. In addition to the requirements of § 20:51:04:02, an applicant for reciprocity shall also meet the following requirements:

(1) The applicant may not have committed any act which may be construed by the board as a violation of state and federal laws, which might impair the discharge of the applicant's duties as a pharmacist; and

(2) The applicant must successfully complete the Multistate Pharmacy Jurisprudence Examination (MPJE), South Dakota edition. A total scaled score of not less than 75 is required to pass this examination.

During the COVID-19 emergency, a pharmacist asked to work in South Dakota, to take care of COVID-19 patients, may work without a SD pharmacist license. If a pharmacist is licensed and in good standing in another state, the board may waive the MPJE requirement and provide a temporary license in order that a pharmacist may begin working in this state with an NABP Passport.

Source: SL 1975, ch 16, § 1; 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).
Law Implemented: SDCL 36-11-19.

20:51:04:04. Application requirements. Applicants must file their official National Association of Boards of Pharmacy reciprocal application with the secretary of the board within 90 days from the date of issue. The application must be accompanied by:

(1) The 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.

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 36-11-19.

20:51:04:05. Appearance before board. Before a reciprocal registration is granted, the applicant may be required to appear in person before the board for final consideration of the reciprocal application. The secretary of the board shall notify the applicant of the time and place of the required appearance.

Source: SL 1975, ch 16, § 1; 10 SDR 117, effective May 8, 1984; 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.

20:51:04:06. Special permit. Repealed.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, 29 SDR 37, effective September 26, 2002.

20:51:04:07. Failure to register is violation. Repealed.

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

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.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.
General Authority: SDCL 36-11-11.
Law Implemented: SDCL 36-11-19.

20:51:04:09. Reciprocity grade fee. Repealed.

Source: 6 SDR 103, effective May 5, 1980; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, 36 SDR 21, effective August 17, 2009.

CHAPTER 20:51:05

RESTRICTED PROFESSIONAL PRACTICES

Section

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

(1) "Controlled drug," 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) "Legend drug," a substance as defined in SDCL 34-20B-28.1(4).

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

20:51:05:01. Transferred to § 20:51:05:15.

20:51:05:02. Transferred to § 20:51:05:16.

20:51:05:03. Oral prescription for some narcotics must be reduced to writing. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 8 SDR 101, effective February 28, 1982.

20:51:05:04. Pharmacist must keep exempt narcotic register. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 6 SDR 103, effective May 5, 1980.

20:51:05:05. Refilling narcotic prescriptions. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 8 SDR 101, effective February 28, 1982.

20:51:05:06. Transferred to § 20:51:05:20.

20:51:05:07. Transferred to § 20:51:05:20.

20:51:05:08. Limitation on sale of self-medications. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, SL 2012, ch 194, § 15, effective July 1, 2012.

20:51:05:09. Sale of certain self-medications require buyers to sign poison register. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, SL 2012, ch 194, § 16, effective July 1, 2012.

20:51:05:10. Limitation on sale of drugs to persons under 16 years of age. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, SL 2012, ch 194, § 17, effective July 1, 2012.

20:51:05:11. Verbal warning required on sale of potent drugs. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, 2012, ch 194, § 18, effective July 1, 2012.

20:51:05:12. Advertising for mail order sale of drugs prohibited. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 6 SDR 103, effective May 5, 1980.

20:51:05:13. Advertising of price or discounts of drugs prohibited. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 3 SDR 45, effective December 18, 1976.

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

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

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 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.

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.

20:51:05:16. Prescription for Schedule II controlled drug requires date and signature of prescriber -- 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 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.

20:51:05:17. Oral 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.

Law Implemented: SDCL 36-11-11.

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.

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.

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 prescriber may be delivered to a pharmacist by handwritten order, facsimile, or electronic equipment where permissible by law. 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 prescriber. 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 on-line 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 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, 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 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 on-line 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. 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 drug prescription prior to authorization from the prescriber, except

during the COVID-19 emergency, when unable to contact a prescriber, the pharmacy may fill a 30 day supply for the patient and should inform the prescriber's office of the fill.

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 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, 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 for nursing facility patients, including over-the-counter medications, are considered prescription medications and must be labeled as required in chapter 44:04:08.

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. A registered pharmacy is authorized to distribute up to five percent of its controlled drugs and legend drugs to a practitioner registered to prescribe, dispense, or distribute such drugs in the course of professional practice or to other registered pharmacies to meet temporary inventory shortages.

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).

CHAPTER 20:51:06

PHARMACY PRACTICE AND REGISTRATION

Section
20:51:06:01 Application for pharmacy permit.
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.
20:51:06:04 False application grounds for suspending or revoking.
20:51:06:05 Must be registered in order to advertise pharmacy name.
20:51:06:06 Transfer of pharmacy registration.
20:51:06:07 Changes in ownership or location must be reported to secretary.

20:51:06:01. Application for pharmacy permit. A registered pharmacist actively conducting a pharmacy in the state of South Dakota must apply each year to the Board of Pharmacy for a permit to conduct the pharmacy for the fiscal year ending June thirtieth. 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), 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 shall be issued to any pharmacist applicant unless such pharmacist applicant is owner, or part owner, of the merchandise and fixtures of the place of business for which pharmacy registration is applied for, or unless application is made jointly with a registered pharmacist owner, or unless the nonpharmacist owner of the merchandise and fixtures of the place of business for which pharmacy registration is applied for, has made affidavit on a form prescribed by the state Board of Pharmacy delegating full and complete authority to the pharmacist applicant to be in active management of said 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.
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 as specified in § 20:51:06:02 shall indicate the pharmacist-in-charge. The term, pharmacist-in-charge, means a pharmacist manager or pharmacist permittee duly licensed in South Dakota who has been so designated by the employer.

The pharmacist-in-charge shall:

(1) Be employed or contracted for pharmacy services at the 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 immediately upon knowledge of termination of employment. A new pharmacist-in-charge shall be designated by the employer within ten working days.

Source: 26 SDR 92, effective January 6, 2000.
General Authority: SDCL 36-11-11(1)(4).
Law Implemented: SDCL 36-11-11(1)(4), 36-11-32.

20:51:06:03. Renewal required each year. 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, except during the COVID-19 emergency if the pharmacy is temporarily closed or the pharmacist in charge is ill where a 30 day extension is allowed.. The fee set by the Board of Pharmacy shall accompany the application. Applications for opening and conducting a new pharmacy in South Dakota shall be filed with the secretary of the Board of Pharmacy at least 30 days before the date when the new pharmacy is to be opened to the public. 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 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 ceiling. The walls 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.

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.
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, 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 pharmacy.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.
General Authority: SDCL 36-11-11.
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, 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, 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.
Law Implemented: SDCL 36-11-31.

20:51:06:06. Transfer of pharmacy registration. Each permit to conduct a pharmacy may be transferred to another 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 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 shall be accomplished by the fee as set by the Board of Pharmacy for permit to conduct a pharmacy and such 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.

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

20:51:06:07. Changes in ownership or location must be reported to secretary. Any change in the location 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 ten days of such occurrence. The pharmacist permittee shall be held responsible for reporting such changes to the Board of Pharmacy. If, such change occurs during the COVID-19 emergency, changes in ownership or location must be reported within 30 days.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.
General Authority: SDCL 36-11-11.
Law Implemented: SDCL 36-11-39.

20:51:06:08. Valid permit must be displayed. A valid permit to conduct a pharmacy 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.
Law Implemented: SDCL 36-11-36.

20:51:06:09. Permit expires 120 days after death of pharmacist. Except in the event of the death of the pharmacist permittee, a permit to conduct a pharmacy is void when the holder of the permit ceases to be in active management of the pharmacy. When a pharmacist permittee dies, the pharmacy for which the pharmacist held a permit to conduct may not be kept open for the transaction of business without a pharmacist on duty and in charge. A permit to conduct a pharmacy in the name of a pharmacist who is deceased shall within 120 days after the death of the permittee become void, unless transfer 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 nonpharmacist 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.

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 considered in violation of the state pharmacy law if public entrances to such general merchandise area are kept open for the transaction of business without a pharmacist on duty in such pharmacy; provided, all entrances to the restricted area and 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 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.
Law Implemented: SDCL 36-11-11.

20:51:06:11. Pharmacy 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 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.

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.

20:51:06:12. Pharmacy requirements for pharmacist owners. 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.

20:51:06:13. Display of nonprescription drugs in pharmacy. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 86, effective November 27, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 24 SDR 160, effective May 26, 1998; repealed, SL 2012, ch 194, § 19, effective July 1, 2012.

CHAPTER 20:51:07

MINIMUM EQUIPMENT REQUIREMENTS

Section

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.

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

20:51:07:02. Publications required. Repealed.

Source: SL 1975, ch 16, § 1; 2 SDR 21, effective September 23, 1975; 6 SDR 103, effective May 5, 1980; 11 SDR 92, effective January 16, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, 14 SDR 19, effective August 11, 1987.

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.

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.

Law Implemented: SDCL 36-11-41.

20:51:07:04. Publication and reference library. Each pharmacy shall maintain the latest copy of South Dakota pharmacy laws and rules and the telephone number of the nearest poison control center. Pharmaceutical reference publications may be printed or computer-accessed. At least one general pharmaceutical information reference must be a printed copy. Additional reference material shall be maintained and shall include, at a minimum, one current reference 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(1).
Law Implemented: SDCL 36-11-41.

CHAPTER 20:51:08

SELF-SERVICE RESTRICTIONS

Section

20:51:08:01. Segregated sales display required. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, SL 2012, ch 194, § 20, effective July 1, 2012.

20:51:08:02. Display of drugs or poisons with general merchandise prohibited. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

20:51:08:03. No drug or poison can be displayed where buyer can pick up unless in restricted drug area. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, SL 2012, ch 194, § 21, effective July 1, 2012.

20:51:08:04. Only pharmacists and persons over 16 can make sales from restricted drug area. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, SL 2012, ch 194, § 22, effective July 1, 2012.

20:51:08:05. Requirements of sale from restricted drug area. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, SL 2012, ch 194, § 23, effective July 1, 2012.

20:51:08:06. Requirements for the sale of items from the restricted drug area. Repealed.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, SL 2012, ch 194, § 24, effective July 1, 2012.

20:51:08:07. Restricted drug areas must be under supervision of pharmacist. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, SL 2012, ch 194, § 25, effective July 1, 2012.

20:51:08:08. Pharmacist responsible to public for every act of selling. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

20:51:08:09. Self-service signs prohibited. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, SL 2012, ch 194, § 26, effective July 1, 2012.

CHAPTER 20:51:09

NONPRESCRIPTION DRUGS

Section

20:51:09:01. Application. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 24 SDR 160, effective May 26, 1998; repealed, SL 2012, ch 194, § 27, effective July 1, 2012.

20:51:09:02. Examination. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, 24 SDR 160, effective May 26, 1998.

20:51:09:03. Original package sales only. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 24 SDR 160, effective May 26, 1998; repealed, SL 2012, ch 194, § 28, effective July 1, 2012.

20:51:09:04. Labeling requirements. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 24 SDR 160, effective May 26, 1998; repealed, SL 2012, ch 194, § 29, effective July 1, 2012.

20:51:09:05. Segregated sales display of nonprescription drugs required. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 24 SDR 160, effective May 26, 1998; repealed, SL 2012, ch 194, § 30, effective July 1, 2012.

20:51:09:06. Restricted sales for the protection of public health. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 24 SDR 160, effective May 26, 1998; repealed, SL 2012, ch 194, § 31, effective July 1, 2012.

20:51:09:07. Course of study kept on file. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 24 SDR 160, effective May 26, 1998; repealed, SL 2012, ch 194, § 32, effective July 1, 2012.

20:51:09:08. Designated household remedies. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, 24 SDR 160, effective May 26, 1998.

20:51:09:09. Nonprescription drugs defined. Repealed.

Source: 24 SDR 160, effective May 26, 1998; repealed, SL 2012, ch 194, § 33, effective July 1, 2012.

CHAPTER 20:51:10

POISONS

Section

20:51:10:01. Poison definitions. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, SL 2012, ch 194, § 34, effective July 1, 2012.

20:51:10:02. Pharmacist exempts from display and sale. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

20:51:10:03. Exemptions. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

20:51:10:04. License period. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

20:51:10:05. Poisons can only be sold in original packages. Repealed

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

20:51:10:06. Licenses may be revoked. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

20:51:10:07. Poison license number must be entered on wholesale purchase order. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

20:51:10:08. Any vendor of poisons must show poison license number on invoices. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

20:51:10:09. Designated poisons. Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, SL 2012, ch 194, § 35, effective July 1, 2012.

CHAPTER 20:51:11

PATENT AND PROPRIETARY MEDICINES

(Repealed. 12 SDR 86, effective November 27, 1985)

CHAPTER 20:51:12

WHOLESALE DRUGS AND MEDICINES

(Repealed. 12 SDR 86, effective November 27, 1985)

CHAPTER 20:51:13

SPECIAL RESTRICTIONS

Section

20:51:13:01. Substitution of drugs prohibited. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

20:51:13:02. Return of unused drugs. Pharmacists 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 drugs by patients in hospice programs, nursing facilities, or assisted living facilities. Only unused unit dose 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 unit dose drug being returned to the pharmacy and that the unit dose 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 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;

(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 prepackaged or repackaged container must be labeled in accordance with this regulation. Labeling must include the following:

(a) Name and strength of the medication;

(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 unit dose 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.

20:51:13:02.02. Redispensing drugs to patient for whom prescribed. Repealed.

Source: 11 SDR 151, effective May 15, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; repealed, 29 SDR 37, effective September 26, 2002.

20:51:13:02.03. Redispensing unit dose drugs returned from hospice programs, nursing facilities, or assisted living facilities. Unused unit dose 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;

(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 dose package by the pharmacy may be redispensed into a unit dose distribution system and mixed with drugs of a different lot number provided that all lot numbers and expiration dates are placed on the unit dose package;

(4) Drugs may be removed from a unit dose 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 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 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.
Law Implemented: SDCL 36-11-11.

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.
Law Implemented: SDCL 36-11-11.

CHAPTER 20:51:14

GENERAL ADMINISTRATION

Section

20:51:14:01. Annual certificate renewal. The fee for annual certificate renewal is $125. Certificates 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.

20:51:14:02. Reinstatement of certificates. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

20:51:14:03. Reciprocity requirements. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

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).

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).

If, during the COVID-19 emergency, a pharmacist is unable to fill a product with an AB rated product, the pharmacist may select a therapeutically equivalent drug product if unable to reach the prescriber. Notification should be made to the prescriber.

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).

Reference: Approved Drug Products with Therapeutic Equivalence Evaluations, 19th Edition, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, 1999. Copies may be obtained from Superintendent of Documents, U.S. Government Printing Office, PO Box 371954, Pittsburgh, PA 15250-7954; cost $78.

CHAPTER 20:51:15

PHARMACIES IN HOSPITALS, NURSING FACILITIES, OR RELATED FACILITIES

Section

20:51:15:01. Definition and general provisions. Definitions and general provisions used in this chapter are as follows:

(1) The terms "part-time," "limited," or "conditional" pharmacy, mean the providing of pharmaceutical services by a registered pharmacist under a pharmacy license issued by the South Dakota Board of Pharmacy 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," a person licensed by the South Dakota State Board of Pharmacy, to prepare, compound, and dispense physicians' prescriptions, drugs, medicines, and poisons, and whose license has not been revoked or suspended;

(3) The term "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 prescription 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) requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training;

(4) "Compounding," 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, 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," 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," a coordinated program of inpatient services providing palliative rather than curative care for a patient.

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.
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 pharmacist.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986.
General Authority: SDCL 36-11-11.
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 South Dakota Board of Pharmacy and shall have a registered 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.
Law Implemented: SDCL 36-11-33.

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

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

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

20:51:15:07. Preparing a solution. The preparation of a solution by a licensed nurse for injection by a licensed nurse is considered 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.
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.
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.

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

20:51:15:10. Registration and renewal. The board may issue to a pharmacist in good standing a permit to conduct a part-time, limited, or conditional pharmacy in a hospital, nursing facility, or related facility for the fiscal year ending June thirtieth if the pharmacist applies yearly on a form supplied by the board and pays a fee of $160. During the COVID-19 emergency, if the pharmacy is temporarily closed, or the pharmacist in charge is ill, a 30 day extension is allowed

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), 36-11-32.
Law Implemented: SDCL 36-11-33.

Cross-Reference: Pharmacy registration, ch 20:51:06; Minimum equipment requirements, ch 20:51:07.

20:51:15:11. Schedule of attendance by pharmacist. A registered 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.
Law Implemented: SDCL 36-11-33.

20:51:15:12. Supervision of drugs located in areas other than pharmacy. Drugs, medications and poisons located in areas of the facility other than in the pharmacy shall be under the general supervision of the registered 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.
Law Implemented: SDCL 36-11-33.

20:51:15:13. Access to pharmacy -- Records. Only a registered 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 when the drug is not available in floor supplies or the emergency drug kit, to meet the immediate need in an emergency. This nurse shall leave in the pharmacy, on a suitable form, a record of any drugs removed, showing the name of the patient, the name of the drug, dosage size, amount taken, the date and the time, and signed by the nurse. Further, 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 years.

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

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 registered 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.
Law Implemented: SDCL 36-11-33.

20:51:15:15. Pharmacist controls emergency drugs in health care facilities. A pharmacist of a registered pharmacy in a health care facility may provide, upon written request of the health care facility's physicians, 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 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 shall inventory 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 pharmacist may provide to a nursing facility a limited quantity of controlled legend drugs pursuant to § 44:04:08:07.01 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 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) The provider pharmacist shall be notified of any drug taken from the emergency kit;

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

(7) 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.

On a case by case basis, during the COVID-19 emergency, the Board may waive the quantity limits in an emergency kit.

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.

20:51:15:16. Minimum standards for pharmacy service. Pharmacy service pursuant to 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.

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.
Law Implemented: SDCL 36-11-33.

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.

20:51:15:17. Federal and state statutes control. Repealed.

Source: SL 1975, ch 16, § 1; repealed, 12 SDR 86, effective November 27, 1985.

CHAPTER 20:51:16

RULES OF PROFESSIONAL CONDUCT

Section

20:51:16:01. Primary obligation is service. Repealed.

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

20:51:16:02. Practice requires knowledge. Repealed.

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

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

(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 practitioner, the pharmacist may apply first aid treatment or administer Naloxone;

(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 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.

20:51:16:05. The pharmacist's relations to fellow pharmacists. In relations to fellow pharmacists, the pharmacist:

(1) Strives to perfect and enlarge the pharmacist's professional knowledge. The pharmacist contributes to the scientific progress of the profession of pharmacy and encourages and participates in research, investigation, and study. The pharmacist keeps informed regarding professional matters by reading current pharmaceutical, scientific, and medical literature, attending seminars and other means;

(2) Seeks to attract to the profession of pharmacy youths of good character and intellectual capacity and aids in their instruction;

(3) The pharmacist associates with organizations having for their objective the betterment of the pharmaceutical profession and contributes time, energy, and funds to carry on the work of these organizations;

(4) The pharmacist keeps the pharmacist's reputation in public esteem by continuously giving the kind of professional service that earns its own reward. The pharmacist does not engage in any activity or transaction that will bring discredit or criticism to self or to the profession;

(5) The pharmacist will expose any corrupt or dishonest conduct of any member of the profession which comes to the pharmacist's certain knowledge, through those accredited processes provided by the civil laws of the rules and regulations of pharmaceutical organizations, and the pharmacist will aid in driving the unworthy out of the calling;

(6) The pharmacist does not lend support or the pharmacist's name to the promotion of objectionable or unworthy products;

(7) The pharmacist courteously aids a fellow pharmacist who may request advice or professional information or who, in an emergency, may need supplies;

(8) The pharmacist will not imitate the labels of a competitor or attempt to take any unfair advantage of a competitor's professional or commercial success. The pharmacist does not fill orders that the pharmacist knows are intended for a competitor. The pharmacist deals fairly with manufacturers and wholesalers and recognizes the significance and legal aspects of brand names and trademarked products. The pharmacist adheres to fair business practices, meets obligations promptly and fulfills agreements and contracts; and

(9) The pharmacist is proud to display in the pharmacist's establishment the pharmacist's own name and the names of other pharmacists employed by the pharmacist.

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.

CHAPTER 20:51:17

AUTOMATED MECHANICAL DISTRIBUTION DEVICES

Section

20:51:17:01. Definitions. Terms used in this chapter mean:

(1) "Automated mechanical distribution device," a mechanical device that delivers a drug or drug device 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) "Health care facility," any state licensed hospital, nursing facility, or related facility that offers supervised care of the sick or injured;

(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," the pharmacist named on the pharmacy permit issued by the Board of Pharmacy 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).
Law Implemented: SDCL 36-11-11(6).

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.

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 from an automated mechanical distribution device until the 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).
Law Implemented: SDCL 36-11-11(6).

20:51:17:02. Procedures for distributing drugs in automated mechanical distribution device. Drugs may be distributed by an automated mechanical distribution device under the following conditions:

(1) The automated mechanical distribution device is controlled by the pharmacist permittee. The pharmacist permittee shall develop policies and procedures to address all situations in which drugs are 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. The health care facility pharmacist shall maintain electronic or written stocking 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 shall designate the person that may have access to that portion, section, 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;

(9) Notwithstanding any of the provisions in this section, the pharmacist permittee of the health care facility pharmacy is responsible for maintaining and enforcing written procedures that establish safeguards for distributing drugs and medicines through the automated mechanical distribution 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).
Law Implemented: SDCL 36-11-11(6).

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.

CHAPTER 20:51:18

POSTING OF PRESCRIPTION DRUG PRICES

(Repealed. 3 SDR 45, effective December 18, 1976)

CHAPTER 20:51:19

CONTINUING EDUCATION

Section

20:51:19:01. Continuing professional education defined. As used in this chapter continuing professional education is accredited, post-registration 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.

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).

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, an active pharmacist must successfully complete 12 hours of continuing education. The 12 hours of continuing education required each year for relicensure must be completed within the 24 months before the pharmacist's certificate of registration expires. When a pharmacist applies for yearly renewal of the pharmacist's certificate of registration pursuant to SDCL 36-11-23, the pharmacist must report completed continuing education hours on a form supplied by the board.

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.

Law Implemented: SDCL 36-11-23.2, 36-11-23.3.

20:51:19:03.01. Extension of time for good cause. For good cause, the board may grant to a pharmacist an extension of time, not exceeding six months, in which to comply with the continuing education requirement in § 20:51:19:03.

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.

20:51:19:04. 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 relative to maintaining the competency of a registrant.

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.

20:51:19:05. 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.

Law Implemented: SDCL 36-11-23.2.

20:51:19:05.01. Audit to verify hours earned. The secretary of the Board of Pharmacy 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 may accept comparable continuing education hours approved by other state boards of pharmacy and 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.
Law Implemented: SDCL 36-11-23.2.

20:51:19:07. Newly licensed registrants. 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 until relicensure.

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.

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.
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. 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 backup material, such as a brochure, a critique of material covered, a script, or a cassette or book for a correspondence course.

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.
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 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 participating;
(5) General title of program;
(6) Type 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.
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.
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.
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 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.
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.
Law Implemented: SDCL 36-11-23.2.

20:51:19:16. Sponsor to provide list of pharmacists attending program. The sponsor of a continuing education program shall provide to the Board of Pharmacy a written list of the pharmacists attending within 45 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.
Law Implemented: SDCL 36-11-23.2.

CHAPTER 20:51:20

COMPUTER PHARMACY

Section

20:51:20:01. Input of drug information into electronic data processing to be by pharmacist or under supervision of pharmacist. When electronic data processing equipment is employed by any pharmacy, input of drug information shall be performed only by a pharmacist or under the immediate and personal supervision of a pharmacist. 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 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.
Law Implemented: SDCL 36-11-11.

20:51:20:02. Requirements for storing prescription information. Electronic data processing equipment, when used to store prescription information, shall meet the following requirements:

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

(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 § 20:51:05:06;

(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.

Source: 5 SDR 77, effective March 20, 1979; 12 SDR 151, 12 SDR 155, effective July 1, 1986.
General Authority: SDCL 36-11-11.
Law Implemented: SDCL 36-11-11.

20:51:20:03. Original prescription to be retained. The original prescription order shall be retained manually or electronically according to law.

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.
Law Implemented: SDCL 36-11-11.

20:51:20:04. Use of common electronic data base. Upon approval of the Board of Pharmacy, two or more pharmacies licensed by the board may utilize a common electronic data base 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 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 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), 36-11-19.2.
Law Implemented: SDCL 36-11-11(13), 36-11-19.2.

CHAPTER 20:51:21

UNIT DOSE SYSTEMS

Section

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

(1) "Automated mechanical distribution device," see § 20:51:17:01 for definition and use;

(2) "Container," 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," a package that contains two or more drugs per compartment;

(4) "Prepackage," 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," 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," 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," a drug package system in which individual doses are not packaged in unit dose packages or unit of issue packages;

(8) "Unit dose," 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," 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," 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," 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 with direct supervision of a pharmacist. Such packaged drugs may only be dispensed or distributed from the premises where 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 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).

20:51:21:02. Transferred to § 20:51:21:01.

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.

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).

20:51:21:04. Pharmacist to select the medication. Repealed.

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

20:51:21:05. Labeling of unit dose package -- Relabeling of unit dose system. Unit dose 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.

After any change in dosage or administration schedule, the pharmacy shall relabel the unit dose system 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 unit dose package. If a specific drug is recalled, all doses labeled with the lot number of the recalled drug shall be removed from the unit dose system. In addition, all doses of that drug not labeled with a lot number shall be removed from the unit dose 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).

20:51:21:05.02. Manufacturer packaging. If the unit dose package or unit of issue package is obtained from the manufacturer and complies with applicable federal requirements, such packaging may be dispensed without the additional labeling as required in § 20:51:21:05.

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).

20:51:21:06. Pharmacist to maintain drug profile. A pharmacist shall maintain a drug profile for each patient whose drugs are delivered in a unit dose 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 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. Definitions. Repealed.

Source: 26 SDR 92, effective January 6, 2000; repealed, 31 SDR 35, effective September 19, 2004.

20:51:22:01. Practice of pharmacy defined. Repealed.

Source: 12 SDR 82, effective November 19, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; repealed, 31 SDR 35, effective September 19, 2004.

20:51:22:02. Pharmacy intern may assist the pharmacist. Repealed.

Source: 12 SDR 82, effective November 19, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 26 SDR 92, effective January 6, 2000; repealed, 31 SDR 35, effective September 19, 2004.

20:51:22:03. Support person may assist the pharmacist. Repealed.

Source: 12 SDR 82, effective November 19, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 13 SDR 179, effective June 2, 1987; 26 SDR 92, effective January 6, 2000; repealed, 31 SDR 35, effective September 19, 2004.

20:51:22:04. Number of support persons allowed. Repealed.

Source: 12 SDR 82, effective November 19, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 21 SDR 35, effective August 30, 1994; repealed, 31 SDR 35, effective September 19, 2004.

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, and clerical functions. Support personnel are expected to perform their duties outside the dispensing area of the pharmacy.

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

CHAPTER 20:51:23

TRANSFER OF PRESCRIPTION INFORMATION

Section

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 authorized on the original prescription;
(2) The transfer is communicated directly between two licensed pharmacists; and
(3) Both the original and the transferred prescriptions are kept for two years from the date of the last refill.

During the COVID-19 emergency, the number of refills is waived and interns may transfer prescriptions. Further, if unable to reach the original pharmacy, a pharmacist may fill one 30-day supply based upon a patient's prescription container with medication name and strength, and directions for use, using the same prescriber. Pharmacist must notify pharmacy and prescriber once able to reach them.

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

20:51:23:02. Requirements of transferring pharmacist. The pharmacist 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 receiving the prescription information;
(c) The name of the pharmacist 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.
Law Implemented: SDCL 36-11-11.

20:51:23:03. Requirements of receiving pharmacist. The pharmacist 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 the pharmacist transferring the prescription information.

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

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.
Law Implemented: SDCL 36-11-11.

20:51:23:05. Pharmacies with electronic data processing equipment. Pharmacies with electronic data processing equipment need not record information on the original prescription if the data processing system 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 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.
Law Implemented: SDCL 36-11-11.

20:51:23:06. Exemption for pharmacies using common electronic data base. Pharmacies electronically accessing the same prescription records on a common electronic data base 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.
Law Implemented: SDCL 36-11-11.

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.

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

20:51:24:04 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.

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 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.

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

20:51:24:03. Reasonable effort to obtain information. A reasonable effort to obtain information is an oral or written request for the information listed in § 20:51:24:02 made by the pharmacist or a designee to the patient or the patient's caregiver.

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 one year 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. Terms used in this chapter mean:

(1) "Adverse medical result," a clinically significant undesirable effect experienced by a patient as a result of a course of drug therapy;
(2) "Caregiver," 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;

(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;

(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 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 in 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;

(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);

(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 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.

20:51:25:04. Standards for counseling. The pharmacist is responsible for meeting standards for counseling as follows:

(1) If a prescription drug is dispensed for the first time to a patient, the pharmacist shall orally counsel the patient or caregiver in person whenever practicable. If the prescription drug is delivered or mailed, the pharmacist shall initiate counseling by telephone. If the counseling cannot be completed by telephone, the pharmacist may use alternative forms of patient information;

(2) If a prescription drug has been previously dispensed to a patient and review of the patient's record reveals any condition listed in § 20:51:25:02, the pharmacist shall orally counsel the patient or caregiver in person whenever practicable. If the prescription drug is delivered or mailed, the pharmacist shall initiate counseling by telephone. If the counseling cannot be completed by telephone, the pharmacist may use alternative forms of information;

(3) If a prescription drug has been previously dispensed to a patient and the patient's record shows no change in the dosage, form, strength, or directions for use, the pharmacist or designee may offer counseling to a patient or caregiver in one or more of the following ways:

(a) Face-to-face;
(b) By a notation affixed to or written on the bag in which the prescription is dispensed; or
(c) By telephone.

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

20:51:25:05. Alternative forms of patient information. Alternative forms of patient information include written information leaflets, pictogram labels, video programs, or information generated by electronic data processing equipment. When used to replace oral counseling, alternative forms of patient information shall advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy, by toll-free telephone, or by collect telephone call. Alternative forms of patient information may also be used to supplement patient counseling.

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

20:51:25:06. Record of counseling. The absence of a record signifies that counseling was accepted and provided or that an offer was made. Failure to complete counseling to a patient or caregiver shall be recorded for the following instances:

(1) The patient or caregiver refuses to accept the pharmacist's personal oral counseling;
(2) Counseling was not practicable; or
(3) Counseling could not be accomplished by telephone contact.

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
NONRESIDENT PHARMACY REGISTRATION

Section

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

(1) "Home state," 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).
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 in the home state or any other state within the last three 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.

During the COVID-19 emergency, a non-resident pharmacy may ship medications to a patient in South Dakota without a license, thereby waiving 20:51:27:02..

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

During the COVID-19 emergency, a non-resident pharmacy may ship medications to a patient in South Dakota without a license, thereby waiving 20:51:27:03.

Source: 24 SDR 40, effective October 5, 1997; 24 SDR 160, effective May 26, 1998.
General Authority: SDCL 36-11-11(4), 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. The pharmacist in charge of a nonresident pharmacy shall report any changes 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. The license of a nonresident pharmacy is not transferable to a new ownership. Any new ownership of a nonresident pharmacy must apply for licensure pursuant to § 20:51:27:02.

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

CHAPTER 20:51:28

ADMINISTRATION OF INFLUENZA IMMUNIZATIONS

Section

20:51:28:01. Authority to administer influenza immunizations. A pharmacist may administer influenza immunizations to eligible patients eighteen 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, 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 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.

During the COVID-19 emergency, a pharmacist who is trained to administer immunizations, may do so without the authorization from the Board if needed to take care of patients. If unable to obtain renewed cardiopulmonary resuscitation credentials, immunization authorization renewals may be granted if credentials are expired by no more than one year.

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.

20:51:28:03. 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.

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.

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.

20:51:28:05. 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;

(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 provider, as identified by the patient;

(5) The name of the pharmacist 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) The name of the vaccine information sheet provided to the patient.

The pharmacist must provide a written report to the patient's primary health care provider of the above information 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, 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, 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 by September 30. Any pharmacists desiring to renew the authorization shall provide the following documentation to the board:

(1) Current certification in basic cardiopulmonary resuscitation; and

(2) Certificate of completion of a minimum of two hours of continuing education related to immunizations.

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.

CHAPTER 20:51:29

REGISTERED PHARMACY TECHNICIANS

Section

20:51:29:00. Definitions.

(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) "Pharmacy technician-in-training," an individual who is registered with the board to receive on-the-job training in a licensed pharmacy for preparation for registration as a pharmacy technician.

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

20:51:29:01. Purpose of registration. A registration program for 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).
Law Implemented: SDCL 36-11-11(14).

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

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. During a COVID-19 emergency, this rule is waived if necessary to care for patients.

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).

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

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

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

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.

During the COVID-19 emergency, the Certification of Technicians within two years of being hired is waived.

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

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

(1) Information sufficient to identify the applicant including name, address, phone number, date of birth, gender, and social security number;
(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).
Law Implemented: SDCL 36-11-11(14).

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

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

20:51:29:10. Sworn signature. The applicant shall sign 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).
Law Implemented: SDCL 36-11-11(14).

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

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

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

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

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

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

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

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, except during the COVID-19 emergency where the pharmacist in charge may determine the ratio. 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).
Law Implemented: SDCL 36-11-11(14).

20:51:29:19.01. Exception to ratio for mail service pharmacy. Repealed.

Source: 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009; repealed, 42 SDR 19, effective August 19, 2015.

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. 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 insure 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 schedule II 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).
Law Implemented: SDCL 36-11-11(14).

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 dispensing device approved by the board. After proper checking and verification with the physician orders by the pharmacist, the technician may replace medications to the automated dispensing device that have been checked by the pharmacist. The pharmacist is not required to accompany the technician when placing medications into the automated dispensing device. The automated dispensing 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).
Law Implemented: SDCL 36-11-11(14).

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, or by the prescriber's agent;

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

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;

(5) Accept new oral prescription medication orders communicated to the pharmacy by a prescriber or the prescriber's agent; or

(6) Open, keep open, or provide pharmaceutical services from a pharmacy without a pharmacist being present as provided in §§ 20:51:06:11, 20:51:15:02, and 20:51:15:04.

A violation of this section constitutes illegal conduct or practice and may be grounds for disciplinary action as provided in § 20:51:29:27.

During the COVID-19 emergency, this rule is waived with tasks to be determined by the supervising pharmacist.

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

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

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 prescriber, 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).
Law Implemented: SDCL 36-11-11(14).

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

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

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

CHAPTER 20:51:30

TELEPHARMACY

Section

20:51:30:01. Definitions. Terms used in this chapter mean:

(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),(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, except during the COVID-19 emergency as needed. 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), 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 to conduct 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), 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), 36-11-72(1).
Law Implemented: SDCL 36-11-71, 36-11-72.

20:51:30:05. License renewal. A remote pharmacy license expires on June 30 of each year, except during a COVID-19 emergency when a 30 day grace period is extended, and may be renewed annually by filing an application provided by the board. The renewal fee is $200.

Source: 35 SDR 183, effective February 2, 2009.
General Authority: SDCL 36-11-72(1).
Law Implemented: SDCL 36-11-72(1).

20:51:30:06. License required. Any pharmacy licensed by the board may operate a remote pharmacy in South Dakota. The remote pharmacy is considered an extension of the central pharmacy. However, the remote pharmacy must have its own license as a pharmacy.

Source: 35 SDR 183, effective February 2, 2009.
General Authority: SDCL 36-11-72(1).
Law Implemented: SDCL 36-11-72(1).

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), 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), 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), 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), 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), 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. During the COVID-19 emergency, technician and intern staffing experience requirements are waived if needed.

Source: 35 SDR 183, effective February 2, 2009.
General Authority: SDCL 36-11-11(1), 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 allowed in accordance with § 20:51:29:19. The total number of allowed technicians may be divided between the central pharmacy and the remote pharmacy in any manner, except during the COVID-19 emergency. 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), 36-11-72(3).
Law Implemented: SDCL 36-11-72(3).

20:51:30:14. Prescription workload. Any central pharmacy providing telepharmacy services shall provide pharmacist staffing to meet the prescription workload of both the central pharmacy and the remote pharmacy.

Source: 35 SDR 183, effective February 2, 2009.
General Authority: SDCL 36-11-11(1), 36-11-72(3).
Law Implemented: SDCL 36-11-72(3).

20:51:30:15. Requirements for prescription orders. Only a registered pharmacist 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 interpreted by 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 the dispensing process. This prescription certification process must be done in real time. All prescription certification 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), 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.
During the COVID-19 emergency, the inspection on weekly intervals is waived as is the monthly inventory of controlled substances.

Source: 35 SDR 183, effective February 2, 2009.
General Authority: SDCL 36-11-11(1), 36-11-72(4),(5).
Law Implemented: SDCL 36-11-72(4),(5).

20:51:30:18. Use of automated mechanical dispensing device. If the remote pharmacy uses an automated mechanical dispensing device, the stocking and loading of this device must either be checked by a pharmacist, prior to use, or employ a secure bar coding system or its equivalent. Policies and procedures consistent with § 20:51:17:02 regarding the operation of the automated mechanical distribution system 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), 36-11-72(6).
Law Implemented: SDCL 36-11-11(6), 36-11-72(6).

CHAPTER 20:51:31

STERILE COMPOUNDING PRACTICES

Section

20:51:31:01. Definitions. Terms used in this chapter mean:

(1) "Ante area," an ISO Class 8 or superior area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, preparation labeling, and other high-particulate generating activities;

(2) "Aseptic preparation," the technique involving procedures designed to preclude contamination by microorganisms during processing;

(3) "Batch preparation," compounding or repackaging of multiple units, in a single process, by the same operator;

(4) "Beyond-use date," the date or time following compounding after which the preparation may not be stored, transported, or used. The beyond-use date is determined from the date or time compounding of the preparation is completed;

(5) "Biological safety cabinet, Class II" or "BSC," a ventilated cabinet having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection;

(6) "Buffer area," a clean room or area where the primary engineering control device is physically located and in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class;

(7) "Compounding," the constitution, reconstitution, combination, dilution, or another process causing a change in the form, composition, or strength of any ingredient or any other attribute of a product;

(8) "Compounding aseptic isolator" or "CAI," a form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations;

(9) "Critical site," a location that includes any component or fluid pathway surfaces (such as injection ports) or openings (such as opened ampoules or needle hubs) exposed and at risk of direct contact with air, moisture, or touch contamination;

(10) "Hazardous drug," a pharmaceutical that is antineoplastic, carcinogenic, mutagenic, or teratogenic;

(11) "HEPA filter," a high efficiency particulate air filter where air is forced through in a uniform flow and 99.97 percent of all particles three-tenths (0.3) microns or larger are removed;

(12) "High-risk preparation," a sterile preparation that is compounded from nonsterile ingredients; that is compounded with nonsterile components, containers, or equipment and requires terminal sterilization; or that meets the conditions of § 20:51:31:21;

(13) "ISO (International Organization for Standardization) Classification of Particulate Matter in Room Air," limits in particles of 0.5 microns or larger in diameter per cubic foot of air:

(a) ISO Class 5, less than 100 particles per cubic foot;
(b) ISO Class 7, less than 10,000 per cubic foot; and
(c) ISO Class 8, less than 100,000 per cubic foot;

(14) "Laminar airflow workbench," or "LAFW," an apparatus designed to provide an ISO Class 5 environment for the preparation of sterile products that uses air circulation in a defined direction that passes through a HEPA filter to remove the initial particles and the particles generated within the controlled environment;

(15) "Low-risk preparation," a sterile preparation that is compounded with sterile equipment, sterile ingredients, and sterile contact surfaces or that meets the conditions of § 20:51:31:19;

(16) Medium-risk preparation," a sterile preparation that is compounded with sterile equipment, sterile ingredients, and sterile contact surfaces and involves complex or numerous manipulations of a sterile product or that meets the conditions of § 20:51:31:20;

(17) "Media-fill test" or "MFT," a test used to validate aseptic technique of compounding personnel or of processes and to ensure that the processes used are able to produce a sterile product without microbial contamination;

(18) "Multiple-dose container," a multiple-unit container for articles or preparations intended for parenteral administration only usually containing antimicrobial preservatives;

(19) "Negative pressure room," a room that is at a lower pressure compared to adjacent spaces, creating a new airflow into the room;

(20) "Positive pressure room," a room that is at a higher pressure compared to adjacent spaces, creating a net airflow out of the room;

(21) "Preparation" or "compounded sterile preparation," a sterile drug or nutrient that is compounded in a licensed pharmacy or other health care-related facility pursuant to the order of a licensed prescriber, which preparation may or may not contain sterile products;

(22) "Product," a commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA; and

(23) "Sterile compounding," the aseptic processing in a clean air environment of any pharmaceutical including the following preparations that are required to be sterile when they are administered to patients; baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, and suspensions), aqueous bronchial and nasal inhalations, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1),(3),(4), and (5).
Law Implemented: SDCL 36-11-11, 36-11-41.

20:51:31:02. Standards and procedures. The standards and procedures outlined in this chapter apply to pharmacy practice when a preparation:

(1) Is prepared according to the manufacturer's labeled instructions and requires other manipulations that expose the original contents to potential contamination;

(2) Contains nonsterile ingredients or employs nonsterile components or devices that must be sterilized before administration; or

(3) Is a biologic, diagnostic, drug, or nutrient that possesses characteristics of either subdivision (1) or (2) of this section and includes the following preparations that are required to be sterile when they are administered to patients: baths and soaks for live organs and tissues, injections, aqueous bronchial and nasal inhalations, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1) and (4).
Law Implemented: SDCL 36-11-11.

20:51:31:03. Manual required. Each pharmacy shall prepare, implement, maintain, and adhere to a written policy and procedure manual for the compounding, dispensing, administration, storage, and use of sterile preparations. The manual shall be available for inspection by the board. The manual shall address the following:

(1) Responsibilities of compounding personnel;
(2) Personnel training and testing;
(3) Competency practices and assessment of compounding personnel;
(4) Quality assurance as described in § 20:51:31:12;
(5) Proper use and deployment of environmental controls;
(6) Gowning and garbing practices;
(7) Inspection of finished products, labeling, storage, and transfer to final use areas for storage or use;
(8) Introduction of supplies and products into the compounding area; and
(9) The formulation, process for compounding, beyond-use dating, and storage requirements for each routinely compounded sterile preparation.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1) and (4).
Law Implemented: SDCL 36-11-11.

20:51:31:04. Physical environment requirements for sterile products. The pharmacy shall have a designated area for compounding sterile preparations with entry restricted to designated personnel. The area shall be used only for sterile compounding. The area shall be structurally isolated from other areas and shall be designed to avoid unnecessary traffic and airflow disturbances. The area shall be of sufficient size to accommodate at least one primary engineering control device and to provide for the storage of drugs and supplies under appropriate temperature, light, moisture, sanitation, ventilation, and security conditions.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1), (3), and (4).
Law Implemented: SDCL 36-11-11.

20:51:31:05. Requirement for primary engineering control device or room. The primary engineering control device or room shall be capable of maintaining at least ISO Class 5 air quality in the area where critical objects are exposed and critical activities are performed. The device shall be capable of maintaining ISO Class 5 air quality during normal activity. A primary engineering control device includes, but is not limited to, a horizontal or vertical laminar airflow workbench or CAI.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1), (4), and (5).
Law Implemented: SDCL 36-11-11, 36-11-41.

20:51:31:06. Placement of primary engineering control device. The primary engineering control device shall be placed in a room where HEPA filters are employed and the air quality is maintained at ISO Class 7. This area shall have cleanable, non-shedding, smooth surfaces; all junctures shall be coved; and all cracks and crevices shall be caulked. The ceiling shall be impervious and hydrophobic. The room may not contain any drains or sinks. Only the furniture, equipment, supplies, and other material required for compounding activities to be performed shall be brought into the room. Such items brought into the room shall be cleaned and disinfected. Placement in rooms of objects and devices not essential to the compounding process is dictated by the measured

effect of those objects and devices on the required environmental quality of air atmospheres and surfaces.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1), (4), and (5).
Law Implemented: SDCL 36-11-11, 36-11-41.

20:51:31:07. Compounding aseptic isolator (CAI). A CAI is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer process. Air exchange into the isolator from the surrounding environment should not occur unless it has first passed through a microbially retentive filter, HEPA minimum.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1), (4), and (5).
Law Implemented: SDCL 36-11-11, 36-11-41.

20:51:31:08. Exception for placement of CAI. The CAI shall be placed in an ISO Class 7 room unless the CAI meets each of the following conditions:

(1) The CAI provides isolation from the room and maintains ISO Class 5 conditions when ingredients, components, and devices are transferred into and out of the CAI during the preparation process; and

(2) The manufacturer provides documentation verifying that the CAI meets the standard in subdivision (1) when the CAI is located in an environment inferior to ISO Class 7.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1), (4), and (5).
Law Implemented: SDCL 36-11-11, 36-11-41.

20:51:31:09. Ante area requirements. An ante area shall be located adjacent to the buffer area and maintained at ISO Class 8 air quality. If the ante area is adjacent to a negative pressure room, then the ante area must maintain ISO Class 7 air quality.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1), (4), and (5).
Law Implemented: SDCL 36-11-11, 36-11-41.

20:51:31:10. Delayed implementation. A pharmacy whose sterile compounding area is in substantial compliance with the physical and structural requirements of this chapter may engage in the compounding of sterile preparations pursuant to the practice standards established by this chapter. However, any pharmacy engaged in the compounding of sterile preparations shall, no later than December 31, 2011, complete any necessary changes or improvements to the sterile compounding area to ensure compliance with the physical and structural requirements of this chapter.

Any pharmacy that commences operation after December 31, 2010, or any new construction or remodeling of a pharmacy sterile compounding area completed after December 31, 2010, shall comply with the physical and structural requirements of this chapter.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1), (4), and (5)
Law Implemented: SDCL 36-11-11, 36-11-41.

20:51:31:11. Cleaning, maintenance, and supplies. The pharmacy shall have the following appropriate equipment and supplies and documented procedures for maintaining an environment suitable for the aseptic processing of sterile preparations:

(1) Required supplies and equipment shall include the following:

(a) Appropriate attire, including non-shedding coveralls or gowns, head and facial covers, face masks, appropriate gloves, and shoe covers; and

(b) A sink with hot and cold running water, with soap available for the purpose of hand and forearm scrubs, which shall be located convenient to the area used for compounding sterile preparations but outside the room; and

(2) Documented procedures shall include the following:

(a) Specific cleaning procedures and frequencies for each compounding area involved;

(b) A list of approved cleaning agents for each procedure;

(c) A written plan and schedule for the evaluation of airborne microorganisms in each controlled air environment (e.g., LAFW, barrier isolators, room, and ante area);

(d) Equipment calibration and monitoring of proper function of equipment, apparatus, and devices used to compound sterile preparations, in accordance with § 20:51:31:25; and

(e) An appropriate cleansing and garbing procedure. Coveralls and gowns may be hung outside the entry of the room and reused for one shift, if the coveralls and gowns are not visibly soiled and have not been worn during the compounding of hazardous drugs.

During the COVID-19 emergency, garbing required for sterile compounding which should be used one time may be re-used per the guidance by the United States Pharmacopeia, Critical Point, or the Centers for Disease control.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1), (3), and (5)
Law Implemented: SDCL 36-11-11, 36-11-41, 36-11-42.

20:51:31:12. Additional records required. In addition to records required in § 20:51:24:02, the pharmacy shall maintain records of lot numbers of the components used in compounding sterile products if:

(1) The preparation will be dispensed to a home care patient; or
(2) Non-sterile ingredients are used in preparing high risk sterile products.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1) and (4).
Law Implemented: SDCL 36-11-11.

20:51:31:13. Quality assurance. The pharmacy shall establish, implement, and document an ongoing quality assurance program in order to maintain and improve facilities, equipment, personnel performance, and the provision of patient care. The two portions of the quality assurance program are as follows:

(1) Monitoring facilities, equipment, and personnel performance, which shall include the following:

(a) Methods for verification of automated compounding devices for parenteral nutrition compounding;

(b) Methods for sampling finished preparations to ensure that the pharmacy is capable of consistently preparing sterile preparations that meet appropriate risk level specifications and to ensure product integrity;

(c) Procedures for inspection of all prescription orders, written compounding procedures, preparation records, and materials used to compound at all contamination risk levels, to ensure accuracy of ingredients, aseptic mixing, sterilizing, packaging, labeling, and expected physical appearance of the finished preparation;

(d) Procedures for visual inspection of preparations to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling;

(e) Procedures for review of all orders and packages of ingredients to ensure that the correct ingredients and quantity of ingredients were compounded;

(f) Methods for routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality;

(g) Methods for ensuring personnel qualifications, training, and performance, including periodic performance of applicable MFT procedures;

(h) Procedures for visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments; and

(i) Methods for establishing beyond-use dates of preparation;

(2) Monitoring patient care, which shall include the following:

(a) Utilizing specific procedures for recording, filing, and evaluating reports of adverse events and the quality of preparation identified in the adverse event;

(b) Utilizing written policies and procedures that include specific procedures or instructions for receiving, acknowledging, and dating the receipt of products;

(c) Reviewing documented patient or caregiver education and training required pursuant to § 20:51:31:31;

(d) Ensuring that a qualified pharmacist is available and accessible at all times to respond to the questions and needs of other health professionals, the patient, or the patient's caregiver; and

(e) Identifying activities and processes that are deemed high-risk, high-volume, or problem-prone and providing effective corrective actions to remedy these activities and processes.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1), 36-11-68.
Law Implemented: SDCL 36-11-11.

20:51:31:14. Pharmacist responsibilities. Each pharmacy shall have a pharmacist responsible for ensuring that:

(1) Preparations are accurately identified, measured, diluted, and mixed and are correctly sterilized, packaged, sealed, labeled, stored, dispensed, and distributed;

(2) Cleanliness is maintained, including preservation of the sterile environment during the compounding process;

(3) Beyond-use dates are established based on direct testing or extrapolation from reliable literature sources. The pharmacy shall maintain written justification of the chosen beyond-use date or, if a written statement is not available, a maximum 24-hour expiration shall be used;

(4) Equipment, apparatus, and devices used to compound a preparation are consistently capable of operating properly and within acceptable tolerance limits;

(5) Procedures are followed for measuring, mixing, diluting, sterilizing, packaging, and labeling of the specific preparation;

(6) Packaging selection is appropriate to preserve the sterility and strength of the preparation; and

(7) All functions performed by non-pharmacists are verified by the pharmacist before the preparation is dispensed to the patient. Pharmacist verification of a preparation shall include visual inspection of labeling, physical integrity, and expected appearance, including final fill amount.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1), 36-11-41, 36-11-46.6.
Law Implemented: SDCL 36-11-11.

20:51:31:15. Training documentation. Documentation of training shall verify that compounding personnel are able to adequately complete the following activities:

(1) Perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces;
(2) Select and appropriately don protective garb;

(3) Maintain or achieve sterility of preparations in ISO Class 5 primary engineering control devices;

(4) Identify, weigh, and measure ingredients;

(5) Manipulate sterile products aseptically, sterilize high-risk preparations, and label preparations; and

(6) Protect personnel and compounding environments from contamination by hazardous drugs.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1).
Law Implemented: SDCL 36-11-11.

20:51:31:16. Reference requirements. The pharmacy shall have current reference materials related to sterile products and preparations. References may be printed or computer-accessed. In addition to meeting the requirements set forth in § 20:51:07:04, any pharmacy involved in sterile compounding shall maintain a minimum of one current reference, including access to current periodic updates, from each of the following categories:

(1) An injectable drug compatibility reference; and

(2) If the pharmacy is compounding hazardous drugs, a reference related to hazardous drugs.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1) and (9).
Law Implemented: SDCL 36-11-11.

20:51:31:17. Labeling requirements. A pharmacist shall label containers as follows:

(1) At the time of delivery, a patient-specific dispensing container used for a preparation shall bear a label with at least the following information:

(a) Name and quantity of all contents;

(b) Patient's name;

(c) For home care patient prescriptions, unique serial number or prescription number;

(d) Preparer's and reviewing pharmacist's initials or unique identifiers;

(e) Stability (beyond-use date) as set forth in the pharmacy's policy and procedure manual (unless the contents will be used within 24 hours of preparation);

(f) The prescribed flow rate in ml/hr, if applicable; and

(g) Auxiliary labels as needed;

(2) Each container of a batch preparation that is compounded in anticipation of later dispensing shall bear a label with at least the following information:

(a) Name and quantity of all contents;

(b) Internal code to identify the date and time of preparation and the preparer's and reviewing pharmacist's initials or unique identifiers;

(c) Stability (beyond-use date) as set forth in the pharmacy's policy and procedure manual; and

(d) Auxiliary labels as needed.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1) and (12), 36-11-46.6.
Law Implemented: SDCL 36-11-11.

20:51:31:18. Microbial contamination risk levels. A pharmacist shall assign each preparation the appropriate risk level--low, medium, or high--according to the corresponding probability of contaminating a preparation with microbial contamination such as microbial organisms, spores, and endotoxins, and chemical and physical contamination such as foreign chemicals and physical matter.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1), (3), and (5).
Law Implemented: SDCL 36-11-11.

20:51:31:19. Low-risk preparations. Any preparation compounded under all of the following conditions is at a low risk of contamination:

(1) The preparations are compounded with aseptic manipulations entirely within ISO Class 5 or superior air quality using only sterile ingredients, products, components, and devices;

(2) The compounding involves only transferring, measuring, and mixing no more than three commercially manufactured sterile products and entries into one container (e.g., bag, vial) of sterile product to make the preparation;

(3) Manipulations are limited to aseptically opening ampoules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, containers of other sterile products, and containers for storage and dispensing.

If a low risk preparation does not pass a sterility test but is properly stored before administration, the preparation may be stored under the following conditions and time period restrictions:

(a) At controlled room temperature for 48 hours;
(b) At a cold temperature for 14 days; or
(c) In a solid-frozen state at minus 20 degrees Celsius or colder for 45 days.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2(3), 36-11-11(1).
Law Implemented: SDCL 36-11-11.

Examples: The single-volume transfer of sterile dosage forms from ampoules, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. When ampoules are employed, solution content shall be passed through a sterile filter to remove any particles. The manual measuring and mixing of no more than three manufactured products including an infusion or diluent solution to compound drug admixtures and nutritional solutions.

20:51:31:20. Medium-risk preparations. Any preparation compounded aseptically under low-risk conditions with one or more of the following additional conditions is at a medium risk of contamination:

(1) Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile preparation for administration either to multiple patients or to one patient on multiple occasions;

(2) The compounding process includes complex aseptic manipulations other than the single-volume transfer;

(3) The compounding process requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

If a medium-risk preparation does not pass a sterility test but is properly stored before administration, the preparation may be stored under the following conditions and time period restrictions:

(a) At controlled room temperature for 30 hours;
(b) At a cold temperature for 9 days; or
(c) In a sold-frozen state at minus 20 degrees Celsius or colder for 45 days.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2(3), 36-11-11(1)
Law Implemented: SDCL 36-11-11.

Examples: Examples of medium-risk compounding include:

(1) Compounding total parenteral nutrition fluids, using manual or automated devices and involving multiple injections, detachments, or attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container;

(2) Filling reservoirs of injection or infusion devices with more than three sterile drug products and evacuating air from those reservoirs before dispensing the filled device; and

(3) Transferring volumes from multiple ampoules or vials into one or more final sterile containers.

20:51:31:21. High-risk preparations. Any preparation that is either contaminated or likely to become contaminated with infectious microorganisms when compounded under any of the following conditions is at a high risk of contamination:

(1) Nonsterile ingredients, including manufactured products not intended for sterile use, are incorporated or a nonsterile device is used in the compounding process before terminal sterilization;

(2) Sterile contents of commercially manufactured products, preparations that lack effective antimicrobial preservatives, and sterile surfaces of devices and containers intended for the preparation, transfer, sterilization, and packaging of preparations are exposed to air quality inferior to ISO Class 5 for more than one hour;

(3) Nonsterile procedures such as weighing and mixing in air quality inferior to ISO Class 7 are performed before sterilization, compounding personnel are not properly garbed and gloved, or water-containing preparations are stored for more than six hours;

(4) The chemical purity and content strength of bulk ingredients, whether the ingredients are in opened or unopened packages, are not verified by examination of labeling and documentation of suppliers or by direct determination.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2(3), 36-11-11(1).
Law Implemented: SDCL 36-11-11.

20:51:31:22. Immediate-use preparations. For the purpose of emergency or immediate patient care, a pharmacy is exempt from requirements described in this chapter for low- and medium-risk preparations if all of the following criteria are met:

(1) Only simple aseptic measuring and transfer manipulations are performed with not more than three sterile commercial drug products including an infusion or diluent solution;

(2) Unless required for the preparation, the compounding procedure occurs continuously without delays or interruptions and does not exceed one hour;

(3) At no point during preparation are critical surfaces and ingredients of the preparation directly exposed to contact contamination, such as human touch, cosmetic flakes or particulates, blood, human body substances (e.g., nasal and oral excretions and secretions), and nonsterile inanimate sources;

(4) Unless immediately and completely administered by the person who prepared it, or immediate and complete administration is witnessed by the preparer, the compounded sterile preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact beyond-use date and time; and

(5) Administration begins not later than two hours after compounding of the preparation has begun. If administration has not begun within two hours after compounding of the preparation has begun, the preparation is promptly and safely discarded. Immediate-use preparations may not be stored for later use.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2(3), 36-11-11(1).
Law Implemented: SDCL 36-11-11.

20:51:31:23. Utilization of single-dose and multiple-dose containers. Any pharmacy utilizing single-dose and multiple-dose containers in sterile compounding shall comply with the following requirements:

(1) Single-dose containers that are opened or needle-punctured shall be used within one hour if opened in air quality conditions inferior to ISO Class 5;

(2) Single-dose vials that are continuously exposed to ISO Class 5 air shall be used within six hours after initial needle puncture;

(3) Opened single-dose ampoules may not be stored for any period of time under any air quality conditions;

(4) Multiple-dose containers that are entered or opened shall be used within 28 days of initial entry or opening unless otherwise specified by the manufacturer; and

(5) Multiple-dose and single-dose sterile products may not be combined for use as multiple-dose applications.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1).
Law Implemented: SDCL 36-11-11.

20:51:31:24. Utilization of proprietary bag and vial systems. A pharmacy shall follow the manufacturer's instructions for sterility, storage, and beyond-use times for attached and activated container pairs of drug products for intravascular administration.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1).
Law Implemented: SDCL 36-11-11.

20:51:31:25. Sterilization methods. The pharmacist shall select the sterilization method that complies with the standards identified in United States Pharmacopoeia, Chapter 797.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1).
Law Implemented: SDCL 36-11-11.

Reference: The United States Pharmacopoeia, Thirtieth Revision - The National Formulary, Twenty-Fifth Edition, May 1, 2007, page 337, published by the United States Pharmacopoeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852. Cost: $800.

20:51:31:26. Media-fill testing by personnel. The pharmacy shall develop, maintain, and implement written procedures that include media-fill testing by personnel authorized to compound preparations. The tests shall be performed without interruption in an ISO Class 5 environment under conditions that closely simulate the stressful conditions encountered during compounding of the specific risk level preparations for which the test is intended. The pharmacy shall maintain records of media-fill testing performed, and results of testing procedures shall be available to the board. Compounding personnel whose media-fill test vials result in gross microbial colonization shall be immediately reinstructed and reevaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

Each person authorized to compound low-risk and medium-risk preparations shall annually perform a successful MFT procedure.

Each person authorized to compound high-risk preparations shall semiannually perform a successful MFT procedure.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1).
Law Implemented: SDCL 36-11-11.

20:51:31:27. Environmental monitoring requirements. Each pharmacy shall meet the following environmental requirements:

(1) All buffer areas, laminar airflow workbenches, and barrier isolators shall be certified for operational efficiency at least every six months and whenever the device or room is relocated or altered or whenever major service to the facility is performed. Inspection and certification records shall be maintained for two years from the date of certification; and

(2) The pharmacy shall establish written procedures appropriate for the risk level preparations compounded by the pharmacy. The procedures shall include environmental testing, end testing, and evaluation of validation results of the following:

(a) Microbial sampling of air within the primary engineering control devices, buffer areas, and ante areas is required every six months; and
(b) Unidirectional air flow shall be maintained and validated.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1).
Law Implemented: SDCL 36-11-11.

Note: It is recommended that this be done using a pressure gauge or a velocity meter installed between the buffer area and ante area. In absence of a pressure gauge or velocity meter, unidirectional flow and velocity should be tested and documented semi-annually at the time of hood and room certification.

20:51:31:28. Storage and delivery of sterile preparations. The pharmacy is responsible for proper packaging, labeling, handling, transport, and storage of preparations compounded and dispensed by the pharmacy and for education, training, and supervision of pharmacy and non-pharmacy personnel responsible for such functions. The pharmacy shall establish, maintain, and implement written policies and procedures to ensure product quality and packaging integrity until the preparation is administered. The policies and procedures shall address:

(1) Storage areas -- Controlled temperature storage areas within the pharmacy shall be monitored at least once daily and the results documented on a temperature log. Temperature-sensing mechanisms shall be suitably placed within the storage space to accurately reflect the area's temperature;

(2) Packaging, handling, and transport, including:

(a) Instruction in proper hand washing, aseptic techniques, site care, and change of administration sets to ensure the quality and sterility of the preparation;

(b) Special requirements for those products and techniques for the pharmacy that compounds or prepares products or devices or uses techniques where in-line filtration, automated

infusion control devices, or replenishment of drug products into reservoirs of portable infusion pumps is required;

(c) Provisions for the return to the pharmacy of unused preparations for appropriate disposition. Unused preparations may be redispensed only if the continuing quality and sterility of the preparation can be fully ensured. To avoid contamination of the ISO Class 5 containment area (hood), any returned preparation may not be placed in the containment area unless properly decontaminated. The pharmacist is the sole authority for determining whether a preparation that was not administered as originally intended may be used for an alternate patient or under alternate conditions; and

(d) Handling of hazardous preparations shall identify safeguards intended to maintain the integrity of the preparations and to minimize the exposure potential of these products to the environment and to personnel who have contact with the products.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1).
Law Implemented: SDCL 36-11-11.

20:51:31:29. Additional requirements for preparation of hazardous drugs. Hazardous drugs may only be prepared for administration under conditions that protect pharmacy personnel in the preparation area. The following requirements shall be met by pharmacies that prepare hazardous drugs:

(1) The pharmacist shall prepare policies and procedures to identify requirements for storage and handling of hazardous drugs to prevent contamination and personnel exposure;

(2) Preparations containing hazardous drugs shall be labeled on the primary container and placed in an overwrap bag that is also properly labeled. Prepared doses of dispensed hazardous drugs shall be labeled and distributed in a manner to minimize the risk of accidental rupture of the primary container. Proper labeling shall include any necessary precautions;

(3) All hazardous drugs shall be compounded in a vertical flow Class II or Class III biological safety cabinet or in a compounding aseptic isolator containment and control device with biohazard control capabilities:

(a) The ISO Class 5 BSC or CAI shall be placed in a contained environment where air pressure is negative and where the ISO Class 5 BSC or CAI is appropriately vented to the outside of the building;

(b) If the pharmacy compounds fewer than five preparations per week in a BSC or CAI and uses a closed system vial transfer device to compound the preparations, the BSC or CAI may be located in a positive pressure room;

(4) Personnel compounding hazardous drugs shall wear proper protective apparel in accordance with documented procedures. Protective apparel may include disposable, non-shedding coveralls or gowns with tight cuffs, face masks, eye protection, hair covers, double gloves, and shoe covers;

(5) Proper safety and containment techniques for compounding hazardous drugs shall be used in conjunction with the aseptic techniques required for processing sterile preparations;

(6) All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before personnel prepare or handle hazardous preparations and shall be verified and documented for each person at least annually;

(7) Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements; and

(8) Each pharmacy shall develop, maintain, implement, and adhere to written procedures for handling both major and minor spills of hazardous drugs. The procedures shall be maintained with the policies and procedures required in § 20:51:31:03.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1) and (5).
Law Implemented: SDCL 36-11-11.

20:51:31:30. Responsibilities for patient care. Pharmacies that provide sterile products to the patient in the home environment shall:

(1) Be knowledgeable of the roles of the physician, patient, pharmacy, and home health care provider related to delivery of care and the monitoring of the patients;

(2) Have a pharmacist accessible at all times to respond to a patient's and other health professional's questions and needs;

(3) Use the clinical and laboratory data of each patient to monitor initial and ongoing drug therapy. If the pharmacist does not have access to the data, the name of the health care provider assuming responsibility for monitoring drug therapy shall be documented in the patient's profile; and

(4) Report to the prescribing physician any knowledge of unexpected or untoward response to drug therapy.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1) and (12), 36-11-68.
Law Implemented: SDCL 36-11-11.

20:51:31:31. Patient or caregiver education and training. If sterile products are provided to the patient in the home environment, the pharmacist, in conjunction with nursing or medical personnel, shall verify and document the patient's or caregiver's training and competence in managing therapy.

Source: 36 SDR 100, effective December 14, 2009.
General Authority: SDCL 36-11-2.2, 36-11-11(1) and (12), 36-11-68.
Law Implemented: SDCL 36-11-11.

CHAPTER 20:51:32

PRESCRIPTION DRUG MONITORING PROGRAM

Section

20:51:32:01. Definitions. Terms defined in SDCL 34-20E-1 have the same meaning in this article.

Source: 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 34-20E-20.
Law Implemented: SDCL 34-20E-1, 34-20E-20.

20:51:32:02. Data submission. Each dispenser may submit the data to the central repository using any electronic device compatible with the board's receiving device or the receiving device of the board's contracted vendor every 24 hours or by midnight of the next business day after dispensing. The data submitted to the central repository may be on electronic media approved by the board accompanied by a transmittal form identifying the dispenser submitting the electronic media, the number of prescription records included on the media, and the individual submitting the media.

If the dispenser does not have an automated recordkeeping system capable of producing an electronic report of the required data in the format established by the American Society for Automation in Pharmacy (ASAP), the dispenser may request a waiver from the electronic reporting requirement from the board.

If the board grants a waiver from the electronic reporting requirement, then the dispenser shall comply with an alternative method of reporting the data as determined by the board, such as submitting the required data on a form approved by the board.

Source: 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 34-20E-20.
Law Implemented: SDCL 34-20E-2, 34-20E-3, 34-20E-20(1).

20:51:32:03. Data elements. The information submitted for each prescription shall include the following items:

(1) Dispenser name and identification number;
(2) Date prescription filled;

(3) Prescription number;
(4) Prescription is new or is a refill;
(5) Identification code for drug dispensed;
(6) Quantity dispensed;
(7) Day's supply dispensed;
(8) Number of refills ordered;
(9) Patient name;
(10) Patient address;
(11) Patient date of birth;
(12) Patient gender;
(13) Prescriber identification number;
(14) Date prescription issued by the prescriber;
(15) Pharmacy phone number;
(16) Code identifying type of payment;
(17) Prescriber last name;
(18) Prescriber first name; and
(19) Prescriber phone number.

Source: 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 34-20E-20(2).
Law Implemented: SDCL 34-20E-2, 34-20E-3, 34-20E-20(2).

20:51:32:04. Access to data. Healthcare practitioners authorized to prescribe or dispense controlled substances may request on-line access to the data for the purpose of providing patient health care. A healthcare practitioner authorized to prescribe may designate one or more persons who are licensed or registered with the respective regulatory board to serve as a delegate. Prior to being granted access to program information, a practitioner or delegate shall submit a request for registration and program access. The board will verify the licensure status of the practitioner or delegate with the appropriate licensing authority. In the case of integration, as defined in SDCL subdivision 34-20E-1(9), the board may allow an entity's credentialing process to verify licensure status. The program safeguards to protect the privacy of the data include a secure login and password for the practitioners authorized to access the data.

The board shall conduct regular reviews of data access by practitioners to identify possible violations of law or breach of professional standards that may have occurred. Whenever such information is identified, the board will notify the appropriate professional licensing, certification or regulatory agency or entity, and provide information necessary for an investigation.

Source: 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 34-20E-20(4).
Law Implemented: SDCL 34-20E-7(1), 34-20E-12, 34-20E-20(4).

20:51:32:05. Disclosure of data. Each request for information from the central repository must be submitted on a form or electronic platform provided by the board and may be mailed, faxed, or submitted electronically to the board office. The information may be mailed, faxed or submitted electronically to the individual requesting the profile, and marked "confidential".

A prescriber or dispenser may request patient information electronically or in writing if the request:

(1) Is signed or submitted on an electronic platform by the prescriber, delegate, or dispenser requesting the information and includes the business name and address;

(2) Includes the patient's name, date of birth, purpose of the request, and the date range for the profile; and

(3) Includes a statement indicating a prescriber or a dispenser and patient relationship exists.

Source: 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 34-20E-20(4).
Law Implemented: SDCL 34-20E-5, 34-20E-7(1).

20:51:32:06. Disclosure of data -- Individual. An individual or the individual's agent, authorized in writing, may request prescription information of the individual or the individual's minor child.

The individual requesting the prescription information or an authorized agent of the individual shall submit a signed, written request on a form provided by the board for records of the individual's prescriptions reported to the program.

The individual or agent will be required to present a current government-issued photo identification at the time of delivery of the request.

An individual who is unable to personally deliver the request to the board office may submit a request by mail or a commercial delivery service. The request shall comply with the provisions above, a copy of the current government issued photo identification shall be enclosed, and the signature of the requesting individual shall be notarized.

Source: 37 SDR 214, effective May 30, 2011.
General Authority: SDCL 34-20E-20.
Law Implemented: SDCL 34-20E-7(2), 34-20E-20(4).

20:51:32:07. Disclosure of data -- Regulatory board. A state board or regulatory agency with appropriate authority may request information electronically or in writing.

The request shall include a statement of its purpose and authority, the name and license number of the individual, the date range requested, and the specific reasons for the request.

The request shall be signed or submitted electronically by the authorized agent and include the mailing address for the board or agency.

Source: 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 34-20E-20.
Law Implemented: SDCL 34-20E-7(3), 34-20E-20(4).

20:51:32:08. Disclosure of data -- Law enforcement. A local, state, and federal law enforcement or prosecutorial official engaged in the enforcement of laws related to controlled substances may request information for the purpose of an investigation or prosecution of the drug-related activity or probation or parole compliance of an individual. The board shall verify the status of the law enforcement or prosecutorial official with the appropriate authority.

The electronic or written request shall include the individual's name and date of birth, the date range requested, and the specific reasons for the request, that must be approved by the board prior to the release of the information.

The request shall be signed by the authorized official and include that person's mailing address.

Source: 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 34-20E-20(4).
Law Implemented: SDCL 34-20E-7(4), 34-20E-20(4).

20:51:32:09. Disclosure of data -- Court orders. The board shall provide program information in response to court orders and warrants. The board shall provide program information in response to court issued subpoenas.

Source: 37 SDR 214, effective May 30, 2011.
General Authority: SDCL 34-20E-20(4).
Law Implemented: SDCL 34-20E-7(7), 34-20E-20(4).

20:51:32:10. Disclosure of data -- Other entities. Other designated entities may request profiles or information as identified in SDCL 34-20E-7.

The request shall include the date range requested, the specific reasons for the request, and the individual's name and birth date if applicable.

The request shall be signed by the authorized individual and include that person's mailing address.

Source: 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 34-20E-20(4).
Law Implemented: SDCL 34-20E-7(5)(6)(8) and (9).

20:51:32:11. Data retention. All dispenser records of prescriptions reported to the program shall be retained by the board for a period of three years following the date of the record. All records of access to or query of program information shall be retained by the board for a period of three years following the date of the record. At least semiannually, all program information identified as exceeding that three-year period shall be deleted from the program and discarded in a manner to maintain the confidentiality of the program information and data. Statistical data and reports from which all personally identifiable information has been removed or which do not contain personally identifiable information may be retained by the board for historical purposes.

Source: 37 SDR 214, effective May 30, 2011.
General Authority: SDCL 34-20E-20.
Law Implemented: SDCL 34-20E-20(2)(4) and (5).

CHAPTER 20:51:33

COMPLAINT PROCEDURES

Section

20:51:33:01. Applicability. The following procedure applies to complaints about holders of the licenses, permits, registrations, or certificates regulated by the Board of Pharmacy.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-11-11(1)(2)(3)(10) and (13).
Law Implemented: SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26, 36-11-28, 36-11-29, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48, 36-11-49, 36-11-65, 36-1lA-14.

20:51:33:02. Complaints. The executive secretary may initiate an investigation based on a written complaint. Any person filing a complaint shall submit the complaint in writing to the executive secretary. A complaint is not a public record. The executive secretary shall dismiss any complaint that concerns matters over which the board does not have jurisdiction, and shall notify the complainant of that action. The executive secretary may also initiate an investigation upon reasonable suspicion that a licensee or registrant is in violation of any applicable standard for professional conduct.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-11-11(1)(2)(3)(10) and (l3).
Law Implemented: SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26, 36-11-28, 36-11-29, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48, 36-11-49, 36-11-65, 36-1lA-14.

20:51:33:03. Investigations. The executive secretary shall initiate an investigation of a complaint by notifying the license, registration, or certificate holder of the complaint and obtaining a response to the complaint. If the executive secretary determines that the complaint concerns compliance with licensing standards and requirements, the executive shall investigate the complaint. The notice shall be in writing and shall include a statement that the licensure, licensee, or registrant is entitled to due process rights, including the right to notice and an opportunity to be heard and to be represented by counsel. The executive secretary may appoint a board member to assist in the investigation.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-11-11(1)(2)(3)(10) and (l3).
Law Implemented: SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26, 36-11-28, 36-11-29, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48, 36-11-49, 36-11-65, 36-11A-14.

20:51:33:04. Completion of complaint investigation. Upon completion of a complaint investigation, the executive secretary may:

(1) Dismiss the complaint as unsubstantiated or requiring no further action. Dismissal of a complaint is not a public record;

(2) Issue a letter of concern, that shall be placed in the licensee's or registrant's permanent records. A letter of concern is not a public record;

(3) Recommend the board issue the licensee or registrant a public reprimand;

(4) Recommend the board re-open and modify the license to include compliance with specified terms and conditions; or

(5) Recommend the board suspend or revoke the license.

If the executive secretary recommends issuance of a public reprimand, re-opening and modification, or suspension or revocation of the license, registration, or certificate held by the licensee or registrant, the executive secretary shall notify the licensee or registrant of the right to contest the recommendation. If contested, the executive secretary shall issue a petition for hearing that sets out the recommendation and the reasons for the recommendation and initiates a contested case hearing. A copy of the petition for hearing shall be sent to the licensee or registrant. The executive secretary and licensee or registrant may enter into a settlement agreement concerning the recommendation to be made to the board.

Source: 45 SDR 86, effective December 24, 2018.

General Authority: SDCL 36-11-11(1)(2)(3)(10) and (13).

Law Implemented: SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26, 36-11-28, 36-11-29, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48, 36-11-49, 36-11-65, 36-1lA-14.

20:51:33:05. Status of complainant. The complainant is not a party to any contested case hearing resulting from the executive secretary's investigation of a complaint, although the complainant may be called as a witness in the hearing. The executive secretary shall notify a complainant of any public final agency action taken as a result of a complaint.

Source: 45 SDR 86, effective December 24, 2018.

General Authority: SDCL 36-11-11(1)(2)(3)(10) and (l3).

Law Implemented: SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26, 36-11-28, 36-11-29, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48, 36-11-49, 36-11-65, 36-1lA-14.

20:51:33:06. Effect of failure to renew during investigation. The holder of a license, registration, or certificate may choose not to renew the license, registration, or certificate after a complaint investigation has been initiated by the executive secretary. A failure to renew after an investigation has been initiated shall be reported as "withdrawn under investigation" in the board's permanent license files and in any national databases to which the board is required to report licensure action.

Source: 45 SDR 86, effective December 24, 2018.

General Authority: SDCL 36-11-11(1)(2)(3)(10) and (13).

Law Implemented: SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26, 36-11-28, 36-11-29, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48, 36-11-49, 36-11-65, 36-1lA-14.

CHAPTER 20:51:34

CONTESTED CASE HEARING PROCEDURES

Section

20:51:34:01. Applicability. The following procedure applies to contested case proceedings for license, registration, or certificate applications and to disciplinary proceedings before the Board of Pharmacy.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-11-11 (1)(2)(3)(10) and (l3).
Law Implemented: SDCL 36-11-28, 36-1lA-45.

20:51:34:02. Petitions for hearing. An applicant for a license, registration, or certificate issued by the board may file a petition for hearing at any time during the processing of an application. The executive secretary may file a petition for hearing to initiate a disciplinary proceeding against a licensee or registrant. A petition for hearing shall be signed by the petitioner and contain the following information: the name and address of the applicant, licensee, or registrant; the basis for the request for hearing; recitation of the applicable statutes or regulations under which the petitioner is requesting board action; and the relief requested by the petitioner.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-11-11(1)(2)(3)(10) and (l3).
Law Implemented: SDCL 36-11-28, 36-11A-45.

20:51:34:03. Filing of petitions for hearing. All petitions for hearng shall be filed with the executive secretary, who shall maintain the record of contested case proceedings held before the board.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-11-11(1)(2)(3)(10) and (13).
Law Implemented: SDCL 36-11-28, 36-11A-45.

20:51:34:04. Scheduling of hearing. Upon receipt of a petition for hearing, the board president may appoint an examiner to conduct the contested case hearing, or may schedule the contested case hearing before the board, as authorized by applicable statutes.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-11-11(1)(2)(3)(10) and (13).
Law Implemented: SDCL 36-11-28, 36-11A-45.

20:51:34:05. Hearing procedure. Contested case hearings shall be conducted in accordance with SDCL chapter 1-26. The parties to a hearing are the executive secretary and the applicant, licensee or registrant. A board member who has participated in any investigation of the matter before the board shall be disqualified from all deliberations and decisions.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-11-11(1)(2)(3)(10) and (13).
Law Implemented: SDCL 36-11-28, 36-11A-45.

20:51:34:06. Final board decision. If the board hears the proceeding, the board shall issue a final decision and require the parties to submit proposed findings of fact and conclusions of law for consideration at the board's next meeting. If a hearing examiner hears the proceeding, the examiner shall issue a proposed decision including findings of fact and conclusions of law. The examiner shall serve the proposed decision upon the board and the parties. The board may request that the parties appear before the board to present oral arguments and objections to the examiner's proposed decision. The board shall issue a final decision and accept, reject, or modify the findings, conclusions, and decisions of the examiner.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-l l-11(1)(2)(3)(10) and (l3).
Law Implemented: SDCL 36-11-28, 36-11A-45.

20:51:34:07. Notice of decision. The board shall issue a notice of decision, accompanied by the final board decision and findings of fact and conclusions of law, to the applicant, licensee, or registrant and executive secretary.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-l 1-11(1)(2)(3)(10) and (13).
Law Implemented: SDCL 36-11-28, 36-11A-45.

20:51:34:08. Assessment of costs of disciplinary hearings. The board may assess the costs associated with a contested case proceeding resulting in disciplinary action, against a licensee or registrant upon motion by the executive secretary. If requesting the assessment of costs, the executive secretary shall present a statement of costs to the board or hearing examiner at the time the board or hearing examiner submits proposed findings of fact and conclusions of law.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-l1-11(1)(2)(3)(10) and (l3).
Law Implemented: SDCL 36-11-28, 36-11A-14, 36-11A-45.

20:51:34:09. Board member conflict of interest. A board member may not participate in a contested case proceeding or disciplinary action if the board member:

(1) Is personally related to a party involved in the contested case proceeding or disciplinary action by two degrees of consanguinity;

(2) Has a direct financial interest in a party involved in the contested case proceeding or disciplinary action through employment or by contract;

(3) Directly supervises and is responsible for peer review of a party involved in the contested case proceeding or disciplinary action; or

(4) Has a spouse who has a direct financial interest in or directly contracts with a party involved in the contested case proceeding or disciplinary action. If a conflict of interest exists, the member shall make an oral statement of recusal on the record at the initiation of the hearing.

A recused member may not participate in board discussions or decision-making regarding that contested case proceeding or disciplinary action.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-11-11(1)(2)(3)(10) and (13).
Law Implemented: SDCL 36-11-28, 36-11A-14, 36-11A-45.

20:51:34:10. Board member potential conflict of interest. A potential conflict of interest is an indirect financial interest, or a personal relationship or another interest in a party involved in a contested case proceeding or disciplinary action that is different from that of the general public, and that a reasonable person would believe might result in bias or prejudgment. A board member shall disclose any potential conflict of interest in a contested case proceeding or disciplinary action on the record at the initiation of the hearing, or during the hearing, if the board member becomes aware of the existence of a potential conflict of interest at that time. Upon the board's own motion or the motion of a party, and considering the rule of necessity if maintenance of a quorum is an issue, the board may recuse a member with a potential conflict of interest if the board determines that the potential conflict of interest raises an unacceptable risk of bias or prejudgment in the contested case proceeding or disciplinary action.

Source: 45 SDR 86, effective December 24, 2018.
General Authority: SDCL 36-11-11(1)(2)(3)(10) and (l3).
Law Implemented: SDCL 36-11-28, 36-11A-14, 36-11A-45.