ARTICLE 20:51

PHARMACISTS

Chapter

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CHAPTER 20:51:01

~~REGISTRATION~~ LICENSURE BY EXAMINATION

Section

20:51:01:01. Application for ~~registration~~ licensure. An applicant for ~~registration~~ licensure as a pharmacist by examination shall apply to 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; 50 SDR 138, effective June 2, 2024.

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~~ license to practice pharmacy and who is examined after December 31, 2009, must have completed a pharmacy practice experience program which meets or exceeds the minimum pharmacy practice experience requirements of the board as defined in chapter 20:51:02.

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

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

Law Implemented: SDCL 36-11-16.

Cross-References:

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

Required hours, § 20:51:02:13.

20:51:01:03. Application requirements. An applicant for ~~registration~~ licensure by examination shall provide the following to the board with the application:

(1) The application fee of thirty-five dollars;

(2) A photo of the applicant;

(3) ~~A list of the applicant's practical experience;~~

~~(4)~~ A transcript showing graduation from a college of pharmacy approved by the American Council on Pharmaceutical Education;

~~(5)~~(4) A government-issued form of photo identification; and

~~(6)~~(5) A criminal background check.

Source: SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 8 SDR 144, effective May 4, 1982; 11 SDR 120, effective March 11, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 14 SDR 121, effective March 28, 1988; 15 SDR 20, effective August 9, 1988; 18 SDR 95, effective November 25, 1991; 22 SDR 133, effective April 25, 1996; 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1), ~~36-11-17~~ 36-11-16.

Law Implemented: SDCL 36-11-16, 36-11-16.1, ~~36-11-17~~.

Cross-References:

Examination, § 20:51:01:04.

~~Approved colleges of pharmacy, § 20:51:01:09.~~

20:51:01:04. Examination. An applicant for ~~registration~~ licensure 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.

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~~.

20:51:01:10. 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. North American Pharmacist Licensure Examination score transfer. An applicant meeting the requirements of this chapter who has taken the North American Pharmacist Licensure Examination in another state may transfer scores through 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 Multistate Pharmacy Jurisprudence Examination, 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; 50 SDR 138, effective June 2, 2024.

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. Repealed.

CHAPTER 20:51:02

INTERNSHIP REQUIREMENTS

Section

20:51:02:01. Definitions. Terms defined in SDCL 36-11-2 have the same meaning in this chapter. As used in this chapter, "pharmacy intern" means:

(1) A person who is registered by the board to engage in the practice of pharmacy while under the supervision of a pharmacist, enrolled in an Accreditation Council for Pharmacy Education (ACPE) accredited school or college of pharmacy, and is progressing toward meeting the requirements for licensure as a pharmacist;

(2) A graduate of an ACPE 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 Certificate, who is currently registered by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(3) A qualified applicant awaiting examination for pharmacist licensure or meeting board requirements for re-licensing; or

(4) A qualified applicant participating in a pharmacy 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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-25.

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

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~~ licensure as a pharmacist pursuant to §20:51:01:10 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~~ Repealed.

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.~~

20:51:02:10. 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~~ licensed 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~~ licensed pharmacist who agrees to supervise the practical experience of a registered pharmacy intern shall ~~certify this on a form provided by the board and~~ agree to abide by pharmacy law and rules. A pharmacist must be readily available and in continuous communication with 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.

A pharmacist shall 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 shall inspect the prepared prescription and verify the accuracy of the preparation, and its labeling, prior to dispensing the prescription to the patient or the 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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-25.

20:51:02:12.01. Required hours. An ~~internship must consist of~~ applicant for licensure as a pharmacist pursuant to §20:51:01:01 must complete a minimum of ~~two thousand~~ one thousand six hundred hours~~, of which one thousand seven hundred forty hours may be a college-based pharmacy practical experience program. The remaining two hundred sixty hours must be acquired under the supervision of one or more preceptors in a board-licensed pharmacy where the goal and objectives of a pharmacy internship, as set forth in § 20:51:02:01.01, apply~~ of internship experience.

Source: 36 SDR 21, effective August 17, 2009; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-25.

CHAPTER 20:51:04

~~REGISTRATION~~ LICENSURE 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~~ for licensure by reciprocity as a pharmacist must include the following:

(1) An Electronic license transfer program official application from National Association of Boards of Pharmacy, completed on the National Association of Boards of Pharmacy website;

(2) A South Dakota reciprocating pharmacist application with non-refundable fee of one hundred fifty dollars;

(3) A non-refundable initial pharmacist licensure fee of thirty-five dollars; and

(4) A criminal background check.

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 36-11-16, 36-11-16.1, 36-11-19.

20:51:04:02. Qualifications for reciprocity. To qualify for reciprocal ~~registration~~ license in South Dakota, an applicant must:

(1) Be a ~~registered~~ licensed pharmacist in the state from which the pharmacist is reciprocating;

(2) Be in good standing as a pharmacist in the state from which the pharmacist is reciprocating at the time of application;

(3) 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 application; and

(4) For any applicant who first became a licensed pharmacist after January 1, 1980, the applicant must have passed the North American Pharmacist Licensure Examination.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 36 SDR 21, effective August 17, 2009; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-19.

20:51:04:04. Application requirements. ~~An applicant shall complete the official National Association of Boards of Pharmacy (NABP) license transfer application with NABP at NABP.pharmacy. Prior to approval of licensure, the board must receive the following:~~

~~(1) A South Dakota reciprocating pharmacist application with a nonrefundable fee of one hundred fifty dollars;~~

~~(2) A nonrefundable initial pharmacist registration fee of thirty-five dollars; and~~

~~(3) A criminal background check~~ Repealed.

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; 50 SDR 138, effective June 2, 2024.

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

~~**Law Implemented:** SDCL 36-11-16.1, 36-11-19.~~

20:51:04:05. Appearance before board. Before a reciprocal ~~registration~~ licensure 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.

20:51:04:08. Certificates of reciprocity identified by letter R. ~~Certificates of registration~~ Licensure granted by reciprocity will be identified by the letter R ~~next~~ preceding the number of such ~~certificates~~ pharmacist license.

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.

20:51:05:22. Distribution of drugs to prescribers or pharmacies. A ~~registered~~ licensed pharmacy may distribute up to five percent of its controlled drugs and legend drugs to a prescriber licensed to prescribe, dispense, or distribute the drugs in the course of professional practice or to other ~~registered~~ licensed pharmacies, to meet temporary inventory shortages. The distribution must be completed using invoices containing the:

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

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

(3) Quantity of each drug sold; and

(4) Date of sale.

The sale of Schedule II drugs must include a completed Drug Enforcement Administration form 222. Copies of the invoices must be retained by both locations involved in the transaction for a period of two years from the date of the transaction.

Source: 11 SDR 92, effective January 16, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-14, 36-11A-4.

CHAPTER 20:51:06

PHARMACY PRACTICE AND ~~REGISTRATION~~ LICENSURE

Section

20:51:06:01. Application for pharmacy ~~permit~~ license --Annual renewal required. A ~~registered~~ licensed pharmacist actively conducting a pharmacy in the state of South Dakota shall apply each year to the board for a ~~permit~~ license to conduct the pharmacy for the year ending June thirtieth on forms provided by the board. The fee is two hundred dollars.

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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-32, 36-11-35.

20:51:06:02. Ownership or control by pharmacist required. A pharmacy ~~permit~~ license may not be issued to any pharmacist applicant unless the applicant is the owner, or part owner, of the place of business for which a pharmacy ~~registration~~ license is applied for, or unless application is made jointly with a ~~registered~~ licensed pharmacist. If the owner of the place of business for which a pharmacy ~~registration~~ license is applied for is not a pharmacist, the owner must sign an affidavit, on a form prescribed by the board, delegating full and complete authority to the pharmacist-in-charge for active management of the pharmaceutical services in the place of business.

A licensed pharmacy may change pharmacist-in-charge on a form provided by the board at any time during the licensed period. The fee for a pharmacist-in-charge change is fifty dollars. The board must be notified within ten days of the change, otherwise the pharmacy license becomes void, and the pharmacy owner must reapply for licensure. A complete inventory of controlled substances, as listed in SDCL chapter 34-20B, must be taken on date of pharmacist-in-charge change. The inventory shall be retained in the licensed pharmacy for a period of two years.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-32, 36-11-34, 36-11-37.

20:51:06:02.01. Pharmacist-in-charge -- Defined, duties. An application for a ~~permit~~ license to conduct a pharmacy as specified in § 20:51:06:02 must indicate the pharmacist-in-charge. For purposes of this section, the term "pharmacist-in-charge," means a pharmacist manager or pharmacist permittee licensed in this state who has been designated by the pharmacy owner.

The pharmacist-in-charge must:

(1) Be employed or under contract for pharmacy services at the pharmacy;

(2) Establish policy and procedure for the pharmacy;

(3) Supervise all pharmacy employees;

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

(5) 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 pharmacist-in-charge shall notify the board immediately upon termination of employment. A new pharmacist-in-charge must be designated by the pharmacy owner within ten working days after the termination date.

Source: 26 SDR 92, effective January 6, 2000; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-32.

20:51:06:03. Application for opening a new pharmacy. An application for an initial pharmacy ~~permit in~~ license within South Dakota must be filed with the board at least thirty days before the pharmacy's opening date. The board may inspect the pharmacy prior to the opening date.

If the proposed new pharmacy is to include a prescription department, the space ~~registered~~ licensed as a pharmacy must be separated from the remainder of the building in which it is located by walls that extend from the floor to a permanent ceiling. The walls may contain doors to the interior of the building. The doors must be closed and locked whenever a ~~registered~~ licensed pharmacist is not on duty, physically present in the building, 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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-32.

20:51:06:04. False application grounds for suspending or revoking. False representation made in an application for a ~~permit to conduct a~~ pharmacy license, or keeping a pharmacy open for the transaction of business without a pharmacist on duty, physically present in the building, and in charge of the pharmacy, except as provided in § 20:51:06:10, are grounds for suspension of revocation of the pharmacy ~~permit~~ license.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-44, 36-11-48.

20:51:06:07. Changes in ownership or location reported to the board--Patients notified of closure of pharmacy. A change in the location, ownership, or name of a pharmacy, or the closure of business as a pharmacy, must be reported to the board at least ten days prior to the change or closure. The ~~pharmacist permittee~~ pharmacist-in-charge is responsible for reporting changes to the board. If a pharmacy permanently closes, patients must be notified thirty days prior to closure.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-39.

20:51:06:08. Valid ~~permit~~ license must be displayed. A valid ~~permit~~ license 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~~ License expires one hundred twenty days after death of pharmacist owner. Except in the event of the death of the ~~pharmacist permittee~~ pharmacist owner, a ~~permit to conduct a~~ pharmacy license is void when the ~~holder~~ pharmacist owner of the ~~permit~~ license ceases to be in active management of the pharmacy. When a ~~pharmacist permittee~~ pharmacist owner dies, the pharmacy may not be kept open for business without a pharmacist on duty and in charge. A ~~permit to conduct a~~ pharmacy license in the name of a deceased pharmacist becomes void unless transfer of the ~~permit~~ license has been made within the one hundred twenty-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 pharmacy.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-38.

20:51:06:10. Provisions for pharmacist temporary absence from pharmacy. Where the ~~registered~~ licensed pharmacy includes a prescription department and a general merchandise area, it is not a violation of SDCL chapter 36-11 or § 20:51:06:04 if public entrances to the general merchandise area are kept open for business without a pharmacist on duty in the pharmacy, provided all entrances to the prescription department are closed for the transaction of business and a sign bearing the words "pharmacy services closed" has been posted by the pharmacist before leaving the premises. The prescription department must include sufficient security measures to protect the department from theft or access by unauthorized personnel. The prescription department must be secured by a continuous partition or wall, extending from the floor to the permanent ceiling, with doors capable of being securely locked to isolate the prescription department.

If the prescription department lacks the barrier and is closed, the entire business must be closed, locked, and secured to protect the area from theft or access by unauthorized personnel.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-40.

20:51:07:01. Pharmacy must comply with all public health regulations. A pharmacy must comply with all public health regulations regarding sanitation and is subject to board inspections. The pharmacy must 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; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(2).

Law Implemented: SDCL ~~36-11-42~~ 36-11-41, 36-11-64.

20:51:07:03. Minimum equipment requirements. A pharmacy ~~permittee~~ owner must make available and maintain all equipment needed to provide pharmacy services for the location, as determined by the pharmacist-in-charge. Any equipment, that requires certification, maintenance, or calibration must be certified, maintained, or calibrated according to the manufacturer and United States Pharmacopeia guidelines. All equipment not in good working condition may not be used in 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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-41(1).

CHAPTER 20:51:13

SPECIAL RESTRICTIONS

Section

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

(1) The facility or hospice program consults with a licensed pharmacist for oversight of 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 drug being returned to the pharmacy and that the unit dose or unit of issue drug has not come into the physical possession of the person for whom it was prescribed;

(2) The ~~pharmacy's manager~~ pharmacist-in-charge 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 or unit of issue drugs returned to the pharmacy;

(3) The drugs are provided in the manufacturer's unit dose packaging or are repackaged by the pharmacy in accordance with chapter 20:51~~;~~:21;

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

(5) If the drug is repackaged by the pharmacy, each single unit dose or each unit of issue prepackaged or repackaged container must include:

(a) The name and strength of the medication;

(b) A suitable expiration date, not later than the expiration date on the manufacturer's container or one year 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 unless maintained in the internal records of the pharmacy; and

(e) The identity of the pharmacist responsible for prepackaging or repackaging unless maintained in the internal records of the pharmacy;

(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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 34-20H-2, 36-11-46.6.

Cross Reference: Unit dose systems, chapter 20:51:21.

20:51:13:02.03. Redispensing unit dose drugs returned from hospice programs, nursing facilities, or assisted living facilities. Unused unit dose or unit of issue drugs that are returned under § 20:51:13:02.01 may be redispensed in accordance with the following requirements:

(1) ~~Drugs that have been repackaged by the pharmacy may be redispensed only one time;~~

~~(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)~~(2) Drugs that have been repackaged into a unit of issue package by the pharmacy may be redispensed into a unit of issue distribution system and mixed with drugs of a different lot number, provided that all lot numbers and expiration dates are placed on the unit of issue package or in the internal record; and

~~(4)~~(3) Drugs may be removed from a unit dose or unit of issue package for dispensing in a traditional dispensing system as described in § 20:51:21:01.

Source: 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 34-20H-2, 36-11-46.6.

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 or unit of issue package. Drugs~~ were repackaged in traditional dispensing system that were not dispensed or drugs transferred directly from one pharmacy to another pharmacy may be repackaged into unit dose or unit of issue packaging if the following information is obtained by the ~~receiving~~ pharmacy:

(1) Date received;

(2) Name of drug;

(3) Strength;

(4) Quantity;

(5) Expiration date not to exceed the shorter of one year from the date the drug is prepackaged or repackaged or the manufacturer's container expiration date;

(6) Manufacturer's lot number;

(7) Manufacturer; and

(8) National Drug Code.

Source: 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 34-20H-2, 36-11-46.6.

20:51:13:03. Free choice of pharmacies. The following notice 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 a prescription filled at the pharmacy of the person's choice. This South Dakota Board of Pharmacy notice 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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL ~~36-12B-1~~ 34-12B-1.

20:51:13:05. Remote pick-up sites. A licensed pharmacy may designate a location where patients may pick up dispensed medications. The pharmacy utilizing the location retains ownership of the medications received by the patient or designated person and therefore is accountable for proper storage and record keeping. To store patient medications awaiting pick-up at a location other than the pharmacy, approval from the Board must be obtained. The following requirements must be met for approval:

(1) A pharmacy must submit the following to the board:

(a) The name, address, and license number of the pharmacy and name of pharmacist in charge responsible for the remote pick-up site;

(b) The name and address of each site; and

(c) A copy of the policies, procedures, and security requirements for the site.

(2) Pick-up site requirements:

(a) Site must have a locked cabinet for storage of prescriptions;

(b) Access to the locked cabinet should be limited to trained designated staff;

(c) Prescriptions will be placed in the locked cabinet immediately upon delivery to the location;

(d) Only the patients name will be listed on the outside of the prescription bag. The receipt with protected health information will be inside of the stapled bag. If someone other than the patient will be picking up the prescription, the name will also be listed on the bag;

(e) The identity of the patient (or other designated person) must be verified. If not personally known by the clerk-the drivers license or other photo ID must be checked;

(f) The person picking up the prescription will sign the receipt or log; and

(g) A designated employee will inventory the prescription bags at least weekly and provide a list of unclaimed bags to the pharmacy.

(3) Pharmacy must maintain a list of all employees at the pick-up site who have been trained and have access to the prescriptions. The pharmacy shall review the policies and procedures with each employee and document the date of the review annually;

(4) A record of shall be maintained in the pharmacy of all prescriptions delivered to the pick-up site; and

(5) Pharmacy staff must conduct and document monthly visits to the site to ensure compliance with policies and procedures.

Source:

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

Law Implemented: SDCL 36-11-2.2(3).

20:51:13:06. Off-site medication-control. A licensed pharmacy may provide a limited number of prescription medications to a clinic for dispensing to patients when access to a pharmacy is limited. The pharmacy providing the medications retains ownership until dispensed to the patient and therefore is accountable for proper storage and record keeping. For medications to be stored offsite in a clinic, policies and procedures must be submitted to the Board for approval. The following requirements must be addressed in policies and procedures:

(1) Location and medication list and quantities;

(2) Medications must be kept in a locked cabinet with access only by licensed health professionals;

(3) Prior to dispensing the medication there must be an order in the patient's record and a copy of the order or prescription is sent to the pharmacy;

(4) Dispensing at the clinic must be done by the prescriber, if the label is prepared by a nurse, the prescriber must verify the drug and the directions prior to dispensing. Labeling must follow ARSD 20:51:05:21;

(5) A written information sheet should be provided to the patient for each prescription dispensed;

(6) Perpetual inventory of all medications stored off-site that includes a record of each time a mediation is dispensed from the supply; and

(7) Pharmacy staff must conduct an on-site inspection of the medications at least every ninety days which includes inventory of medications, expiration dates, proper storage conditions, and review of procedures with clinic staff.

Source:

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

Law Implemented: SDCL 36-11-2.2(3).

CHAPTER 20:51:14

GENERAL ADMINISTRATION

Section

20:51:14:01. Annual ~~certificate~~ pharmacist license renewal. The fee for an annual ~~certificate~~ pharmacist license renewal is $125. ~~Certificates~~ Pharmacist licenses expire on September ~~30~~ thirtieth following issuance and must be renewed annually by October ~~1~~ first.

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.

CHAPTER 20:51:15

PHARMACIES IN HOSPITALS, NURSING FACILITIES, OR RELATED FACILITIES

Section

20:51:15:01. Definition and general provisions. Terms used in this chapter mean:

(1) “Chart order,” a lawful order entered on the chart or medical record of a patient or resident of a licensed healthcare facility by a practitioner, or a designated agent, for a drug or device;

(2) "Hospice program," a coordinated program of inpatient services providing palliative rather than curative care for a patient;

(3) "Part-time pharmacy," the provision of pharmaceutical services by a ~~registered~~ licensed pharmacist under a pharmacy license issued by the board, on less than a full-time operation basis, in hospitals, nursing facilities, and related facilities in which pharmaceutical services are limited to inpatients;

(4) "Pharmaceutical services":

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

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

(c) Any other act, service, operation, or transaction incidental to subsections (4)(a) and (b) requiring, involving, or employing the science or art of any branch of the pharmaceutical profession.

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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-33.

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

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

General Authority: SDCL 36-11-11.

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, must be licensed as a pharmacy. The pharmacy must meet all requirements of South Dakota and federal law and the rules of the board and must have a ~~registered~~ licensed pharmacist in charge of the pharmacy.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-33.

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-33.

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

For purposes of this section, a container is "original" if it has been packaged by a licensed manufacturer and is labeled in compliance with federal and state law.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-33.

20:51:15:07. Preparing a solution. ~~The preparation, by a nurse licensed pursuant to SDCL chapter 36-9, of a solution for injection, is considered a step in the administration of medication~~ Repealed.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

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

~~**Law Implemented:** SDCL 36-11-2.2.~~

20:51:15:10. Registration and renewal. The board may issue to a pharmacist in good standing a ~~permit~~ license to operate a part-time pharmacy in a hospital, nursing facility, or related facility for the year ending June thirtieth, if the ~~pharmacist~~ owner applies yearly on a form supplied by the board and pays a fee of one hundred sixty dollars.

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; 50 SDR 138, effective June 2, 2024.

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

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

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-33.

20:51:15:13. Access to pharmacy -- Records. Only a ~~registered~~ licensed pharmacist may have access to the pharmacy ~~stock of drugs~~ in the hospital, nursing facility, or related facilities. If the pharmacist is absent from the hospital or other like facility, a registered nurse designated by the hospital may obtain, from ~~a hospital~~ the pharmacy ~~stock of drugs, a unit dose of~~ a drug~~,~~ or medication necessary to administer to a patient in carrying out treatment and medication orders as prescribed by a licensed prescriber when the drug is not available in floor supplies, or the emergency drug kit, to meet the immediate need of the patient. The 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, the dosage form and strength, the amount taken, and the date and time the drugs were removed, and shall sign the record. The nurse shall leave the record and the container from which the dose was taken, in order that it may be properly checked by the pharmacist. These records must be kept for two years.

Source: SL 1975, ch 16, § 1; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2.2, 36-11-33, 36-11-34, 36-11-68.

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~~ a licensed 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~~ licensed pharmacy in a health care facility may provide, upon written request of the health care facility's prescribers, a defined supply of ~~legend~~ drugs in an emergency drug kit or crash cart. The emergency drugs must 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 must remain the property of the ~~registered~~ licensed pharmacy and must be stored on-site in a suitable, controlled location in the health care facility. ~~The emergency drug supplies are governed by 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 must be identified for replacement by a pharmacist; and~~

~~(4) The pharmacy staff shall restock the contents of the emergency drug supply after each reported use or at least monthly.~~ The pharmacy staff shall inspect all emergency drugs 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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2.2, 36-11-33, 36-11-34.

20:51:15:15.01. Pharmacist controls emergency kit in nursing facility. A ~~registered~~ ~~pharmacist~~ licensed pharmacy may provide to a nursing facility a limited quantity of controlled legend drugs ~~pursuant to §§ 44:58:07:09 and 44:73:08:11~~, a limited amount of noncontrolled legend drugs, and nonprescription drugs, for emergency and supportive treatment, if 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 medical director, director of nursing, and provider pharmacist shall jointly determine and prepare a limited list of emergency drugs by identity and quantity. No more than ten different controlled drugs are stored in the emergency box, which may contain no more than twenty doses of any controlled drug;

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

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

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

(5) The provider pharmacy may utilize an automated medication distribution device to store, distribute, and record transactions as an emergency kit or for first dose medications~~. If the pharmacy uses an automated medication distribution device, the pharmacy must apply for a separate pharmacy permit to do so unless there is a permitted pharmacy within that physical location~~; and

(6) The provider pharmacy must provide each facility where an emergency kit is placed with a contact number to a pharmacist twenty-four hours a day.

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

Source: 26 SDR 92, effective January 6, 2000; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2.2, 36-11-33, 36-11-34.

20:51:19:03. Hours required. To qualify for a ~~certificate of registration~~ renewal of a pharmacist license or reinstatement, a pharmacist must successfully complete twelve hours of continuing education. The twelve hours of approved continuing education required each year for renewal must be completed within the twenty-four months before the pharmacist's ~~certificate of registration~~ license expires. If a pharmacist applies for yearly renewal of the pharmacist's ~~certificate of registration~~ license pursuant to SDCL 36-11-23, in order to receive renewal, the pharmacist must have completed the required hours. If the pharmacist has a certification to administer immunizations, the pharmacist must complete one hour of continuing education related to immunizations, which may be one of the required twelve hours.

For the purposes of this section:

(1) "Approved continuing education," means those continuing pharmaceutical educations programs made available by an approved provider.

(2) "Approved provider," means any association, corporation, educational institution, organization, or person who has been accredited by the Accreditation Council on Pharmaceutical Education as having met its criteria, indicating the ability to provide quality continuing pharmaceutical education programs or any sponsor approved by the board in § 20:51:19:09.

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; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1), 36-11-23.2.

Law Implemented: SDCL 36-11-23.1 to 36-11-23.3, inclusive.

20:51:19:05.01. Audit to verify hours earned. The board shall audit at least five percent of the ~~registered~~ licensed 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; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-23.2.

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

20:51:19:14. Attendance by board or council members. Any member or staff 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.

20:51:25:05. 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.

20:51:27:02. Application form. The application form for licensure of a nonresident pharmacy must include the information required by SDCL 36-11-19.3 and:

(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 or the nonresident pharmacy owner, in the home state or any other state within the last four years and the reason for the action;

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

(4) A list of all other states in which the pharmacy is licensed; ~~and~~

(5) A description of pharmacy services provided to patients located in South Dakota; and

(6) An inspection performed by the regulatory or licensing agency of the home state, any accreditation agency recognized by the board, or the United States Food and Drug Administration, that has been conducted on-site at the licensed pharmacy within the last four years. Any deficiencies on the inspection that require corrective action must be provided with the application.

Source: 24 SDR 40, effective October 5, 1997; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-19.3.

20:51:27:04. Report of change in ownership or location. The owner of a nonresident pharmacy or persons delegated by the owner shall report the following to the board:

(1) Change in pharmacist-in-charge, notify within ten days of change in position status;

(2) Ownership change, notify within thirty days of after the transaction. The license of a nonresident pharmacy is not transferable to a new owner. Any new majority owner of a nonresident pharmacy must apply for licensure pursuant to § 20:51:27:02;

(3) Change in location, notify within thirty days after the transaction. If the location change is to a different state, a new application is required pursuant to § 20:51:27:02; and

(4) Closure of a nonresident pharmacy, notify at least ten days prior to closure.

Source: 24 SDR 40, effective October 5, 1997; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-19.3, 36-11-37.

20:51:28:02.02. Qualifications for pharmacy technicians to administer immunizations. A pharmacy technician may administer immunizations if the technician:

(1) Is registered as a certified pharmacy technician in this state;

(2) Has successfully completed an approved immunization training program for technicians;

(3) Is certified in cardiopulmonary resuscitation; ~~and~~

(4) Is directly supervised by an on-site pharmacist who has a current authorization to administer immunizations in this state; and

(5) Has completed one hour of continuing education related to immunizations annually.

All technician immunization training, continuing education, and cardiopulmonary resuscitation documents must be kept in the pharmacy for five years and available for inspection at any time.

Source: 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(13), 36-11-19.1(1).

Law Implemented: SDCL 36-11-2(26), 36-11-19.1(1).

20:51:29:00. Definitions. Terms used in this chapter mean:

(1) "Certified technician," an individual described in SDCL subdivision ~~36-11-2(26)~~ 36-11-2(22) who has gained certification through training and examination pursuant to § 20:51:29:06; and

(2) ~~"Grandfathered technician," an individual not requiring certification, who worked as a technician prior to July 1, 2014, and who has been continuously employed by a pharmacy since that time;~~

~~(3)~~ "Pharmacist intern" has the definition set forth in § 20:51:02:01~~; and;~~

~~(4) "Technician-in-training," an individual who is registered with the board to receive on-the-job training in a licensed pharmacy in preparation for certification as a pharmacy technician. A technician-in-training must become a certified technician within two years of registration with the board~~.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

20:51:29:01. Purpose of registration. A registration program for all pharmacy technicians is established for the primary purpose of assuring the competency of registered pharmacy technicians and for purposes of identifying, tracking, and bringing disciplinary actions against pharmacy technicians.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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 the 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 required by rule may be subject to disciplinary action in accordance with § 20:51:29:27. Prior to renewal of registration 6 hours of continuing education must be completed. The continuing education required to maintain national certification meets this requirement.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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 thirty days of accepting employment in a South Dakota pharmacy as a pharmacy technician ~~or pharmacy technician-in-training~~.

The board may issue an initial pharmacy technician registration ~~or pharmacy technician-in-training~~ registration to any individual who is sixteen years of age or older, and is employed by a pharmacy or is enrolled in a pharmacy technician job exploration program through the high school they are attending. ~~An individual who was registered by the board prior to July 1, 2011, may renew the individual's registration provided all other requirements for renewal are met and the individual maintains a pharmacy technician registration or national certification on an uninterrupted basis. An 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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

20:51:29:04. College or vocational based training program. A person who is enrolled in a college- or vocational-based technician training program shall obtain a pharmacy ~~technician-in-training~~ technician registration prior to beginning on-site practical experience. ~~The technician-in-training program may not exceed two years' duration.~~

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(13), 36-11-25.

Law Implemented: SDCL 36-11-2~~(26)~~(22),36-11-25.

20:51:29:06. Certification of pharmacy technicians. A pharmacy technician ~~shall~~ may obtain national certification ~~within two years of registration with the board~~. ~~The board may not renew the registration of a pharmacy technician who was initially registered after July 1, 2011, unless the pharmacy technician is nationally certified~~. To obtain registration as a certified technician, the person must be certified by a national organization and ~~has~~ have passed a pharmacy technician certification examination that is accredited by the National Commission for Certifying Agencies ~~or is in the two-year technician-in-training period~~.

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

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

20:51:29:07. Registration application form--Fee. The application form for registration as a pharmacy technician must contain:

(1) The applicant's name, address, phone number, date of birth, gender, social security number, and email address;

(2) The applicant's work experience;

(3) Current and past places of employment; ~~and~~

(4) A non-refundable fee; and

(5) Proof of six hours of continuing education obtained within the last twenty-four months or proof of current pharmacy technician certification.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-11(13).

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

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

20:51:29:09. Felony or misdemeanor crimes. The applicant shall declare any history of being charged with, convicted of, or entering a plea of guilty or no contest to, a felony or misdemeanor crime other than any traffic violation with a fine under one hundred dollars.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

20:51:29:12. Registration fee. The fee for initial registration is twenty-five dollars. The renewal fee for the registration is twenty-five dollars. Fees shall be paid at the time the new application or the renewal application is submitted.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

20:51:29:13. Timeliness of initial application or renewal application. An initial application may be denied if not received within the period specified in § 20:51:29:03. A renewal application may be denied if not received by the October thirty-first expiration date. 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 actions as set forth in § 20:51:29:27.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

20:51:29:14. Registration certification. The pharmacy technician shall maintain a certificate of registration as a pharmacy technician. The pharmacist-in-charge 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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-2.2, 36-11-34.

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

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

20:51:29:16. Training and utilization of pharmacy technicians. The pharmacist-in-charge of a pharmacy shall ensure that a technician receives adequate training in the tasks performed by pharmacy technicians working at that pharmacy. A 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 the frequency of review in its policies. 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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

20:51:29:19. Ratio. Up to three pharmacy technicians may be on duty in a pharmacy for every pharmacist on duty. A pharmacy intern does not count in this ratio.

Source: 31 SDR 35, effective September 19, 2004; 42 SDR 19, effective August 19, 2015; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

Cross-Reference: Number of interns, § 20:51:02:11.01.

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

(1) Medication must be dispensed pursuant to a legal prescription;

(2) The technology must include tablet or product imaging or bar code scanning, to ensure accuracy in the prescription filling process;

(3) A role-based access software automation system that places stop points within the prescription filling process must be used, and the system must require a pharmacist's intervention before the prescription may 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 must be used;

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

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

(7) All non-pharmacist personnel who input patient drug information into a computer or whose duties include receiving, packaging, or shipping of drugs; or who have access to any areas where drugs are dispensed must be registered as pharmacy technicians and meet the requirements of chapter 20:51:29 or be registered as a pharmacy intern under chapter 20:51:02;

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

(9) Drug information must be 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, must be in place;

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

(12) There must be written policies and procedures for training personnel, including ongoing training programs for all personnel and documentation of that training for each employee; and

(13) There must be a monitoring program designed to prevent diversion of controlled substances. This includes perpetual inventory of all scheduled controlled drugs. Routine audits must be 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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-19.2, 36-11-33.

20:51:29:20. Delegation and supervision of technical functions. A pharmacist may delegate technical dispensing functions to a pharmacy technician provided the pharmacist is on site supervising the performance of the delegated functions. 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 mechanical distribution device. The technician may place medications into the automated mechanical distribution device that have been checked by the pharmacist. The pharmacist is not required to accompany the technician when placing medications into the automated mechanical distribution device. The automated mechanical distribution device must be capable of printing out a record of medications filled by the technician. The record must be checked and verified by the pharmacist daily.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(5)(13).

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-44.

20:51:29:21. Technical functions. At the discretion of the supervising pharmacist, technical functions that may be delegated to a pharmacy technician include:

(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. Any changes other than the number of refills on the prescription may not be accepted by a technician and must be accepted by a pharmacist or pharmacy intern;

(3) Contacting prescribers to obtain prescription refill authorization;

(4) Collecting pertinent patient information;

(5) Inspecting drug supplies provided and controlled by a South Dakota licensed pharmacy, including drug supplies maintained in an automated mechanical distribution device, emergency medical room, ambulance, long-term care facility, hospital nursing unit, or hospice facility; and

(6) Assisting the pharmacist with the preparation of medications for administration to the patient topically, by injection, or by other approved methods.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

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 verbal prescription medication orders communicated to the pharmacy by a prescriber or the prescriber's agent; or

(6) Provide pharmaceutical services in a pharmacy without a pharmacist being present, except as authorized in chapter 20:51:30.

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; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-26.

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.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22).

20:51:29:24. Confidentiality. In the absence of express written consent from the patient or a 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 as outlined in SDCL 36-11-69, any of the following information:

(1) The contents of any prescription drug order or medication, the therapeutic effect thereof, or the nature of professional pharmaceutical services rendered to the patient;

(2) The nature, extent, or degree of illness suffered by the patient; or

(3) Any medical information furnished by the prescriber.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-69.

20:51:29:25. Illegal or unethical behavior. A pharmacy technician may not exhibit illegal or unethical behavior in connection with the technician's pharmacy employment. Illegal or unethical behavior includes: 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 for in § 20:51:29:27.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-26.

20:51:29:26. Denial of registration. The board may deny an application for registration as a pharmacy technician for any violation of:

(1) The laws of this state, another state, or the United States, relating to prescription drugs, controlled substances, or nonprescription drugs; or

(2) This chapter.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-2~~(26)~~(22), 36-11-26.

20:51:29:27. Disciplinary actions. For violations of this chapter, the board may:

(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 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) Refer the pharmacy technician to the Health Professionals' Assistance Program; or

(7) Issue a letter of concern or public reprimand.

Source: 31 SDR 35, effective September 19, 2004; 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-2A-2, 36-2A-6, 36-11-2~~(26)~~(22), 36-11-26.

CHAPTER 20:51:30

TELEPHARMACY

Section

20:51:30:03. Ownership or control by pharmacist required. The board may not issue a ~~permit~~ license 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~~ thirtieth.

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.

20:51:30:09. Restricted ~~area posted~~ access to remote pharmacy. ~~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~~ remote pharmacy. 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).

20:51:30:12. Technician and intern staffing requirements. Each remote pharmacy must be staffed with registered certified pharmacy technicians or registered pharmacy interns. A pharmacy technician working at a remote pharmacy without an onsite pharmacist, pharmacy intern, or experienced telepharmacy technician, must have a minimum of ~~two~~ one thousand hours of experience as a registered pharmacy technician in accordance with chapter 20:51:29 and shall be certified in accordance with § 20:51:29:06. ~~One thousand~~ Five hundred hours of this experience must be in a telepharmacy with an onsite pharmacist, intern, or another pharmacy technician meeting the experience requirements for technicians in this section. An intern may work at a remote pharmacy if the intern has at least five hundred hours of experience as a registered pharmacy intern in accordance with chapter 20:51:02.

Source: 35 SDR 183, effective February 2, 2009; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1)(13), 36-11-72(3).

Law Implemented: SDCL 36-11-2(26), 36-11-25, 36-11-71.

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. However, each remote pharmacy must have at least one pharmacy technician or pharmacy intern, that meets the criteria in § 20:51:30:12, 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).

20:51:30:15. 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~~ verifies the dispensing process. This prescription ~~certification~~ verification process must be done in real time. All prescription ~~certification~~ verification must be documented in the computer record. The computer must be capable of carrying the initials of the technician preparing the prescription and the pharmacist verifying the prescription. Verification is required for both new prescriptions and refills;

(5) When the patient receives a prescription, the pharmacist must use audiovisual communication to counsel the patient regarding use of the prescription being dispensed. Counseling is required only for new prescriptions. The pharmacist must meet the counseling standards in accordance with § 20:51:25:04;

(6) The remote pharmacy must maintain a log, signed by the patient, that documents a patient's refusal for counseling by the pharmacist.

Source: 35 SDR 183, effective February 2, 2009.

General Authority: SDCL 36-11-11(1), 36-11-72(2),(3),(4),(5).

Law Implemented: SDCL 36-11-72(2),(3),(4),(5).

20:51:30:18. Use of automated prescription 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~~ dispensing device must be developed and submitted to the board for consideration. After approval, these policies and procedures must be available at both the central pharmacy and the remote pharmacy.

Source: 35 SDR 183, effective February 2, 2009; 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(1),(6), 36-11-72(6).

Law Implemented: SDCL 36-11-11(6), 36-11-72(6).

20:51:31:32. Compounding and hazardous drug handling standards -- United States Pharmacopeia compounding standards implemented by reference. All sterile compounding, nonsterile compounding, and repackaging must be handled in accordance with federal law, this chapter, and the United States Pharmacopeia–National Formulary (February 1, 2024), General Chapter 797 *Pharmaceutical Compounding – Sterile Preparations,* General Chapter 795 *Pharmaceutical Compounding – Nonsterile Preparations,* General Chapter 800 *Hazardous Drugs – Handling in Healthcare Settings,* and General Chapter 825 *Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging*.

Source: 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3)(8).

Law Implemented: SDCL 36-11-2.2(3), 36-11-11(3)(8), 36-11-46.

Reference: United States Pharmacopeia--Compounding Compendium (February 1, 2024), available at https://online.uspnf.com/uspnf. Cost: ~~$800~~ $250 for individual user.

20:51:31:33. Policy and procedure manual. The pharmacist-in-charge must prepare and maintain a policy and procedure manual for compounding practices. The policy and procedure manual must include a quality assurance program, all applicable United States Pharmacopeia requirements, and be available for inspection by the board.

Source: 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3)(8).

Law Implemented: SDCL 36-11-2.2(3), 36-11-46.

Reference: United States Pharmacopeia--Compounding Compendium (February 1, 2024), available at https://online.uspnf.com/uspnf. Cost: ~~$800~~ $250 for individual user.

20:51:31:34. Compounding requirements. Any pharmacy that engages in compounding must adhere to physical, equipment, and environmental requirements established by United States Pharmacopeia. Pharmacy compounding staff shall have access to current reference materials applicable to compounding.

Source: 50 SDR 138, effective June 2, 2024.

General Authority: SDCL 36-11-11(3)(8).

Law Implemented: SDCL 36-11-2.2(3), 36-11-46.

Reference: United States Pharmacopeia--Compounding Compendium (February 1, 2024), available at https://online.uspnf.com/uspnf. Cost: ~~$800~~ $250 for individual user.

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, 36-11A-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 (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, 36-11A-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, 36-11A-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 (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, 36-11A-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, 36-11A-14.

20:51:36:02. License required. Any pharmacy acting as a central fill pharmacy in this state must be ~~permitted~~ licensed pursuant to SDCL 36-11-32 and not ~~permitted~~ licensed as a pharmacy under SDCL 36-11-33. Any central fill pharmacy located outside the state must be licensed as a non-resident pharmacy. Any originating pharmacy located in this state must be ~~permitted~~ licensed as a full-time pharmacy.

Source: 50 SDR 138, effective June 2, 2024.

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

Law Implemented: SDCL 36-11-19.2, 36-11-19.3, 36-11-30.

20:67:02:01. Application and fee. A wholesale or other distributor must apply each year to the board, electronically or on a form supplied by the secretary of the board, for a license to engage in distribution of prescription drugs. Each application shall be accompanied by a license fee of ~~$200~~ five hundred dollars.

Source: 18 SDR 95, effective November 25, 1991; 24 SDR 160, effective May 26, 1998; 45 SDR 86, effective December 24, 2018.

General Authority: SDCL 36-11A-14(1),(6).

Law Implemented: SDCL 36-11A-7, 36-11A-8.

20:67:02:10. Out-of-state wholesale or other drug distributor application -- Other state license required. Out-of-state wholesale or other drug distributors must meet the application and fee requirements of this chapter and must also submit a copy of their wholesale drug distributor's license or its equivalent from the state in which the distributor is located if a license is issued by that state. Any applicant located outside of the state must provide a copy of a the most recent inspection that has been conducted within the last four years by the facilities home state licensing agency or any other agency approved by the board. If there are any findings or deficiencies that are observed during the inspection an explanation of corrections must be included with the application.

Source: 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

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

Law Implemented: SDCL 36-11A-7, 36-11A-11, 36-11A-28.