ARTICLE 20:51

PHARMACISTS

Chapter

CHAPTER 20:51:01

REGISTRATION BY EXAMINATION

Section

20:51:01:08 Repealed.

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

20:51:01:10 Application requirements for graduates from colleges of pharmacy located outside the United States.

20:51:01:11 NAPLEX score transfer ~~form~~.

20:51:01:12 Registration fee nonrefundable, Repealed.

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).

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

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

20:51:01:09. Approved colleges of pharmacy. Approved colleges of pharmacy are those colleges of pharmacy which have demonstrated that the standards of their respective professional degree programs are at least equivalent to the minimum standards of accreditation established by the Accreditation Council for Pharmacy Education, 20 North Clark Street, Suite 2500 190 S. LaSalle St. Suite 3000, Chicago, IL 60602-5109 60603-3446; Phone: 312-664-3575; Web site: www.acpe-accredit.org.

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

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

Law Implemented: SDCL 36-11-16.

20:51:01:11. ~~NAPLEX~~ North American Pharmacist Licensure Examination (NAPLEX) score transfer ~~form~~. An applicant meeting the requirements of this chapter who has taken the NAPLEX examination in another state may transfer scores ~~on an official NAPLEX score transfer form furnished by~~ through the National Association of Boards of Pharmacy. To be eligible for 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

20:51:02:01 Definitions.

20:51:02:01.01 Goal and objectives of internship.

20:51:02:02 Repealed.

20:51:02:03 Repealed.

20:51:02:04 Registration.

20:51:02:04.01 South Dakota State University College of Pharmacy practice experiences, Repealed.

20:51:02:04.02 Identification.

20:51:02:05 Renewal of certificate.

20:51:02:06 Repealed.

20:51:02:07 Affidavit needed for each practical experience.

20:51:02:08 Report required at end of each practical experience.

20:51:02:09 Repealed.

20:51:02:10 Practical experience defined.

20:51:02:11 Supervising pharmacist requirements.

20:51:02:11.01 Number of interns.

20:51:02:12 Repealed.

20:51:02:12.01 Required hours.

20:51:02:13 Internship experiences from other states.

20:51:02:13.01 Foreign pharmacy graduates.

20:51:02:14 Credit given for military and research activities.

20:51:02:15 Badge ~~and certificate~~ required.

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

20:51:02:17 Sanctions.

20:51:02:01. Definitions. Terms ~~used in this chapter mean~~ defined in SDCL 36-11-2 have the same meaning in this article. In addition, terms as used in this article, 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 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** 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 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 licensure or meeting board requirements for re-licensing; or

~~(d)~~(4) A qualified applicant participating in a residency or fellowship program.

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

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

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

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

20:51:02:04.01. 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 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 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 during all professional activities of the entire internship~~ communication with the intern. Interns may receive written or verbal prescriptions if the pharmacist reviews and makes the necessary professional determinations about the medication order~~, including the name of the drug, its strength and dosage, directions for use, and the number of allowable refills~~.

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

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

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

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

Law Implemented: SDCL 36-11-25.

20:51:02:12.01. Required hours. An internship shall consist of a minimum of ~~2000~~ two thousand hours, of which ~~1740~~ one thousand seven hundred and 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 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 obtain a minimum of ~~1500~~ one thousand five hundred hours of internship in a licensed pharmacy or other board-approved location before receiving a ~~South Dakota~~ pharmacist license.

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

General Authority: SDCL 36-11-11(1), 36-11-16, 36-11-25.

Law Implemented: SDCL 36-11-16, 36-11-25.

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

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

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

Law Implemented: SDCL 36-11-25.

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

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

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

Law Implemented: SDCL 36-11-25.

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

(1) Revoke a registration;

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

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

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

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

Law Implemented: SDCL 36-11-25.

CHAPTER 20:51:04

REGISTRATION BY RECIPROCITY

Section

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

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

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

(3) The applicant must have engaged in the practice of pharmacy for a period of at least one year or have met the pharmacy practice experience requirements of this state within the one year

period immediately prior to the date of such application; and

(4) ~~For any applicant who obtained his or her original license after January 1, 1980, the~~ 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~~ complete the official National Association of Boards of Pharmacy ~~reciprocal~~ license transfer application ~~with the secretary of the board within 90 days from the date of issue. The application must be accompanied by~~ 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

20:51:05:00 Definitions.

20:51:05:01 Transferred.

20:51:05:02 Transferred.

20:51:05:03 Repealed.

20:51:05:04 Repealed.

20:51:05:05 Repealed.

20:51:05:06 Transferred.

20:51:05:07 Transferred.

20:51:05:08 Repealed.

20:51:05:09 Repealed.

20:51:05:10 Repealed.

20:51:05:11 Repealed.

20:51:05:12 Repealed.

20:51:05:13 Repealed.

20:51:05:14 No advertising permitted on prescription blanks furnished to ~~doctors~~ prescribers.

20:51:05:15 Controlled drug to be dispensed only by prescription.

20:51:05:15.1 Identification required for controlled drug prescription.

20:51:05:16 Prescription for Schedule II controlled drug requires date and signature of prescriber -- Not refillable.

20:51:05:17 Oral prescription permitted for Schedule II controlled drug in emergency.

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

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

restricted.

20:51:05:20 ~~Legend~~Noncontrolled 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:

(1) "Controlled drug," a substance as defined in SDCL ~~36-11-2(5)~~ 36-11-2.1 which 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;

(2) "Dialysate," a solution comprised of dextrose or icodextrin for use in peritoneal dialysis and approved by the federal Food and Drug Administration; and

(3) "Legend drug," a substance as defined in SDCL ~~34-20B-28.1(4)~~ 34-20-28.1(3).

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

20:51:05:15. Controlled drug to be dispensed only by prescription. No pharmacist may dispense a controlled drug unless the controlled drug is dispensed pursuant to the prescription of a practitioner licensed to prescribe controlled drugs. A pharmacist shall exercise sound professional judgment with respect to the legitimacy of prescription orders. Any facsimile transmission of a Schedule II controlled drug prescription must comply with the requirements of § 44:58:08:18.03. A prescription must be dated and signed on the date issued. The prescription must bear the name and address of the patient and the name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the ~~practitioner~~ prescriber. Where an oral prescription for a schedule II controlled drug is not permitted, a prescription order must be written in ink or typewritten and manually dated and signed by the ~~practitioner~~ prescriber or issued and signed electronically where permissible by law. A prescription for a Schedule II controlled drug shall not be filled later than six months after date of issue.

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

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

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

20:51:05:15.01. Identification required for controlled drug prescription. Except for patients in a health care facility, licensed pursuant to chapter 34-12, the pharmacy must require a valid government issued form of identification for anyone attempting to purchase or pick up a prescription for a controlled substance listed in SDCL 34-20B, unless the person is known to the

pharmacist. 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), 34-20B-3.

Law Implemented: SDCL 34-20B-46, 34-20B-47, 34-20B-48.

20:51:05:18. Partial filling of prescription for Schedule II controlled drug. A pharmacist may partially fill a prescription for a Schedule II controlled drug according to the procedure set out in §§ 44:58:08:18, ~~and~~ 44:58:08:18.01, 21 CFR §§ 1306.12, and 1306.13, and 21 U.S.C. 829 § 702 in effect on September 12, 2023.

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

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

Law Implemented: SDCL 36-11-11.

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

the initials or name of the dispensing pharmacist. After six months or the dispensing of all authorized refills, whichever comes first, a new controlled drug prescription is required either orally, in writing, or electronically where permissible by law from the prescriber. Any prescription renewed by the prescriber shall be considered a new and separate prescription, assigned a new serial number, and subject to the restrictions in this section.

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

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

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

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

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

20:51:05:20. ~~Legend~~ Noncontrolled legend drug to be dispensed by prescription only -- Refill restricted. A pharmacist may only dispense a noncontrolled legend drug or medicine pursuant to the written, oral, or electronic prescription~~ of a practitioner licensed to prescribe drugs and medicines~~. A prescription by a prescriber may be delivered to a pharmacist by handwritten order, facsimile, or electronic equipment where permissible by law. An oral prescription shall be reduced promptly to writing by the pharmacist and the written record filed or electronically recorded in the same manner as though it were a written prescription. No noncontrolled legend drug prescription may 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 be entered on the back of the original prescription or captured electronically and shall indicate the quantity dispensed, date refilled, and the initials or name of the dispensing pharmacist. In the discretion of the pharmacist, when the prescriber is unable to be contacted, the pharmacist may fill up to a thirty day supply of a noncontrolled legend drug required to maintain the patient's health.

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

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

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

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

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

20:51:05:21. Labeling of prescription container for controlled or noncontrolled legend drug. A pharmacist filling a prescription for a controlled or noncontrolled legend drug shall attach to ~~the~~ 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, precautions, if any, the name, strength, and quantity of the drug, 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)~~.

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

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

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

(3) Quantity of each drug sold; and

(4) Date of sale.

Schedule II drugs must have a completed DEA form 222 to accompany the invoice. The

invoices shall be retained by both locations involved in the transaction for a period of two years as required by 21 CFR §1307.11, in effect on September 12, 2023.

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

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

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

CHAPTER 20:51:06

PHARMACY PRACTICE AND REGISTRATION

Section

20:51:06:13 Repealed.

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 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), 36-11-32.

Law Implemented: SDCL 36-11-32.

20:51:06:02. Ownership or control by pharmacist required. No permit to conduct a pharmacy shall be issued to any pharmacist applicant unless ~~such pharmacist~~ the applicant is 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~~. In those instances of a nonpharmacist owner of the ~~merchandise and fixtures of~~ the place of business for which a pharmacy registration is applied for, ~~has made~~ the nonpharmacist owner must make affidavit on a form prescribed by the ~~state Board of Pharmacy~~ board delegating full and complete authority to the pharmacist applicant to be in active management of ~~said~~ the place of business ~~for the fiscal year ending June 30~~.

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-32.

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

The pharmacist-in-charge shall:

(1) Be employed or contracted for pharmacy services at the licensed 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 be designated by the ~~employer~~ pharmacy owner within ten working days.

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

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

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 for opening and conducting a new pharmacy in South Dakota shall be filed with the ~~secretary of the Board of Pharmacy~~ board at least ~~30~~ thirty days before

the date when the new pharmacy is to be opened to the public. ~~If the applicant for a permit to open and conduct a new pharmacy in South Dakota will not be the owner of the merchandise and fixtures of the proposed new pharmacy to the extent that the applicant will be self-employed, the place and space to be registered as a pharmacy shall not include any floor space where general merchandise is offered for sale at retail.~~ The board may inspect the new pharmacy prior to opening.

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

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-32.

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

§ 20:51:06:10, shall be grounds for suspending or revoking such permit to conduct a pharmacy.

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

General Authority: SDCL 36-11-11.

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

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-31.

20:51:06:06. Transfer of pharmacy registration. ~~Each permit to conduct a pharmacy may be transferred to another pharmacist registered under the laws of this state, without payment of an additional fee; provided, an application for the transfer is made and the same is filed with the secretary of the Board of Pharmacy no less than ten days before the transfer of such active management is made. Any application for transfer made at a later date than ten days before the transfer of such active management is made shall be accomplished by the fee as set by the Board of Pharmacy for permit to conduct a pharmacy and such application for transfer shall be approved by the members of the Board of Pharmacy before permit to conduct a pharmacy is issued by the secretary of the Board of Pharmacy on such application~~ 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~~ board. Any change in the location ~~of a pharmacy, or any change in the ownership of the merchandise and fixtures of a pharmacy~~, name or ~~the~~ cessation of business as a pharmacy, shall be reported to the ~~secretary of the Board of Pharmacy~~ board within ten days of such occurrence. A change of majority ownership of the pharmacy requires and application and fee. The pharmacist permittee shall be held responsible for reporting such changes to the ~~Board of Pharmacy~~ board. If a business as a pharmacy ceases, 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.

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 pharmacist who is deceased shall within ~~120~~ one hundred twenty days after the death of the permittee become void~~, unless transfer of the permit has been made within the 120-day period to a pharmacist owner or to an employee pharmacist manager for whom an affidavit has been filed by a nonpharmacist owner or owners of the merchandise and fixtures of the pharmacy~~.

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-38.

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

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

(2) A prescription department or 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~~.

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

20:51:06:11. Pharmacy requirements for nonpharmacist owners. If a pharmacist permittee has the authority to be in active management of a pharmacy by affidavit of ~~nonpharmacist individuals or by affidavit of~~ a nonpharmacist officer ~~of a corporation~~ or owner, and if the pharmacy ~~regularly~~ registered by the ~~Board of Pharmacy~~ board 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; and

(2) A prescription department or restricted ~~floor~~ area where ~~only packaged~~ drugs~~,~~ or 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~~ The prescription department shall include sufficient security measures to protect the area from theft or access by unauthorized personnel when closed.

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~~ business is open to the public. When there is no pharmacist on duty, except as outlined in § 20:51:06:10, the entire business is closed, locked, and

secured. The pharmacy shall include sufficient security measures to protect the facility from theft or access by unauthorized personnel when closed and has a way to detect entry in the building after hours.

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

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

General Authority: SDCL 36-11-11.

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~~ pharmacy shall maintain all equipment needed to perform professional pharmacy services provided at the location as the pharmacist in charge determines to be necessary. The equipment, which requires certification, maintenance or calibration must be certified, maintained, or calibrated according to the manufacturer and USP guidelines. All equipment failing to be in good working condition must not be used in the pharmacy.

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-41.

20:51:07:04. Publication and reference library. ~~Each pharmacy shall maintain~~ 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 publications may be printed or computer-accessed. ~~At least one general pharmaceutical information reference must be a printed copy. Additional reference~~ Reference material shall be maintained and shall include, at a minimum, one current 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~~.

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

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

Law Implemented: SDCL 36-11-41.

CHAPTER 20:51:13

SPECIAL RESTRICTIONS

Section

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

20:51:13:02. Return of unused drugs. ~~Pharmacists~~ Except as authorized by ARSD 20:51:21 and 20:51:35, pharmacists and pharmacies are prohibited from accepting from patients or their agents for reuse, reissue, or resale any unused drugs, prescribed medications, poisons, sickroom supplies, or hygienic surgical appliances or garments. However, in a hospital with a licensed pharmacy, unused drugs, sickroom supplies, hygienic surgical appliances or garments, or other items dispensed for hospital inpatients may be returned to the pharmacy for credit and disposition by a pharmacist if the integrity of the products and packages is maintained.

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

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

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

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

(1) The facility or hospice program consults with a licensed pharmacist to oversee the drug distribution to ensure that a person trained and knowledgeable in the storage, use, and administration of the drug has been in control of any ~~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 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 and strength of the medication;

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

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

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

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

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

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

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

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

(9) The drugs are not controlled drugs.

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

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

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

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

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

Cross Reference: Section 20:51:21:01(4)(5)(8)(9)(11).

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

(1) Drugs ~~may not be removed and repackaged from the returned unit dose package prior to redispensing~~ that have been repackaged by the pharmacy may only be redispensed one time. In order for a pharmacy to redispense the medication the label and or record must have the expiration date and lot number;

(2) Drugs in a manufacturer's unit dose package may be redispensed as often as necessary, if the integrity of the original product and package is maintained;

(3) Drugs which have been repackaged into a unit ~~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;

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

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

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

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

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

20:51:13:05. Medication disposal. A pharmacy may allow for patients to dispose of unused medications at the pharmacy location after the pharmacy has modified its Drug Enforcement Agency registration to a collector and has a proper disposal device as per 21 CFR § 1317, in effect on September 12, 2023.

Source:

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

20:51:13:06. Remote prescription pickup sites. A pharmacy may elect to have medications

picked up by patients or caregivers at a certain location away from the pharmacy for patient convenience. When electing to establish a pickup site, the pharmacy must have written board approval of each location before the pharmacy may use the remote pickup site.

Policies and procedures are established and reviewed frequently and must include:

(1) Security;

(2) Staff training;

(3) Counseling and the offer to counsel;

(4) Delivery of medications;

(5) Pick up transaction;

(6) Return of prescriptions to pharmacy; and

(7) Records.

Records for the remote pickup site shall be maintained in the pharmacy for two years. Remote pickup sites are treated as an extension of the pharmacy from which medications are delivered. The pickup site may be inspected by the board at any time.

Source:

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-1, 36-11-11.

CHAPTER 20:51:14

GENERAL ADMINISTRATION

Section

20:51:14:04 Equivalent drug products, Repealed.

20:51:14:01. Annual certificate renewal. The 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

20:51:15:16 Minimum standards for pharmacy service, Repealed.

20:51:15:17 Repealed.

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

(1) ~~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 on less than a full-time operation basis, in hospitals, nursing facilities, and related facilities and where such pharmaceutical services are limited to inpatients;

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

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

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

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

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

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

~~(5) "Dispensing," includes, but is not limited to, issuing to a patient, or to a person acting on a patient's behalf one or more unit doses of medication in a suitable container with appropriate~~

~~labeling. Dispensing affects one or many patients. Dispensing, while including compounding, also includes the act of packaging a drug or medication either from a bulk container, or as a result of compounding, in a container other than the original and labeling the new container with all required information;~~

~~(6)~~(3) "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)~~(4) "Hospice program," a coordinated program of inpatient services providing palliative rather than curative care for a patient.

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-33.

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-33.

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

medication.

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-33.

20:51:15:09. 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 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), 36-11-32.

Law Implemented: SDCL 36-11-33.

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

20:51:07.

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-33.

20:51:15:13. Access to pharmacy -- Records. Only a registered pharmacist may have access to the pharmacy stock of drugs in the hospital, nursing facility, or related facilities. However, when the pharmacist is absent from the hospital or other like facility, a registered nurse designated by the hospital may obtain from a hospital pharmacy stock of drugs a unit dose of a drug or medication necessary to administer to a bona fide patient in carrying out treatment and medication orders as prescribed by a licensed ~~physician~~ 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, dosage size, amount taken, the date and the time, and signed by the nurse. Further, the nurse shall leave with the record the container from which the ~~emergency~~ dose was taken ~~for drug administration purposes~~ in order that it may be properly checked by the pharmacist. Such records shall be kept for ~~three~~ two years.

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-33.

20:51:15:15. 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 meet the immediate therapeutic needs of a patient to prevent harm to the patient due to a delay in obtaining such drugs from the pharmacy. The emergency drugs shall remain the property of the registered pharmacy and shall be stored on-site in a suitable controlled location in the health care facility. The emergency drug supplies shall comply with the following requirements:

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

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

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

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

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

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

Law Implemented: SDCL 36-11-33.

20:51:15:15.01. Pharmacist controls emergency kit in nursing facility. A registered 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 requested in

writing by the medical director The pharmacist shall retain control of all medications provided in emergency kits.

The provider pharmacist shall comply with the following requirements:

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

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

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

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

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

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

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

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

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

(5) The pharmacy may utilize an automated medication distribution device to store, distribute, and record transactions as an emergency kit or for first dose medications. If the pharmacy uses an

automated medication distribution device, the pharmacy must apply for a separate pharmacy license to do so unless there is a licensed 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 24 hours a day.

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

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

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

Law Implemented: SDCL 36-11-33.

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.~~

Section

20:51:16:01 Repealed.

20:51:16:02 Repealed.

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

20:51:16:04 The pharmacist's relations to other health professions.

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

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

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

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

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

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

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

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

(7) Supports constructive efforts ~~in~~ 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 only fair and honest remuneration for services.

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

General Authority: SDCL 36-11-43.

Law Implemented: SDCL 36-11-43.

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

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

(2) Refuse to prescribe or diagnose, but refer those needing such services to a licensed ~~practitioner~~ prescriber. In an emergency and pending the arrival of a qualified ~~practitioner~~ prescriber, the pharmacist may ~~apply first~~ render 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 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 36-11-43.

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 delivers a drug or drug device located in a health care facility, other than by administration or dispensing and uses automated data processing technology to do the following:

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

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

(c) Document both stocking and removal transactions;

(2) "Automated prescription dispensing device," a mechanical device that aids in the process of dispensing medication in a retail pharmacy or healthcare facility which may include storing, counting, and labeling medications; 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 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," means the pharmacist named on the pharmacy permit license issued by the Board of Pharmacy board 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)~~.

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 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)~~.

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~~ in charge. The pharmacist ~~permittee~~ in charge shall develop policies and procedures to address all situations in which drugs are stocked, secured, removed, and accounted for;

(2) The automated ~~mechanical distribution~~ device shall be stocked with a ~~limited~~ supply of drugs only by a ~~health care facility~~ pharmacist or a person authorized by the pharmacist ~~permittee~~ 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~~ permitee-in-charge shall designate ~~the person that~~ persons who may have access to ~~that portion, section,~~ all or part of the automated mechanical distribution device in which the drugs or medicines are stored;

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

(a) The name of the drug;

(b) The strength of the drug;

(c) The lot or control number; and

(d) The expiration date of the drug;

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

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

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

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

~~(d) The date of issue;~~

~~(6) When repackaging drug dosage forms from original manufacturers' containers, the new package must assure the stability of each drug and meet the storage and packaging standards on pages 10, 11, 12, 13, 1786, and 1787 of the United States Pharmacopeia, Twenty-third Revision - The National Formulary, Eighteenth Edition, January 1, 1995;~~

~~(7)~~(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;~~

~~(9)~~(6) Notwithstanding any of the provisions in this section, the pharmacist ~~permittee~~ permittee-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 or dispensing 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)~~.

~~**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 device -- license required. A pharmacy that uses an automated mechanical distribution device or an automated prescription dispensing device to store, distribute, dispense, or track medications outside of the premises of the pharmacy license, shall apply to the board to license the automated device as a pharmacy.

Source:

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

Law Implemented: SDCL 36-11-11.

CHAPTER 20:51:19

CONTINUING EDUCATION

Section

20:51:19:03. Hours required. To qualify for ~~relicensure, an active~~ certificate of registration

renewal or reinstatement, a pharmacist must successfully complete ~~12~~ twelve hours of continuing education. The ~~12~~ twelve hours of 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 a pharmacist applies for yearly renewal of the pharmacist's certificate of registration pursuant to SDCL 36-11-23, the pharmacist must ~~report completed continuing education hours on a form supplied by the board~~ have completed the required hours. If the pharmacist has a certification to administer immunizations, the pharmacist must have one hour of continuing education related to immunizations.

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

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

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

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

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

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

Law Implemented: SDCL 36-11-23.2.

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

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

General Authority: SDCL 36-11-23.2.

Law Implemented: SDCL 36-11-23.2.

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

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

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

Law Implemented: SDCL 36-11-23.2.

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

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

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

Law Implemented: SDCL 36-11-23.2.

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

~~(1) Cassette and audio visual presentation;~~

~~(2) In-company professional seminars;~~

~~(3) Accredited school of pharmacy continuing education programs;~~

~~(4) Post graduate courses in pharmaceutical sciences;~~

~~(5) Correspondence courses;~~

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

~~(7) Continuing education television series;~~

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

~~(9) Professional society and association sponsored programs;~~

~~(10) Study groups~~ 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 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 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.

Law Implemented: SDCL 36-11-23.2.

20:51:19:11. Forms required for continuing education sponsors. ~~The form for approval of continuing education programs may be obtained from the board office. The~~ A form which includes the following information shall be submitted to the board ~~on the form~~:

(1) Name of sponsor and address;

(2) Name of person in charge;

(3) Location of program;

(4) Estimated number of pharmacists and technicians participating;

(5) General title of program;

(6) Type 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 program objectives will be met;

(8) Estimated contact time;

(9) How attendance or participation will be proven;

(10) How certificates will be awarded;

(11) Copy of examination, if utilized.

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

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

Law Implemented: SDCL 36-11-23.2.

20:51:19:16. Sponsor to provide list of pharmacists and technicians attending program. The sponsor of a continuing education program shall provide to the Board of Pharmacy a written or

electronic list of the pharmacists and technicians attending within ~~45~~ thirty days after completion of the program or a licensed pharmacist or registered technician 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, 36-11-11(13).

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

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~~ a prescription software platform is employed by any pharmacy, input of ~~drug~~ prescription information shall be performed only by a pharmacist ~~or under the immediate and personal supervision of a pharmacist~~ technician, or intern. The pharmacist must certify the accuracy of the information ~~to be~~ entered and verify the prescription order ~~at the time of entry~~. The identity of the pharmacist must be ~~carried~~ included in the record.

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

1986.

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

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

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

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

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

(4) Be capable of recording and carrying in the record all dates of refills of any prescription and the initials of the pharmacist. This shall meet the requirements of §~~ 20:51:05:06~~ 20:51:05:20;

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

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

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

entered into the platform via scan or electronic record.

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

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 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~~ prescription software platform are exempt from chapter 20:51:23 if the requirements of this section are met.

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

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

Law Implemented: SDCL 36-11-11(13), 36-11-19.2.

CHAPTER 20:51:21

UNIT DOSE SYSTEMS

Section

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

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

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

(3) "Customized patient medication package," a package that contains two or more drugs per compartment;

(4) "Prepackage," to prepare a drug in a container for dispensing, prior to the receipt of an order. Such packaging may be in a unit dose, single dose, or unit of issue package for use in a unit

dose dispensing system, in a container suitable for a traditional dispensing system, or in a customized patient medication package;

(5) "Repackage," to prepare a unit dose, single dose, unit of issue package, customized patient medication package, or traditional dispensing system package for dispensing pursuant to an existing order;

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

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

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

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

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

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

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

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

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

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

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

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

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

20:51:21:03. Pharmacist to interpret original order of practitioner. ~~A pharmacist in the pharmacy shall interpret the original order of a practitioner for a specific patient~~ 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 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~~

according to § 20:51:13:02.01(5).

After any change in dosage or administration schedule, the pharmacy shall 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)~~.

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

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

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

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

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

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

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

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

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

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)~~.

CHAPTER 20:51:22

SUPPORT PERSONNEL

Section

20:51:22:06 Identification of pharmacy support personnel.

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 medication, that have been delegated to the pharmacy support personnel by the supervising pharmacist:

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

(2) Open drug shipment and affix appropriate inventory or price stickers to drug stock bottles or containers;

(3) Perform administrative duties, such as filing processed, hard-copy prescriptions and other pharmacy records;

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

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

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

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

Law Implemented: SDCL 36-11-11.

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

Source:

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

Law Implemented: SDCL 36-11-11.

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 ~~number of refills~~ total quantity authorized on the original prescription;

(2) The transfer is communicated directly between two licensed pharmacists or registered 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.

Law Implemented: SDCL 36-11-11.

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.

Law Implemented: SDCL 36-11-11.

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 both the transferring and receiving pharmacist or intern transferring the prescription information; and.

(3) Any unclear information on a facsimile must be clarified verbally.

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

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

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

General Authority: SDCL 36-11-11.

Law Implemented: SDCL 36-11-11.

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

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

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

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

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

~~(c) The quantity dispensed;~~

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

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

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

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

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

CHAPTER 20:51:24

PATIENT RECORD SYSTEM

Section

20:51:24:01. Transitory patient defined. ~~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 maintain a patient record system for patients for whom it dispenses prescription drug orders. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs or drug devices at the time a prescription drug order is presented for dispensing.

The record shall include as much of the following information as the pharmacy is able to obtain:

(1) The full 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 period immediately preceding the most recent entry, showing the prescription number, name and strength of the drug or drug device, the quantity and date received, and the name of the practitioner;

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

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

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

(9) If the patient is nonhuman, 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. Terms used in this chapter mean:

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

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

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

General Authority: SDCL 36-11-68.

Law Implemented: SDCL 36-11-68.

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

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

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

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

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

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

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

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

(9) Clinical abuse or misuse.

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

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

General Authority: SDCL 36-11-68.

Law Implemented: SDCL 36-11-68.

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

(1) The name and description of the drug;

(2) The dosage form, dose, route of administration, and duration of drug therapy;

(3) The intended use of the drug and its expected action;

(4) Special directions and precautions for preparation, administration, and use by the patient;

(5) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(6) Techniques for self-monitoring drug therapy;

(7) Storage requirements;

(8) Prescription refill information;

(9) Action to be taken if a dose is missed; and

(10) The pharmacist's comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

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

General Authority: SDCL 36-11-68.

Law Implemented: SDCL 36-11-68.

NONRESIDENT PHARMACY REGISTRATION

Section

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

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

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

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

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

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

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

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

Law Implemented: SDCL 36-11-19.3.

20:51:27:03. Application fee. The fee to accompany the initial application and each application for renewal is ~~$200~~ 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 ~~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~~ of the following changes to the Board of Pharmacy within the indicated timeframe:

(1) Change in pharmacist-in-charge, notify within ten days;

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

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

(4) Cessation of business as 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

20:51:28:01. Authority to administer ~~influenza~~ immunizations. A pharmacist may administer ~~influenza~~ immunizations recommended by the Advisory Committee on Immunization Practices vaccination schedules to eligible patients ~~18~~ three years of age and older if the pharmacist meets the qualifications set forth in this chapter and has been granted authorization by the board.

Source: 29 SDR 37, effective September 26, 2002; 47 SDR 42, effective October 12, 2020.

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

Law Implemented: SDCL 36-11-19.1.

20:51:28:01.01. Authority to administer immunizations. ~~A pharmacist may administer immunizations by prescription drug order signed by a practitioner or by protocol signed by a physician if the pharmacist meets the criteria set forth in § 20:51:28:02 and is authorized by the board~~ Repealed.

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

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

~~**Law Implemented:** SDCL 36-11-19.1.~~

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

(4) Is directly supervised by a 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 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, 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 a 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 and available for inspection at any time.

Source:

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

Law Implemented: SDCL 36-11-19.1, 36-11-2.

CHAPTER 20:51:30

TELEPHARMACY

Section

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

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

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

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

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

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

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

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

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

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

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

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

20:51:30:12. Technician and intern staffing requirements. Each remote pharmacy must be staffed with South Dakota registered pharmacy technicians or interns. A pharmacy technician working at a remote pharmacy shall have a minimum of ~~2000~~ two thousand hours of experience as a registered pharmacy technician in accordance with chapter 20:51:29 and shall be certified through one of the certification programs recognized by the board. One thousand hours of this experience must be in a telepharmacy with an onsite pharmacist, intern or experienced telepharmacy technician. An intern working at a remote pharmacy shall have a minimum of ~~500~~ 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), 36-11-72(3).

Law Implemented: SDCL 36-11-72~~(3)~~.

CHAPTER 20:51:31

~~STERILE~~ COMPOUNDING PRACTICES

Section

20:51:31:17 Labeling requirements, Repealed.

20:51:31:18 Microbial contamination risk levels, Repealed.

20:51:31:19 Low-risk preparations, Repealed.

20:51:31:20 Medium-risk preparations, Repealed.

20:51:31:21 High-risk preparations, Repealed.

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.

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.

20:51:31:38 Non-hazardous, non-sterile drugs exclusions.

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

~~(23)~~(4) "Sterile compounding," the aseptic processing ~~in a clean air environment~~ of any pharmaceutical including the following preparations that are required to be sterile when they are administered to patients; baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, and suspensions), aqueous bronchial and nasal inhalations, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

Source: 36 SDR 100, effective December 14, 2009.

General Authority: SDCL 36-11-2.2, 36-11-11(1),(3),(4), and (5).

Law Implemented: SDCL 36-11-11, 36-11-41.

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

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

~~(2) Contains nonsterile ingredients or employs nonsterile components or devices that must be~~

~~sterilized before administration; or~~

~~(3) Is a biologic, diagnostic, drug, or nutrient that possesses characteristics of either subdivision (1) or (2) of this section and includes the following preparations that are required to be sterile when they are administered to patients: baths and soaks for live organs and tissues, injections, aqueous bronchial and nasal inhalations, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants~~ 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. USP Compounding standards implemented by reference**.** All sterile and nonsterile compounding and repackaging must be handled in accordance with federal laws, § 20:51:31, and current United States Pharmacopeia–National Formulary (USP-NF), including but not limited to 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 36-11-2.2, 36-11-11(3).

Law Implemented: SDCL 36-11-11.

Reference: The United States Pharmacopeia. (n.d). USP NF/PF Compounding Compendium available at https://online.uspnf.com/uspnf Cost for USP/NF Subscription: $800 for individual user.

20:51:31:33. Policy and procedure manual. A policy and procedure manual must be prepared and maintained for compounding practices. The policy and procedure manual must include a quality assurance program, all applicable USP requirements, and be available for inspection by the board.

Source:

General Authority: SDCL 36-11-2.2, 36-11-11(3).

Law Implemented: SDCL 36-11-11.

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

Source:

General Authority: SDCL 36-11-2.2, 36-11-11(3).

Law Implemented: SDCL 36-11-11.

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. Any medication or compounded preparation shall be delivered or shipped in appropriate temperature-controlled packaging or delivery containers as defined by USP standards.

Source:

General Authority: SDCL 36-11-2.2, 36-11-11(3).

Law Implemented: SDCL 36-11-11.

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, federal, and USP requirements.

Source:.

General Authority: SDCL 36-11-2.2, 36-11-11(3).

Law Implemented: SDCL 36-11-11.

20:51:31:37. Quality assurance. Any pharmacy which compounds prescriptions must have a quality assurance program. The following shall be included in compounding continuous quality assurance programs:

(1) Documented ongoing program for the monitoring of personnel, components, equipment, and facilities used for preparation of compounded pharmaceuticals. Quality assurance programs must conform to USP requirements.

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

(3) The pharmacist is also 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, shall have documented training and competency testing as outlined in USP.

(5) Training shall be conducted by qualified individuals on a continuing basis with frequencies outlined in USP to ensure that compounding pharmacy personnel remain up to date with operations, policies, and procedures.

(6) Only personnel authorized by the pharmacist in charge shall be in the immediate vicinity of compounding operations.

(7) A compounded drug will be deemed adulterated if it has been prepared, packed, or held under insanitary conditions. Insanitary conditions may expose products to contamination with filth which may be rendered injurious to health.

Source:

General Authority: SDCL 36-11-2.2, 36-11-11(3).

Law Implemented: SDCL 36-11-11.

20:51:31:38. Non-hazardous, non-sterile drugs exclusions. The following of medication manipulations are excluded from USP requirements:

(1) Dispensing of nonsterile products with a formulation commercially available, where the packaging details the exact compounding process;

(2) The addition of a flavoring agent to a drug product; and

(3) Reconstitution with the addition of distilled or purified water.

Source:

General Authority: SDCL 36-11-2.2, 36-11-11(3).

Law Implemented: SDCL 36-11-11.

CHAPTER 20:51:36

CENTRAL FILL PHARMACIES

Section

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

(1) Central Fill Pharmacy, a pharmacy under the same ownership or contracted to provide prescription filling on behalf of an 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 and dispenses the prescription to the patient or agent of the patient.

Source:

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

Law Implemented: SDCL 36-11-30.

20:51:36:02. License required. Any pharmacy acting as a central fill pharmacy in this state must be licensed as a full-time pharmacy in South Dakota. Any pharmacy located outside the state of South Dakota, acting as a central fill pharmacy must be licensed as a non-resident pharmacy in

South Dakota. Any originating pharmacy located in this state must be licensed as a full-time pharmacy in South Dakota.

Source:

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

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

20:51:36:03. Requirements for central fill. The following items are required for all pharmacies which utilize a central fill process.

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 electronic computer system as defined in § 20:51:20:04;

(3) A pharmacist from either the originating pharmacy or the central fill pharmacy must perform a prospective Drug Utilization Review 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 on the process of the central fill procedure that outlines the expectations of both pharmacies and ensures patient safety and privacy.

Source:

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

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

20:51:36:04. Label requirements. The prescription label for medications filled by a central fill pharmacy must meet the requirements in §§ 20:51:05:21 and 44:58:08:20, and must have wording indicating that the prescription was filled at a central fill pharmacy. The label must contain

the name, address, and phone number of the originating pharmacy.

Source:

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

Law Implemented: SDCL 36-11-11.

20:51:37:05. Patient notification. The originating pharmacy shall post a sign to provide notice to patients that this pharmacy utilizes a central fill pharmacy process.

Source:

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

Law Implemented: SDCL 36-11-11.

20:51:36:06. Patient requests. A patient may request that they wish 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 36-11-11.