ARTICLE 20:51

PHARMACISTS

Chapter

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CHAPTER 20:51:01

REGISTRATION BY EXAMINATION

Section

20:51:01:01. Application for registration. An applicant for registration as a pharmacist by examination shall apply ~~on forms provided by~~ 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.

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.

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

(1) The ~~certificate of registration~~ application fee of ~~$35~~ thirty-five dollars;

(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; and

(6) A criminal background check.

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

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

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

~~Cross-Reference~~ Cross-References:

Examination, § 20:51:01:04.

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

20:51:01:09. Approved colleges of pharmacy. ~~A~~pproved 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20 North Clark Street, Suite 2500, Chicago, IL 60602-5109; Phone: 312-664-3575; Web site: www.acpe-accredit.org Repealed.

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

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

~~**Law Implemented:** SDCL 36-11-16.~~

20:51:01:11. ~~NAPLEX~~ North American Pharmacist Licensure Examination score transfer ~~form~~. An applicant meeting the requirements of this chapter who has taken the ~~NAPLEX examination~~ North American Pharmacist Licensure Examination in another state may transfer scores ~~on an official NAPLEX score transfer form furnished by~~ through the National Association of Boards of Pharmacy. To be eligible for licensure, an applicant must complete the requirements of § 20:51:01:03 and receive a passing grade in the ~~MPJE~~ 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.

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

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

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

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

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

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

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

CHAPTER 20:51:02

INTERNSHIP REQUIREMENTS

Section

20:51:02:16 Denial of pharmacy intern registration.

20:51:02:17 Sanctions, Repealed.

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

(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~~ who is 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~~ an Accreditation Council for Pharmacy Education (ACPE) accredited 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)~~(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 ~~(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)~~(3) A qualified applicant awaiting examination for pharmacist licensure or meeting board requirements for re-licensing; or

~~(d)~~(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.

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

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

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

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

Source: 31 SDR 35, effective September 19, 2004; 36 SDR 21, effective August 17, 2009.

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

~~**Law Implemented:** SDCL 36-11-25.~~

20:51:02:05. Renewal of certificate. Each pharmacy intern shall apply for renewal ~~of his or her certificate~~ before October ~~1~~ first 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~~ approve the application 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.

20:51:02:11. Supervising pharmacist requirements. A registered pharmacist who agrees to supervise the practical experience of a registered pharmacy intern ~~must~~ shall 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 readily available and in continuous ~~contact with and actually giving instructions to the intern~~ 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~~, including the name of the drug, its strength and dosage, directions for use, and the number of allowable refills~~.

A pharmacist ~~must~~ 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 ~~must~~ 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.

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

Source: 36 SDR 21, effective August 17, 2009.

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

Law Implemented: SDCL 36-11-25.

20:51:02:13. Internship experiences from other states. The ~~South Dakota Board of Pharmacy~~ board 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~~ another 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~~ shall obtain a minimum of ~~1500 hours of~~ one thousand five hundred internship hours 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.

20:51:02:15. 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~~ board 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 or federal statutes or ~~for any violation of state~~ pharmacy laws or rules~~)~~ of any state.

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 ofthis 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~~ Repealed.

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

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

~~**Law Implemented:** SDCL 36-11-25.~~

CHAPTER 20:51:04

REGISTRATION BY RECIPROCITY

Section

20:51:04:02. Qualifications for reciprocity. ~~The following qualifications are required~~ To qualify for reciprocal registration in South Dakota, an applicant must:

(1) ~~The applicant must be~~ Be a registered pharmacist ~~by examination~~ in the state from which the pharmacist ~~will reciprocate~~ is reciprocating;

(2) ~~The applicant must be~~ Be in good standing as a pharmacist, in ~~that~~ the state from which the pharmacist is reciprocating at the time ~~the pharmacist applies for reciprocity~~ of application;

(3) ~~The applicant must have~~ 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~~ one-year period immediately prior to the date of ~~such~~ application; and

(4) For any applicant who ~~obtained his or her original license~~ first became a licensed pharmacist 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.

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

(1) ~~The~~ A South Dakota reciprocating pharmacist application with a nonrefundable ~~application~~ fee of ~~$150~~ one hundred fifty dollars;

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

(3) A criminal background check.

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

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

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

CHAPTER 20:51:05

RESTRICTED PROFESSIONAL PRACTICES

Section

20:51:05:18 Partial filling of prescription for Schedule II controlled drug.

20:51:05:19 Prescription required to dispense Schedule III or IV controlled drug -- Refill restricted.

20:51:05:20 Legend drug to be dispensed by prescription only -- Refill restricted.

20:51:05:21 Labeling of prescription container for controlled or noncontrolled legend drug.

20:51:05:22 Distribution of drugs to ~~other practitioners~~ prescribers or pharmacies.

20:51:05:23 Distribution of dialysate or dialysis devices by the manufacturer or manufacturer's agent to a patient -- Exempt from pharmacy licensure.

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

(1) "Controlled drug," a substance as defined in SDCL ~~36-11-2(5)~~ 36-11-2.1 ~~which~~ that is controlled under the provisions of SDCL chapter 34-20B and is listed in SDCL ~~34-20B-11~~ 34-20B-12 to 34-20B-26, inclusive~~.~~; and

(2) "Legend drug," as defined in SDCL ~~34-20B-28.1(4)~~ 34-20B-28.1.

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

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

Law Implemented: SDCL ~~36-11-11~~ 36-11-20.

20:51:05:14. No advertising permitted on prescription blanks furnished to doctors. ~~No prescription blank furnished a doctorshall carryany advertising or the name of any registered pharmacy~~ Repealed.

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

~~**General Authority:** SDCL 36-11-11~~

~~**Law Implemented:** SDCL36-11-11.~~

20:51:05:15. Controlled drug to be dispensed only by prescription. ~~No~~ A pharmacist may not dispense a controlled drug unless the controlled drug is dispensed pursuant to the prescription of a ~~practitioner~~ prescriber licensed to prescribe controlled drugs. A pharmacist shall exercise sound professional judgment with respect to the legitimacy of prescription orders. ~~Any~~ A 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~~:

(1) The name and address of the patient ~~and the~~;

(2) The controlled drug name, strength, dosage form, quantity prescribed, and directions for use~~,~~; and

(3) The name, address, and registration number of the ~~practitioner~~ prescriber. ~~Where~~

If an oral prescription for a ~~schedule~~ 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~~ prescriber or issued and signed electronically where permissible by law. A prescription for a Schedule II controlled drug may not be filled later than six months after the date of issuance.

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~~ (4).

Law Implemented: SDCL~~36-11-11(1), 34-20B-41~~ 36-11-2.2.

Cross References:

Facsimile transmission of ~~schedule~~ Schedule II prescriptions, § 44:58:08:18.03.

Manner of issuance of prescriptions, § 44:58:08:05.

20:51:05:15.01. Identification required for controlled drug prescription. Except for inpatients in a health care facility licensed pursuant to SDCL chapter 34-12, the pharmacy must have a policy to verify the identity of anyone attempting to purchase or pick up a prescription for a controlled substance listed in SDCL chapter 34-20B. The pharmacy shall post a notice to the public that states "No prescription for a controlled drug may be sold without verification of purchaser identity per ARSD 20:51:05:15.01".

Source:

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

Law Implemented: SDCL 36-11-68.

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~~ procedures set ~~out~~ forth in §§ 44:58:08:18~~,~~ and 44:58:08:18.01, 21 C.F.R. §§ 1306.12 and 1306.13 (January 24, 2024).

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.

Cross Reference: Prescriptions, chapter 44:58:08.

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

~~Electronic data processing equipment, when~~ If a prescription software platform is used to maintain patient files, the program must provide ~~on-line~~ retrieval of original prescription information for those prescription orders ~~which~~ that 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~~ two years from the last dispensing date. The identity of the pharmacist dispensing a refill must be included in the record.

A pharmacist may not fill ~~any~~ an 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), 36-11-68.

Law Implemented: SDCL ~~36-11-11(1)~~36-11-2.2, 36-11-20, 36-11-68.

20:51:05:20. Legend drug to be dispensed by prescription only -- Refill restricted. A pharmacist may ~~only~~ dispense a legend drug or medicine only pursuant to the written, oral, or electronic prescription of a ~~practitioner~~ licensed ~~to prescribe drugs and medicines~~ prescriber. A prescription ~~by a prescriber~~ may be delivered to a pharmacist by handwritten order, facsimile, or electronic equipment ~~where permissible~~ if permitted by law. ~~An~~ A pharmacist or intern shall reduce an oral prescription ~~shall be reduced~~ promptly to ~~writing by the pharmacist and the~~ a written record filed or electronically recorded in the same manner as ~~though it were~~ a written prescription. ~~No~~ A noncontrolled legend drug prescription may not be refilled except as designated in the original prescription or as subsequently authorized by the prescriber and not after twelve months from the original issue date. Each refill ~~shall~~ must be entered on the back of the original prescription or captured electronically and ~~shall~~ must indicate the quantity dispensed, the date refilled, and the initials or name of the dispensing pharmacist. If the prescriber is unable to be contacted to authorize refills, the pharmacist may fill up to a thirty-day supply of a noncontrolled legend drug, if in the professional judgement of the pharmacist, the drug is necessary to maintain the patient's health.

~~Electronic data processing equipment when~~ If a prescription software program is used to maintain patient files, the program must provide on-line retrieval of all original prescription information for those prescription orders ~~which~~ that 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~~ must be filed and retained for two years from the last dispensing date. ~~Electronic records~~ The prescription software program must contain daily back-up functionality to protect against record loss and ~~be capable of printing~~ have the capability to print the documentation of the record at the board's request.

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

~~from the prescriber.~~

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

General Authority: SDCL 36-11-11(1), 36-11-68.

Law Implemented: SDCL ~~36-11-11(1)~~ 36-11-2.2, 36-11-20, 36-11-68.

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~~ each 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~~, and precautions, if any, when using the drug; the name, strength, and quantity of the drug~~,~~; the number of refills remaining; and the initials of the dispensing pharmacist. ~~The prescription label for controlled drugs must comply with the label requirements of § 44:58:08:20, including the transfer auxiliary label warning.~~

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

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)~~36-11-46.6.

Cross Reference: Storage and labeling of medications and drugs, § 44:73:08:04.

20:51:05:22. Distribution of drugs to ~~other practitioners~~ prescribers or pharmacies. A registered pharmacy ~~is authorized to~~ may distribute up to five percent of its controlled drugs and legend drugs to a ~~practitioner registered~~ prescriber licensed to prescribe, dispense, or distribute ~~such~~ the drugs in the course of professional practice or to other registered 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.

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

Law Implemented: SDCL~~36-11-11(1)~~36-11-14, 36-11A-4.

CHAPTER 20:51:06

PHARMACY PRACTICE AND REGISTRATION

Section

20:51:06:01. Application for pharmacy permit -- Annual renewal required. A registered pharmacist actively conducting a pharmacy in the state of South Dakota ~~must~~ shall apply each year to the ~~Board of Pharmacy~~ board for a permit to conduct the pharmacy for the ~~fiscal~~ year ending June thirtieth on forms provided by the board. The fee is ~~$200~~ 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.

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

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

20:51:06:02. Ownership or control by pharmacist required. ~~No~~ A pharmacy permit ~~to conduct a pharmacy shall~~ may not be issued to any pharmacist applicant unless ~~such pharmacist~~ the applicant is the owner, or part owner, of the ~~merchandise and fixtures of the~~ place of business for which a pharmacy registration is applied for, or unless application is made jointly with a registered pharmacist ~~owner, or unless the nonpharmacist~~. If the owner of the ~~merchandise and fixtures of the~~ place of business for which a pharmacy registration is applied for ~~has made~~ is not a pharmacist, the owner must sign an affidavit, on a form prescribed by the ~~state Board of Pharmacy~~ board, delegating full and complete authority to the ~~pharmacist applicant to be in~~ pharmacist-in-charge for active management of ~~said~~ the pharmaceutical services in the place of business ~~for the fiscal year ending June 30~~.

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

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

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

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~~ must indicate the pharmacist-in-charge. ~~The~~ For purposes of this section, the term~~,~~ "pharmacist-in-charge," means a pharmacist manager or pharmacist permittee ~~duly~~ licensed in ~~South Dakota~~ this state who has been ~~so~~ designated by the ~~employer~~ pharmacy owner.

The pharmacist-in-charge ~~shall~~ must:

(1) Be employed or ~~contracted~~ under contract 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~~.~~; 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 ~~secretary of the Board of Pharmacy~~ board immediately upon ~~knowledge of~~ termination of employment. A new pharmacist-in-charge ~~shall~~ must be designated by the ~~employer~~ pharmacy owner within ten working days after the termination date.

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

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

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

20:51:06:03. ~~Renewal required each year~~ Application for opening a new pharmacy. ~~Application for the renewal of a permit to conduct a pharmacy shall be filed with the secretary of the Board of Pharmacy before July 1 each year. The fee set by the Board of Pharmacy shall accompany the application. Applications~~ An application for ~~opening and conducting a new~~ an initial pharmacy permit in South Dakota ~~shall~~ must be filed with the ~~secretary of the Board of Pharmacy~~ board at least ~~30~~ thirty days before the pharmacy's opening 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.~~ The board may inspect the pharmacy prior to the opening date.

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~~ must be separated from the remainder of the building in which it is located by walls ~~extended~~ that extend from the floor to ~~the~~ a permanent ceiling. The walls may contain doors to the interior of the building ~~which shall~~. The doors must be closed and locked whenever a registered pharmacist is not on duty, physically present in the building, and in charge of the pharmacy.

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

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

effective July 1, 1986.

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

Law Implemented: SDCL 36-11-32.

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

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

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

Law Implemented: SDCL 36-11-44, ~~36-11-62~~ 36-11-48.

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~~ Repealed.

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~~ Repealed.

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~~ the board -- Patients notified of closure of pharmacy. ~~Any~~ A change in the location, ownership ~~of a pharmacy, or any change in the ownership of the merchandise and fixtures of a pharmacy,~~ or name of a pharmacy, or ~~the cessation~~ the closure of business as a pharmacy, ~~shall~~ must be reported to the ~~secretary of the Board of Pharmacy within~~ board at least ten days ~~of such occurrence~~ prior to the change or closure. The pharmacist permittee ~~shall be held~~ is responsible for reporting ~~such~~ changes to the ~~Board of Pharmacy~~ 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.

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

Law Implemented: SDCL 36-11-39.

20:51:06:09. Permit expires ~~120~~ one hundred twenty 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 deceased pharmacist ~~who is deceased shall within 120 days after the death of the permittee become~~ becomes void unless transfer of the permit has been made within the ~~120-day~~ 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 ~~merchandise and fixtures of the~~ pharmacy.

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

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

Law Implemented: SDCL 36-11-38.

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

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

~~(2) A restricted drug area where only packaged drugs or 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.~~

Where the registered pharmacy includes a prescription department and a general merchandise area, ~~It shall~~ it is not ~~be considered in~~ a violation of ~~the state pharmacy law~~ SDCLchapter 36-11 or § 20:51:06:04 if public entrances to ~~such~~ the general merchandise area are kept open for ~~the transaction of~~ business without a pharmacist on duty in ~~such~~ the 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. 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.

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

Law Implemented: SDCL~~36-11-11~~ 36-11-40.

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~~ Repealed.

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~~ Repealed.

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

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

~~**Law Implemented:** SDCL 36-11-34.~~

CHAPTER 20:51:07

MINIMUM EQUIPMENT REQUIREMENTS

Section

20:51:07:01. Pharmacy must comply with all public health regulations. ~~The~~ A pharmacy ~~shall~~ must comply with all public health regulations regarding sanitation and ~~shall~~ 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.

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

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

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

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

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

~~(3) A poison register;~~

~~(4) A supply of labels, including poison labels;~~

~~(5) Permanent file for all prescriptions;~~

~~(6) Locked space for narcotics and dangerous drugs;~~

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

~~(8) Refrigerated storage space for biologicals and drugs affected by extreme temperatures~~ A pharmacy permittee 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.

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

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

20:51:07:04. Publication and reference library. ~~Each pharmacy shall maintain~~ All pharmacy staff must have access to ~~the latest copy of~~ South Dakota pharmacy laws and rules, federal laws and rules, all governing or regulatory agency documents needed to conduct pharmacy services, and the telephone number of the nearest poison control center. ~~Pharmaceutical reference~~ The required publications and materials may be printed or ~~computer-accessed~~ online. ~~At least one general pharmaceutical information reference must be a printed copy. Additional reference~~ Reference material ~~shall~~ must be maintained and ~~shall~~ must include~~, at a minimum,~~ one current drug information 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.~~

that the pharmacist-in-charge determines to be necessary to provide pharmacy services to patients at that location.

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

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

Law Implemented: SDCL 36-11-41(2).

CHAPTER 20:51:13

SPECIAL RESTRICTIONS

Section

20:51:13:02. Return of unused drugs. ~~Pharmacists~~ Except as otherwise provided by chapters 20:51:21 and 20:51:35, pharmacists and pharmacies ~~are prohibited from accepting~~ may not accept 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~~ In a hospital with a licensed pharmacy, unused drugs, sickroom supplies, hygienic surgical appliances or garments, ~~or~~ and 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)~~ 34-20H-2, 36-11-33.

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

(1) The facility or hospice program consults with a licensed pharmacist ~~to oversee~~ 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 ~~unit dose~~ 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 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 a hermetically sealed single unit dose container that meets Class A or Class B standards on pages 1937 and 1938 of the United States Pharmacopeia~~ in accordance with chapter 20:51:21;

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

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

(a) ~~Name~~ The 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 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;

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

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

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

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

(9) The drugs are not controlled drugs.

Unused drugs that are returned under this section may be redispensed pursuant to § 20:51:13:02.03.

Source: 10 SDR 38, effective October 27, 1983; 12 SDR 82, effective November 19, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 29 SDR 37, effective September 26, 2002; SL 2004, ch 249, § 3, effective July 1, 2004.

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

Law Implemented: SDCL ~~36-11-11(1), 36-11-46~~ 34-20H-2, 36-11-46.6.

~~**Reference:** Pages 1937 and 1938, **The United States Pharmacopeia, Twenty-fourth Revision The National Formulary, Nineteenth Edition**, January 1, 2000, published by the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852. Photocopies of pages 11, 1937, and 1938 may be obtained without charge from the State Board of~~

~~Pharmacy, 4305 South Louise Avenue, Suite 104, Sioux Falls, SD 57106.~~

Cross Reference: Unit dose systems, 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 ~~under~~ in accordance with the following ~~conditions~~ requirements:

(1) Drugs ~~may not be removed and repackaged from the returned unit dose package prior to redispensing~~ 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) Drugs ~~which~~ that have been repackaged into a unit ~~dose~~ of issue package by the pharmacy may be redispensed into a unit ~~dose~~ 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 ~~dose~~ of issue package or in the internal record; and

(4) Drugs may be removed from a unit dose or unit of issue package for dispensing in a traditional dispensing system as ~~defined~~ described 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~~ 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. ~~However, drugs~~ Drugs transferred directly from one pharmacy to another pharmacy may be repackaged into unit dose or unit of issue 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~~ Manufacturer's 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~~ 34-20H-2, 36-11-46.6.

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~~ a prescription filled at the pharmacy of ~~his~~ the person's choice. This ~~regulation of the~~ 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.

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

Law Implemented: SDCL ~~36-11-11~~ 34-12B-1.

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

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 registry fee for annual certificate renewal is ~~$125~~ one hundred fifty dollars. Certificates 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.

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)~~ Repealed.

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~~ Terms used in this chapter ~~are as follows~~ 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) The terms~~ "~~part-time~~ Part-time~~,~~" ~~"limited," or "conditional"~~ pharmacy," ~~mean~~ the ~~providing~~ provision of pharmaceutical services by a registered pharmacist under a pharmacy license issued by the ~~South Dakota Board of Pharmacy~~ board, on less than a full-time operation basis, in hospitals, nursing facilities, and related facilities ~~and where such~~ in which 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)~~ (4) ~~The term~~ "~~pharmaceutical~~ Pharmaceutical services" ~~means and includes~~:

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

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

(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)~~subdivisions subsections (4)(a) and (b) 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(1).

Law Implemented: SDCL 36-11-33.

20:51:15:03. Central area to be licensed as a pharmacy. The central area in a hospital, nursing facility, and related facilities, where drugs are procured, stored, and issued, and where pharmaceutical services are performed ~~shall~~, must 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~~ board and ~~shall~~ must 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(1)(3).

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.

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.

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 licensed pursuant to SDCL chapter 36-9, of a solution for injection ~~by a licensed nurse,~~ is considered a step in the administration of medication.

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

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

Law Implemented: SDCL ~~36-11-33~~ 36-11-2.2.

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.~~ Repealed.

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~~ operate 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~~ 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.

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

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

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

20:51:15:12. Supervision of drugs located in areas other than pharmacy. Drugs~~,~~ and medications ~~and poisons~~ located in areas of ~~the~~ a facility, other than in the pharmacy ~~shall~~, must be under the general supervision of the ~~registered pharmacist employed or otherwise engaged~~ pharmacist-in-charge.

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

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

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

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~~ If 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~~ prescriber when the drug is not available in floor supplies, or the emergency drug kit, to meet the immediate need ~~in an emergency~~ of the patient. ~~This~~ 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 ~~size~~ form and strength, the amount taken, and the date and ~~the~~ time the drugs were removed, and ~~signed by the nurse~~ shall sign the record. ~~Further, the~~ The nurse shall leave ~~with~~ the record and 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~~ These records ~~shall~~ must be kept for ~~three~~ two years.

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

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

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

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~~ prescribers, a defined supply of legend drugs in an emergency drug kit or crash cart. The emergency drugs ~~shall~~ 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 ~~shall~~ must remain the property of the registered pharmacy and ~~shall~~ must be stored on-site in a suitable, controlled location in the health care facility. The emergency drug supplies ~~shall comply with the~~ 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 ~~shall~~ must be identified for replacement by a pharmacist; and

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

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

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

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

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~~ §§ 44:58:07:09 and 44:73:08:11, ~~and~~ a limited amount of noncontrolled legend drugs, and nonprescription drugs, for emergency and supportive treatment, ~~when~~ 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 provider pharmacy shall provide to the Board of Pharmacy yearly the name of each nursing facility where emergency drugs are kept and stored;~~

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

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

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

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

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

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

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

~~(7)~~ (4) The emergency kit ~~shall~~ must 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~~ must be labeled clearly, ~~and unmistakably,~~ that it is an emergency kit and is for

emergency use only. The emergency kit ~~shall~~ 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 ~~shall~~ must 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 36-11-2.2, 36-11-33, 36-11-34.

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

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

~~**General Authority:** SDCL 36-11-11.~~

~~**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.~~

CHAPTER 20:51:16

RULES OF PROFESSIONAL CONDUCT

Section

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

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

(2) ~~Uses~~ Use 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~~ Seek to enlist and to merit the confidence of the ~~pharmacist's patrons~~ public. The pharmacist zealously guards this confidence. The pharmacist considers the knowledge and confidence ~~which~~ that the pharmacist gains of the ailments of ~~patrons~~ patients as entrusted to the pharmacist's honor, and does not divulge ~~such~~ these facts;

(4) ~~Holds~~ Hold the health and safety of the pharmacist's ~~patrons~~ patients 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~~ Keep 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~~ Be a good citizen and ~~upholds~~ uphold and ~~defends~~ defend the laws of the states and nation; the pharmacist ~~keeps~~ shall keep informed concerning pharmacy and drug laws and other laws pertaining to health and sanitation, and ~~cooperates~~ cooperate with ~~the~~ enforcement authorities;

(7) ~~Supports~~ Support constructive efforts ~~in~~ on 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~~ seek 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~~ these services to a licensed ~~practitioner~~ prescriber~~. In an emergency and pending the arrival of a qualified practitioner, the pharmacist may apply first aid treatment~~;

(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~~ must 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~~ licensed prescriber 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 34-12B-4, 36-11-43, 34-12B-6.

CHAPTER 20:51:17

AUTOMATED MECHANICAL DISTRIBUTION AND DISPENSING DEVICES

Section

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

(1) "Automated mechanical distribution device," a mechanical device that is located in a health care facility, 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 the identity of all personnel who have access to drugs or drug devices stocked within the device; and

(c) Document both stocking and removal transactions;

(2) "Automated prescription dispensing device," a mechanical device that aids in the process of dispensing medication in a retail pharmacy or health care facility including storing, counting, and labeling medications; and

(3) "Health care facility," any ~~state licensed hospital, nursing facility, or related facility that offers supervised care of the sick or injured~~ facility licensed pursuant to SDCL chapter 34-12

~~(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 permitissued 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)~~(5).

Law Implemented: SDCL ~~36-11-11(6)~~ 36-11-15, 36-11-30, 36-11-33.

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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~~ Repealed.

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

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

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

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

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

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

Law Implemented: SDCL~~36-11-11(6)~~ 36-11-2.2, 36-11-34.

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

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

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

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

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

~~(c) The date of stocking~~;

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

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

(a) The name of ~~the~~ each drug;

(b) The strength of ~~the~~ each drug;

(c) The manufacturer's lot or internal control number of each drug; and

(d) The expiration date of ~~the~~ each 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)~~(5) When using automated mechanical or electronic devices as pharmaceutical tools, the ~~health care facility~~ pharmacy must arrange to provide pharmaceutical services if the device fails;

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

~~(9)~~(6) Notwithstanding any ~~of the~~ provisions ~~in~~ of this section, the ~~pharmacist permittee~~ pharmacist-in-charge of the ~~health care facility~~ pharmacy is responsible for maintaining and enforcing written procedures that establish safeguards for distributing or dispensing 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)~~(5).

Law Implemented: SDCL ~~36-11-11(6)~~ 36-11-2.2, 36-11-34, 36-11-46.4, 36-11-46.6.

~~**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.~~

20:51:17:03 Stand-alone automated mechanical distribution device and automated prescription dispensing device -- License required. When a stand-alone automated mechanical distribution device or an automated prescription dispensing device is used to store, distribute, dispense, or track drugs, where there is no pharmacy license on the premises, the owner of the device must apply to the board to license the automated device as a pharmacy.

Source:

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

Law Implemented: SDCL 36-11-30, 36-11-33, 36-11-34.

CHAPTER 20:51:19

CONTINUING EDUCATION

Section

20:51:19:03. Hours required. To qualify for ~~relicensure, an active~~ a certificate of registration renewal or reinstatement, a pharmacist must successfully complete ~~12~~ twelve hours of continuing education. The ~~12~~ twelve hours of approved continuing education required each year for ~~relicensure~~ renewal must be completed within the ~~24~~ twenty-four months before the pharmacist's certificate of registration expires. ~~When~~ If a pharmacist applies for yearly renewal of the pharmacist's certificate of registration pursuant to SDCL 36-11-23, in order to receive renewal, the pharmacist ~~must report completed continuing education hours on a form supplied by the board~~ 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 purpose 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.

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

General Authority: SDCL ~~36-11-10,~~ 36-11-11(1), 36-11-23.2.

Law Implemented: SDCL ~~36-11-23.2,~~ 36-11-23.1 to 36-11-23.3, inclusive.

20:51:19:04. Hours defined. The hourly value for continuing education credit is defined as the measurement of value applied to a particular accredited continuing pharmacy educational activity as assigned by the ~~Board of Pharmacy~~ board relative to maintaining the competency of a registrant.

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

General Authority: SDCL ~~36-11-10,~~ 36-11-11(1), 36-11-23.2.

Law Implemented: SDCL ~~36-11-23.2~~ 36-11-23.1 to 36-11-23.4, inclusive.

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

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

General Authority: SDCL 36-11-23.2.

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

20:51:19:06. Continuing education from other states. The ~~Board of Pharmacy~~ board may accept ~~comparable~~ continuing education hours obtained in any state, if the program is approved by the other ~~state boards~~ state's board 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(1), 36-11-23.2.

Law Implemented: SDCL 36-11-23.2.

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

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

General Authority: SDCL ~~36-11-10,~~ 36-11-11(1), 36-11-23.2.

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

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~~ Repealed.

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~~ be approved by the ~~Board of Pharmacy~~ board. Sponsors must apply for approval to the board, on forms furnished by the board, at least ~~30~~ thirty days before the initiation of the course. The board shall send written notice of its approval or disapproval to sponsors.

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

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

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

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

Law Implemented: SDCL 36-11-23.2, 36-11-23.4.

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~~ must be completed by the sponsor and submitted to the board. The form must include the following information ~~shall be submitted to the board on the form~~:

(1) Name of the sponsor and address;

(2) Name of the person in charge;

(3) Location of the program;

(4) Estimated number of the pharmacists and technicians participating;

(5) General title of the program;

(6) Type of 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 the program objectives will be met;

(8) Estimated contact time;

(9) How attendance or participation will be proven;

(10) How certificates will be awarded; and

(11) ~~Copy~~ A copy of any examination, if utilized.

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

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

Law Implemented: SDCL 36-11-23.2, 36-11-23.4.

20:51:19:16. Sponsor to provide list of pharmacists and technicians attending program. The sponsor of a continuing education program shall provide to the ~~Board of Pharmacy~~ board a written or electronic list of the pharmacists and technicians attending within ~~45~~ thirty 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~~ 36-11-23.1 to 36-11-23.4, inclusive.

CHAPTER 20:51:20

COMPUTER PHARMACY

Section

20:51:20:01. Input of drug information into ~~electronic data processing~~ prescription software platform 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.~~ Only a pharmacist, technician, or intern may input prescription information into a prescription software platform. The pharmacist must certify the accuracy of the information ~~to be~~ entered and verify the prescription order ~~at the time of entry~~. The identity of the pharmacist must be ~~carried~~ included in the record.

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

General Authority: SDCL 36-11-11(12), 36-11-68.

Law Implemented: SDCL ~~36-11-11~~ 36-11-25, 36-11-34, 36-11-68.

20:51:20:02. Requirements for storing prescription information. ~~Electronic data processing equipment when~~ If a prescription software platform is used to store prescription information, ~~shall meet the following requirements~~ the platform must:

(1) ~~Guarantee~~ Maintain the confidentiality and integrity of the information contained in the ~~data bank~~ platform;

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

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

(4) Be capable of recording and ~~carrying~~ storing ~~in the record~~ all dates ~~of refills~~ of any prescription refill and the initials of the pharmacist~~. This shall meet the requirements of § 20:51:05:06~~ as required by §§20:51:05:18 to 20:51:05:20, inclusive;

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

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

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

General Authority: SDCL 36-11-11(12), 36-11-68.

Law Implemented: SDCL ~~36-11-11~~ 36-11-68.

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

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

General Authority: SDCL 36-11-11(12), 36-11-68.

Law Implemented: SDCL~~36-11-11~~ 36-11-68.

20:51:20:04. Use of common ~~electronic data base~~ prescription software platform. ~~Upon approval of the Board of Pharmacy, two~~ Two or more affiliated pharmacies licensed by the board may utilize a common ~~electronic data base~~ prescription software platform to practice pharmacy as ~~provided by~~ defined in SDCL 36-11-2.2. Prescriptions may be refilled at any of these pharmacies as long as each pharmacy is identified by a unique code that documents the location of each filling and provisions are made to assure that the number of authorized refills is not exceeded. ~~Application for approval must be made on a form supplied by the Board of Pharmacy.~~

A nonresident pharmacy not licensed by the board and sharing a common ~~electronic data base~~ prescription software platform with a pharmacy licensed by the board may not practice pharmacy in this state~~, but may refill a prescription if requested by the patient as long as the number of authorized refills is not exceeded. Information must be verified and communicated orally between two licensed pharmacists at the time of refilling~~.

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

Source: 16 SDR 98, effective December 3, 1989; 26 SDR 92, effective January 6, 2000.

General Authority: SDCL 36-11-11~~(13)~~(12)~~, 36-11-19.2~~.

Law Implemented: SDCL ~~36-11-11(13)~~ 36-11-2.2, 36-11-19.2, 36-11-19.8, 36-11-68.

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)~~ (2) "Customized patient drug 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 drug package;~~

~~(5) "Repackage," means to prepare a unit dose, single dose, unit of issue package, customized patient medication drug 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," means a drug package system in which individual doses are not packaged in unit dose packages or unit of issue packages;~~

~~(8)~~ (3) "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)~~ (4) "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)~~ (5) "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)~~ 36-11-2.2.

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

For purposes of this section:

(1) "Prepackaged," means to prepare a drug in a container for dispensing, prior to the receipt of an order. The 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 drug package; and

(2) "Repackaged," means to prepare a unit dose, single dose, unit of issue package, customized patient drug package, or traditional dispensing system package for dispensing pursuant to an existing order.

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)~~ 36-11-2.2.

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~~ Repealed.

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

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

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

20:51:21:05. Labeling of unit dose and unit of issue package -- Relabeling of unit dose and unit of issue system. Unit dose and unit of issue packages ~~shall~~ must 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~~ in accordance with subdivision 20:51:13:02.01(5).

After any change in dosage or administration schedule, the pharmacy ~~shall~~ must relabel the unit ~~dose system~~ of issue package 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)~~ 36-11-2.2.

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

For the purpose of this section, "Unit dose distribution system," means a drug distribution system that is in a pharmacy outlet, hospital, or other health care 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.

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)~~ 36-11-2.2.

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 or unit of issue 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)~~ 36-11-68.

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 or unit of issue 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)~~ 36-11-34.

CHAPTER 20:51:22

SUPPORT PERSONNEL

Section

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

Appropriately trained pharmacy support personnel may perform the following nontechnical functions involving the handling of prescription drugs, delegated to them by the pharmacist:

(1) Placing a prescription container into a bag or sack for delivery to the patient as part of the sales transaction after the accuracy of the prescription has been verified by the pharmacist;

(2) Opening drug shipments and affixing appropriate inventory or price stickers to drug stock bottles or containers;

(3) Answering telephones and filing processed, hard-copy prescriptions and other pharmacy records;

(4) Receiving a patient's request for a prescription refill, excluding the processing of the refill request; and

(5) Delivering drugs to patient care areas, long-term care facilities, patient residences, or patient employment locations, excluding the restocking of automated medication distribution systems.

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

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

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

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

Source:

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

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

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~~ total quantity authorized on the original prescription;

(2) The transfer is communicated directly between two licensed pharmacists or registered pharmacy interns, either verbally or by facsimile; and

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

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

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

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

20:51:23:02. Requirements of transferring pharmacist or intern. The pharmacist or intern 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 or intern receiving the prescription information;

(c) The name of the pharmacist or intern transferring the prescription information; and

(d) The date of the transfer.

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

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

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

Law Implemented: SDCL ~~36-11-11~~ 36-11-2.2, 36-11-25.

20:51:23:03. Requirements of receiving pharmacist or intern. The pharmacist or intern 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 transferring and the receiving pharmacist or intern transferring the prescription information.; and

(3) Clarify verbally any unclear information on a facsimile.

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

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

Law Implemented: SDCL 36-11-11 36-11-2.2, 36-11-25.

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

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

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

Law Implemented: SDCL ~~36-11-11~~ 36-11-68.

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

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

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

Law Implemented: SDCL ~~36-11-11~~ 36-11-2.2, 36-11-68.

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

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

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

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

~~(b) The hospital prescription number;~~

~~(c) The quantity dispensed;~~

~~(d) The date of dispensing; and~~

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

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

~~**General Authority:** SDCL 36-11-11.~~

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

CHAPTER 20:51:24

PATIENT RECORD SYSTEM

Section

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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~~ Repealed.

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~~ must maintain a ~~patient~~ record system ~~for~~ of patients for whom it dispenses prescription drug orders. The patient record system ~~shall~~ must 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~~ must include as much of the following information as the pharmacy is able to obtain:

(1) The full legal 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~~ two-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~~ prescriber;

(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~~ and drug devices currently being used by the patient, which may relate to a prospective drug review; ~~and~~

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

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

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

General Authority: SDCL 36-11-68.

Law Implemented: SDCL 36-11-68.

20:51:24:04. Maintenance of records. A pharmacy shall maintain information in a patient record system for at least ~~one year~~ two years 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~~ Definition. ~~Terms used in this chapter mean:~~

~~(1)~~ "Adverse ~~medical result,~~ drug reaction," when used in this chapter, means 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~~ when a prescription drug order or ~~prescription~~ refill request is presented for dispensing ~~for the purpose of identifying any of the following conditions~~ in order to identify:

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

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

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

(4) Drug-disease contraindications, or 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, or the potential for or the occurrence of an adverse ~~medical effect~~ drug reaction as a result of the patient using two or more drugs together;

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

(8) Drug-allergy interactions, or 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~~ prescriber.

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

General Authority: SDCL 36-11-68.

Law Implemented: SDCL 36-11-2.2, 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~~ Patient counseling ~~may include any of the following elements of patient counseling, as applicable~~ involves:

(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~~ effects, adverse ~~effects or~~ drug reactions, 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 36-11-2(19), 36-11-68.

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20:51:27:02. Application form. The application form for licensure of a nonresident pharmacy ~~shall~~ must include the ~~following~~ information ~~in addition to that~~ 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 non-resident pharmacy owner, in the home state or any other state within the last ~~three~~ four years and the ~~resolution of any such~~ reason for the action; ~~and~~

(3) If the ~~pharmacist-in-charge~~ 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.

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

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

Law Implemented: SDCL 36-11-19.3.

20:51:27:03. Application fee. The fee to accompany the initial application for a nonresident pharmacy license and each application for renewal is ~~$200~~ two hundred dollars.

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

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

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

20:51:27:04. Report of change in ownership or location. The ~~pharmacist in charge of a nonresident pharmacy~~ owner of a nonresident pharmacy or persons delegated by the owner 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 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 after the transaction. The license of a nonresident pharmacy is not transferable to a new ~~ownership~~ owner. Any new ~~ownership~~ 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.

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

Law Implemented: SDCL 36-11-19.3.

CHAPTER 20:51:28

ADMINISTRATION OF ~~INFLUENZA~~ IMMUNIZATIONS

Section

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

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

(2) Has successfully completed an approved training program;

(3) Is certified in cardiopulmonary resuscitation; and

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

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

Source: 47 SDR 42, effective October 12, 2020.

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

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

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.

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

Source:

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).

CHAPTER 20:51:29

REGISTERED PHARMACY TECHNICIANS

Section

20:51:29:20 Delegation and supervision of technical functions.

20:51:29:21 Technical functions.

20:51:29:22 Tasks a pharmacy technician may not perform.

20:51:29:23 Misrepresentative deeds.

20:51:29:24 Confidentiality.

20:51:29:25 ~~Illegal/unethical~~ Illegal or unethical behavior.

20:51:29:26 Denial of registration.

20:51:29:27 ~~Sanctions~~ Disciplinary actions.

20:51:29:00. 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);~~ "Certified technician," an individual described in SDCL subdivision 36-11-2(26) who has gained certification through training and examination pursuant to § 20:51:29:06;

(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~~,~~" ~~as defined~~ has the definition set forth in § 20:51:02:01; and

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

~~(5) "Pharmacy technician-in-training,~~ Technician-in-training," an individual who is registered with the board to receive on-the-job training in a licensed pharmacy ~~for~~ in preparation for ~~registration~~ certification as a pharmacy technician. 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.

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

20:51:29:01. Purpose of registration. A registration program for all 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~~ identifying, tracking, and bringing disciplinary actions against pharmacy technicians.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012.

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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~~ 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 ~~provided~~ required by rule may be subject to disciplinary ~~sanction as provided by rule~~ action in accordance with § 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)(13), ~~36-11-11(14)~~.

Law Implemented: SDCL ~~36-11-11(14)~~ 33-11-2(26).

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

~~Effective July 1, 2014, the~~ The board ~~shall not~~ may 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~~ 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 ~~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~~ An individual whose registration or national certification lapses for a period of ~~one year must~~ 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)(13), ~~36-11-11(14)~~.

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

20:51:29:04. College or vocational based training program. ~~Any~~ A person who is enrolled in a ~~college~~ college- or vocational-based technician training program ~~is required to~~ shall 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' duration.

Source: 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012.

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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)(13), ~~36-11-11(14)~~ 36-11-25.

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26), 36-11-25.

20:51:29:06. Certification of pharmacy technicians. ~~The national certification of~~ A pharmacy ~~technicians is required~~ technician shall obtain national certification within two years of registration with the board. ~~Effective July 1, 2014, the~~ The board ~~shall~~ may 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)~~ 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.

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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

(1) ~~Information sufficient to identify the applicant including~~ The applicant's name, address, phone number, date of birth, gender, ~~and~~ social security number, and email address;

(2) ~~Work~~ The applicant's work experience; ~~and~~

(3) Current and past places of employment; and

(4) A non-refundable fee.

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

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

Law Implemented: SDCL 36-11-2(26), 36-11-11~~(14)~~(13).

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

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

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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

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

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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.

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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~~ Repealed.

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~~ twenty-five dollars. The renewal fee for the registration is ~~$25~~ twenty-five dollars. 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)(13), ~~36-11-11(14)~~.

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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

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

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

20:51:29:14. Registration certification. The pharmacy technician shall maintain ~~the original~~ a 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)(13), ~~36-11-11(14)~~.

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26), 36-11-2.2, 36-11-34.

20:51:29:15. Notification to the board. ~~Within~~ A pharmacy technician shall, within ten days of any change ~~of~~ in 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)(13), ~~36-11-11(14)~~.

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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~~ The pharmacist-in-charge of a pharmacy ~~to~~ shall ensure that a technician receives adequate training in the tasks performed by pharmacy technicians working at that pharmacy. ~~Any~~ 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 ~~in its policies~~ 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.

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

20:51:29:17. Identification of pharmacy technicians. A pharmacy technician shall, while on duty, 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)(13), ~~36-11-11(14)~~.

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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)(13), ~~36-11-11(14)~~.

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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.~~ 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 ~~(§ 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)(13), ~~36-11-11(14)~~.

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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 ~~to pharmacists that~~ who may be on duty in a hospital, mail order, ~~and~~ or long-term care pharmacy ~~will be~~ is determined by the ~~pharmacist in charge~~ pharmacist-in-charge. ~~However, all of~~ Regardless of the ratio, the following requirements must be met:

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

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

(3) A role-based access software automation system that places stop points within the prescription filling process ~~is~~ must be used, ~~which requires~~ and the system must require a pharmacist's intervention before ~~allowing~~ the prescription ~~to~~ 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~~ age-appropriate dosage ranges ~~is~~ must be used;

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

(6) Electronic surveillance technology ~~is~~ must be 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, or shipping of drugs~~,~~; or who have access to any areas where drugs are dispensed ~~are~~ must be registered as pharmacy technicians and meet the requirements ~~in~~ of chapter 20:51:29;

(8) In hospital and long-term care pharmacies, nursing personnel in facilities served by the pharmacy shall have telephone access to a pharmacist ~~24~~ twenty-four hours a day, ~~7~~ seven days a

week. In mail order pharmacies, a patient ~~has~~ shall have access to a pharmacist ~~24~~ twenty-four hours a day, ~~7~~ seven days a week on a dedicated pharmacist staff line;

(9) Drug information~~, both electronic and hard copy, is~~ 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 ~~are~~ must be written policies and procedures for all ~~pharmacy functions --~~ clerical, supportive, technical, and clinical pharmacy functions;

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

(13) There ~~is~~ must be a ~~strict~~ monitoring program designed to prevent diversion of controlled substances. This includes perpetual inventory of all ~~schedule II~~ scheduled controlled drugs ~~as well as selected high-risk schedule III, IV, and V drugs~~. Routine audits ~~are~~ 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.

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26), 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, ~~but only if~~ provided the pharmacist is on site supervising the performance of 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~~ mechanical distribution device ~~approved by the board. After proper checking and verification with the physician orders by the pharmacist, the~~ The technician may ~~replace~~ place medications ~~to~~ into the automated ~~dispensing~~ 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 ~~dispensing~~ mechanical distribution device. The automated ~~dispensing~~ mechanical distribution device must be capable of printing out a record of medications filled by the technician. The record ~~shall~~ must be checked and verified by the pharmacist daily.

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

General Authority: SDCL 36-11-11(1)(5)(13), ~~36-11-11(14)~~.

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26), 36-11-44.

20:51:29:21. Technical functions. At the discretion of the supervising pharmacist, technical functions ~~which~~ that 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~~;~~. 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 ~~dispensing~~ distribution device, emergency medical room, ambulance ~~vehicle~~, long-term care facility, ~~a~~ hospital nursing unit, or ~~a~~ 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.

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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

(6) ~~Open, keep open, or provide~~ Provide pharmaceutical services ~~from~~ in a pharmacy without a pharmacist being present ~~as provided in §§ 20:51:06:11, 20:51:15:02, and 20:51:15:04~~, except as authorized in chapter 20:51:30.

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

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

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26), 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 or in the operation or conduct of~~ a pharmacy.

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

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26).

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 ~~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~~ as outlined in SDCL 36-11-69, any of the following information:

(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~~ the patient;

(2) The nature, extent, or degree of illness suffered by ~~any~~ the 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)(13), ~~36-11-11(14)~~.

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26), 36-11-69.

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

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

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26), 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 ~~the~~:

(1) 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~~

(2) This chapter~~)~~.

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

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-11-2(26), 36-11-26.

20:51:29:27. ~~Sanctions~~ Disciplinary actions. ~~The board may impose the following disciplinary sanctions for~~ 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 ~~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~~ Refer the pharmacy technician to the Health Professionals' Assistance Program; or

(7) Issue a ~~citation and warning~~ letter of concern or public reprimand.

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

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

Law Implemented: SDCL ~~36-11-11(14)~~ 36-2A-2, 36-2A6, 36-11-2(26), 36-11-26.

CHAPTER 20:51:30

TELEPHARMACY

Section

20:51:30:01. Definitions. Terms ~~used in this chapter mean:~~ defined in SDCL 36-11-71 have the same meaning when used in this chapter.

~~(1) "Automated mechanical distribution device," as defined in § 20:51:17:01;~~

~~(2) "Central pharmacy," as defined in SDCL 36-11-71(1);~~

~~(3) "Remote pharmacy," as defined in SDCL 36-11-71(2);~~

~~(4) "Telepharmacy practice," as defined in SDCL 36-11-71(3).~~

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

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

Law Implemented: SDCL ~~36-11-11(1)(4)(5),~~ 36-11-71.

20:51:30:10. ~~Toll-free telephone~~ Telephone number. The remote pharmacy ~~shall~~ must provide a ~~toll-free~~ telephone number that patients and prescribers may use to contact the central pharmacy. The telephone number ~~shall~~ must be printed on the label of each prescription container.

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

General Authority: SDCL 36-11-11(1)(4), 36-11-46.6, 36-11-72(2),(5).

Law Implemented: SDCL ~~36-11-72(2),(5)~~ 36-11-71.

20:51:30:12. Technician and intern staffing requirements. Each remote pharmacy must be staffed with ~~South Dakota~~ registered pharmacy technicians or pharmacy interns. A pharmacy technician working at a remote pharmacy without an onsite pharmacist, pharmacy intern, or experienced telepharmacy technician, ~~shall~~ must have a minimum of ~~2000~~ two 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 ~~through one of the certification programs recognized by the board~~. One thousand 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 ~~working~~ may work at a remote pharmacy ~~shall have a minimum of 500~~ 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.

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

Law Implemented: SDCL ~~36-11-72(3)~~ 36-11-2(26), 36-11-25, 36-11-71.

CHAPTER 20:51:31

~~STERILE~~ COMPOUNDING PRACTICES

Section

20:51:31:22 Immediate-use preparations, Repealed.

20:51:31:23 Utilization of single-dose and multiple-dose containers, Repealed.

20:51:31:24 Utilization of proprietary bag and vial systems, Repealed.

20:51:31:25 Sterilization methods, Repealed.

20:51:31:26 Media-fill testing by personnel, Repealed.

20:51:31:27 Environmental monitoring requirements, Repealed.

20:51:31:28 Storage and delivery of sterile preparations, Repealed.

20:51:31:29 Additional requirements for preparation of hazardous drugs, Repealed.

20:51:31:30 Responsibilities for patient care, Repealed.

20:51:31:31 Patient or caregiver education and training, Repealed.

20:51:31:32 Compounding and hazardous drug handling standards -- United States Pharmacopeia compounding standards implemented by reference.

20:51:31:33 Policy and procedure manual.

20:51:31:34 Compounding requirements.

20:51:31:35 Delivery service.

20:51:31:36 Disposal of pharmaceutical hazardous waste.

20:51:31:37 Quality assurance.

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)~~ (2) "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~~

(3) "Nonsterile compounding," the process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug or bulk drug substance to create a non-sterile preparation; and

~~(23)~~ (4) "Sterile compounding," the aseptic processing ~~in a clean air environment~~ of any pharmaceutical ~~including the following preparations~~ preparation that ~~are~~ is 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 36-11-2.2(3)~~, 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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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 Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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~~ Repealed.

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.~~

20:51:31:32. 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:

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 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:

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 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:

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 for individual user.

20:51:31:35. Delivery to patients. The pharmacist-in-charge shall ensure the environmental control, stability, and sterility of all preparations delivered or shipped to patients.

Source:

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

Law Implemented: SDCL 36-11-44.

20:51:31:36. Disposal of pharmaceutical hazardous waste. The pharmacist-in-charge is responsible for ensuring that there is a designated process for proper disposal of pharmaceutical hazardous waste in accordance with applicable state and federal requirements.

Source:.

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

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

20:51:31:37. Quality assurance. Any pharmacy that compounds prescriptions must have a quality assurance program with the following elements:

(1) A documented, ongoing program for the monitoring of personnel, components, equipment, and facilities used for preparation of compounded pharmaceuticals that conforms to applicable state and federal law;

(2) If errors have occurred, the pharmacist-in-charge is responsible for conducting a full investigation. A written record of the investigation must be completed and include conclusions and follow-up.

(3) The pharmacist-in-charge is responsible for proper maintenance, cleanliness, and use of facilities and equipment used in compounding;

(4) All pharmacists and pharmacy technicians, who assist in compounding drug products, must have documented training and competency testing as required by state and federal law; and

(5) Training must be conducted by qualified individuals on a continuing basis with frequencies outlined in United States Pharmacopeia to ensure that compounding pharmacy personnel remain up to date with operations, policies, and procedures;

(6) Only personnel authorized by the pharmacist-in-charge may be in the immediate vicinity of compounding operations; and

(7) A compounded drug is adulterated if it has been prepared, packed, or held under insanitary conditions. For the purpose of this section, "insanitary conditions" means a condition of exposure to contamination with filth which may be rendered injurious to health.

Source:

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

Law Implemented: SDCL 36-11-2.2(3), 36-11-42, 36-11-46.

CHAPTER 20:51:36

CENTRAL FILL PHARMACIES

Section

20:51:36:01 Definitions. Terms used in this chapter mean:

(1) "Central fill pharmacy," a pharmacy under the same ownership as the originating pharmacy or contracted to provide prescription filling or processing on behalf of the originating pharmacy; and

(2) "Originating pharmacy," a pharmacy that receives prescription drug orders from a patient, an agent of the patient, or a prescriber, and outsources the filling or processing of the order to a central fill pharmacy that dispenses the prescription to the patient or agent of the patient.

Source:

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

Law Implemented: SDCL 36-11-2.2, 36-11-19.1.

20:51:36:02. License required. Any pharmacy acting as a central fill pharmacy in this state must be permitted pursuant to SDCL 36-11-32 and not permitted 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 as a full-time pharmacy.

Source:

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

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

20:51:36:03. Requirements for central fill. The originating pharmacy and central fill pharmacy must:

(1) Be under the same ownership or have a signed legal contract to provide central fill services;

(2) Share a common prescription software platform, as described in § 20:51:20:04;

(3) Ensure a pharmacist, from either pharmacy, performs a prospective drug utilization review in accordance with § 20:51:25:02 before dispensing any prescription. The identity of the pharmacist must be available to both pharmacies in the prescription record; and

(4) Have a policy and procedure, approved by both pharmacies, that outlines each pharmacy's role in the transaction and ensures patient safety and privacy.

Source:

General Authority: SDCL 36-11-11(1)(3)(12).

Law Implemented: SDCL 36-11-2.2, 36-11-68, 36-11-69.

20:51:36:04. Label requirements. The label for prescriptions filled by a central fill pharmacy must meet the requirements in §§ 20:51:05:21 and 44:58:08:20 and must indicate that the prescription was filled at a central fill pharmacy. The label must contain the name, address, and phone number of the originating pharmacy.

Source:

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

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

20:51:36:05. Patient notification. The originating pharmacy must post a sign to provide notice to patients that the pharmacy utilizes a central fill pharmacy service.

Source:

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

Law Implemented: SDCL 36-11-36.

20:51:36:06. Patient requests. A patient may request not to utilize central fill pharmacy service. The pharmacy must comply with the request.

Source:

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

Law Implemented: SDCL 34-12B-1.