

# **Laws and Rules Related to the Practice of Pharmacy in South Dakota**

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Current statement.

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## CHAPTER [36-11](#)

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### **36-11-1. Public interest in regulation of practice.**

The practice of pharmacy in South Dakota is hereby declared to be a professional practice affecting the public health, safety, and welfare and is subject to regulation in the public interest.

**Source:** SL 1967, ch 102, § 1.

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### **36-11-2. Definition of terms.**

Terms used in this chapter mean:

- (1) "Association," the South Dakota Pharmacists Association;
- (2) "Biological product," as defined in 42 U.S.C. 262(i), as of January 1, 2018;
- (3) "Board" or "board of pharmacy," the State Board of Pharmacy in South Dakota;
- (4) "Brand name," the proprietary or registered trademark name given to a drug product by its manufacturer, labeler or distributor and placed on the drug or on its container, label or wrapping at the time of packaging;
- (5) "Chemicals," the chemical materials or medicine;
- (6) "Compounding," the preparation, mixing, assembling, packaging or labeling of a drug or drug device as the result of a practitioner's prescription drug order or an initiative based on the pharmacist/patient/practitioner relationship in the course of professional practice or for the purpose of or as an incident to research, teaching or chemical analysis and not for sale or dispensing. The term also includes the preparation of drug or drug devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;
- (7) "Delivery," the actual, constructive or attempted transfer of a drug or drug device from one person to another, whether or not for a consideration;
- (8) "Dispense" or "Dispensing," the preparation and delivery of a drug to a patient or a patient's agent pursuant to a prescription drug order in a suitable container with appropriate labeling for subsequent administration to or use by a patient. The term includes preparation of labels for drug devices if the labeling is related to the dosage and administration of drugs;

- (9) "Distributing," the delivery of a drug or drug device other than by administration or dispensing;
- (10) "Drug administration," the direct application of a drug or drug device by injection, inhalation, ingestion or any other means to the body of a patient or research subject;
- (11) "Drug device," equipment, process, biotechnological entity, diagnostic agent or other product used in combination with a drug to provide effective management of medication regimens;
- (12) "Drug utilization review program," any program operated solely or partially as a professional standards review organization whose purpose is to educate pharmacists and practitioners on severe adverse reactions to drugs, therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions and clinical abuse or misuse, as well as to identify and reduce the frequency of patterns of potential and actual fraud, abuse, gross overuse, inappropriate care or medically unnecessary care associated with specific drugs or groups of drugs among practitioners, pharmacists and patients;
- (13) "Equivalent drug product," a drug product, other than a biological product, that is considered to be therapeutically equivalent to other pharmaceutically equivalent products as determined by the latest edition of Approved Drug Products with Therapeutic Equivalence Evaluations, as adopted by the board pursuant to chapter [1-26](#);
- (14) "Interchangeable biological product," a biological product that the U.S. Food and Drug Administration either has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. 262(k)(4), as of January 1, 2018, or has determined is therapeutically equivalent as set forth in the latest edition of, or any supplement to, the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations publication as adopted by the board pursuant to chapter [1-26](#);
- (15) "Labeling," the process of preparing and affixing a label to any drug or drug device container exclusive of the labeling by the manufacturer, packer or distributor of a nonprescription drug or commercially packaged legend drug or drug device;
- (16) "Medical device," an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, that is intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in man or other animals or is intended to affect the structure or any function of the body of man or other animals, that does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and that is not dependent upon being metabolized for achievement of any of its principal intended purposes;
- (17) "Medicines," drugs or chemicals or their preparations in suitable form for the prevention, relief or cure of diseases when used either internally or externally by man or for animals;
- (18) "Nonprescription drugs," drugs that are labeled for use by the general public in accordance with § 502 of the Federal Food, Drug and Cosmetic Act as amended through January 1, 1997, and may be sold without a prescription drug order in accordance with § 503 of the Federal Food, Drug and Cosmetic Act as amended through January 1, 1997. The term does not include drugs which are required by federal law to bear the statement, "Caution: federal law prohibits dispensing without prescription," drugs intended for human use by hypodermic injection, or animal remedies regulated by chapter [39-18](#);
- (19) "Patient counseling," oral communication by the pharmacist of information to the patient or caregiver, as defined in rules promulgated pursuant to chapter [1-26](#), to improve therapy by ensuring proper use of drugs and drug devices;



- (20) "Pharmaceutical care," provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to cure or prevention of a disease, elimination or reduction of a patient's symptoms or arresting or slowing of a disease process;
- (21) "Pharmacist," a person licensed by the board to engage in the practice of pharmacy;
- (22) "Pharmacy," any place within or outside this state licensed by the board where drugs are dispensed and pharmaceutical care is provided to residents of this state;
- (23) "Practitioner," a person licensed, registered or otherwise authorized by the jurisdiction in which the person is practicing to prescribe drugs in the course of professional practice;
- (24) "Prescription drug order," a written or oral order of a practitioner for a drug or drug device for a specific patient;
- (25) "Proper name," the nonproprietary name for a biological product designated by the U.S. Food and Drug Administration license for use upon each package of the product;
- (26) "Registered pharmacy technician," a person registered by the board who is employed by a pharmacy to assist licensed pharmacists in the practice of pharmacy by performing specific tasks delegated by and under the immediate personal supervision and control of a licensed pharmacist, as permitted by the board;
- (27) "Retail place of business," any place where merchandise is sold at retail and from which original packages of nonprescription drugs are sold or taken to be sold at retail;
- (28) "Reverse distributor," any person or business registered with the Drug Enforcement Administration that accepts drug products from vendors and returns the drug products to manufacturers for credit or destruction.

**Source:** SDC 1939, § 27.1001; SL 1967, ch 102, § 2; SL 1973, ch 244, §§ 1, 6; SL 1974, ch 249; SL 1978, ch 271, § 2; SL 1983, ch 271; SL 1986, ch 306, § 3; SL 1986, ch 310; SL 1990, ch 306, § 1; SL 1992, ch 270, § 1; SL 1993, ch 277, § 1; SL 1993, ch 278, § 4; SL 1997, ch 216, § 1; SL 2003, ch 203, § 1; SL 2004, ch 248, § 1; SL 2012, ch 194, § 9; SL 2018, ch 231, § 1.

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### **36-11-2.1. Drugs defined.**

Drugs are defined as follows:

- (1) Articles recognized in the official United States Pharmacopoeia or the official National Formulary, as adopted by the board of pharmacy pursuant to chapter [1-26](#), or recognized in the official Homeopathic Pharmacopoeia of the United States as in effect on January 1, 1993;
- (2) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals;
- (3) Articles (other than food) intended to affect the structure or any functions of the human body; and
- (4) Articles intended for use as a component of any articles specified in this section.

The term "drugs" excludes medical devices.

**Source:** SL 1993, ch 278, § 3.

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### **36-11-2.2. Practice of pharmacy defined.**

The practice of pharmacy means:

- (1) Interpretation and evaluation of prescription drug orders and dispensing in the patient's best interest;
- (2) Provision of patient counseling and pharmaceutical care; and
- (3) The responsibility for compounding, distributing, labeling, and storage of drugs and for maintaining proper records for them.

The practice of pharmacy does not authorize a pharmacist to prescribe drugs as a practitioner or to dispense drugs without a prescription drug order.

Nothing in this section may be construed to prevent or restrict the practices, services, or activities of a person licensed in this state by any other law from engaging in the profession or occupation for which he is licensed if he is performing services within his authorized scope of practice.

**Source:** SL 1993, ch 278, § 1.

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**36-11-3. South Dakota Pharmacists Association--Purpose--Annual meeting.**

Those registered pharmacists of this state electing to participate shall constitute an association under the name and title of the South Dakota Pharmacists Association. The purpose of the association is to serve as the state professional society of pharmacists which represents the profession of pharmacy, enhances the public's awareness of pharmacy, and serves the best interest of public health and pharmacy. The South Dakota Pharmacists Association shall be conducted as a nonprofit corporation pursuant to the terms of its articles of incorporation. The members of the association who have secured a current annual certificate of registration to practice pharmacy in this state and who have elected to participate in the association are entitled to all of the rights and privileges of the association and may vote, serve as an officer or director of the association, and participate in all of the meetings of the association. The association shall hold an annual meeting at such time and place as it determines.

**Source:** SDC 1939, § 27.1002; SL 1967, ch 102, § 3; SL 1996, ch 230, § 1; SL 2005, ch 199, § 31.

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**36-11-4. Composition of State Board of Pharmacy--Terms and appointment of members--Removal of member.**

The State Board of Pharmacy shall include four professional members who shall hold their offices for terms of three years or until their successors are appointed and qualified. No member may serve more than three consecutive full terms. The appointment of a person to an unexpired term is not considered a full term. The Governor may remove any member of the board for just cause.

**Source:** SDC 1939, § 27.1003; SL 1967, ch 102, § 4; revised pursuant to SL 1973, ch 2, § 58; SL 2005, ch 199, § 32; SL 2007, ch 213, § 2.

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**36-11-4.1. Lay member of board--Appointment and term of office.**

The membership of the Board of Pharmacy shall include one lay member who is a user of the services regulated by the board. The term lay member who is a user refers to a person who is not licensed by the board but where practical uses the service licensed, and the meaning shall be liberally construed to implement the purpose of this section. The lay member shall be appointed by the Governor and shall have the same term of office as other members of the board.

**Source:** SL 1973, ch 2, § 58.

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**36-11-5. Meetings of board--Quorum.**

The Board of Pharmacy shall hold meetings for the examination of applicants for registration and the transaction of such other business as shall pertain to its duties. Special meetings of the board may be held whenever it shall be deemed necessary by a majority of the members thereof. Two members of such board shall constitute a quorum.

**Source:** SL 1967, ch 102, § 5.

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**36-11-5.1. Board continued within Department of Health--Records and reports.**

The Board of Pharmacy shall continue within the Department of Health, and shall retain all its prescribed functions, including administrative functions. The board shall submit such records, information, and reports in the form and at such times as required by the secretary of health, except that the board shall report at least annually.

**Source:** SL 1973, ch 2, § 56 (n); SL 2003, ch 272, § 42.

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**36-11-6. Use of funds by Pharmacists Association--Approval of expenditures--Filing statement.**

The board may, upon receipt, pay to the South Dakota Pharmacists Association eighty percent of all fees the board receives for renewals of certificates of registration as a pharmacist. The association shall use the funds for the following association activities to benefit the public and the profession: continuing education, matters related to registration standards for pharmacists, professional service standards, and general operating expenses related to the activities enumerated in this section. The association shall also use funds received to pay any legislated assessment to support a diversion program for chemically impaired pharmacists. Expenditures of funds shall be approved by the president and treasurer of the association. The association shall annually file in the office of the board an itemized statement of the receipts of the association and disbursements from the receipts.

**Source:** SDC 1939, § 27.1004; SL 1967, ch 102, § 5; SL 1996, ch 230, § 2; SL 2005, ch 199, § 33.

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**36-11-7. Salary and expenses of secretary.**

The secretary of the Board of Pharmacy shall receive a salary which shall be fixed by the board. He shall also receive his traveling and other expenses incurred in the performance of his official duties pursuant to § [3-9-2](#).

**Source:** SDC 1939, § 27.1005; SL 1967, ch 102, § 6; SL 1986, ch 27, § 27.

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**36-11-8. Compensation of personnel from fees received.**

Expenses and compensation for services of the board, its inspectors, employees, and legal counsel shall be paid from the fees received by the board from license, registration, and other fees, and no part thereof shall be paid out of the general fund.

**Source:** SDC 1939, § 27.1005; SL 1967, ch 102, § 6.

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**36-11-9. Annual report to Governor--Contents.**

The Board of Pharmacy shall report annually to the Governor as provided by law for state officers and boards.

**Source:** SL 1967, ch 102, § 5; revised pursuant to SL 1971, ch 10; SL 2005, ch 199, § 34.

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**36-11-10. Residual and implied powers of board.**

The Board of Pharmacy shall have all other powers and authority expressly conferred upon it or reasonably implied from the provisions of this chapter.

**Source:** SL 1967, ch 102, § 5.

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**36-11-11. Promulgation of rules .**

The Board of Pharmacy may promulgate rules pursuant to chapter [1-26](#) as follows:

- (1) Pertaining to the practice of pharmacy;
- (2) Relating to the sanitation of persons and establishments licensed under the provisions of this chapter;
- (3) Pertaining to establishments licensed under the provisions of this chapter wherein any drug is compounded, prepared, dispensed or sold;
- (4) Providing for minimum equipment and standards of establishments licensed under the provisions of this chapter;
- (5) Pertaining to the sale of drugs by or through any mechanical device;
- (6) In cooperation with other governmental agencies where there exists a joint responsibility for protecting the public health and welfare;
- (7) Pertaining to the sale of nonprescription drugs;
- (8) To adopt such publications or supplements thereto as shall from time to time be deemed necessary to describe the drugs, medicines, prescription drugs, dispensing physician or other terms used in § [36-11-2](#);
- (9) Pertaining to the posting of prescription prices on the premises of a pharmacy department to provide consumers with comparative pricing information;
- (10) Pertaining to registration of drug wholesalers and manufacturers;
- (11) Pertaining to home health care and service;
- (12) Pertaining to computerized pharmacy;
- (13) Pertaining to the registration of registered pharmacy technicians and the suspension or revocation of registration; an annual registration fee not to exceed thirty dollars; and tasks that may not be delegated by a licensed pharmacist to a registered technician;
- (14) Redispensing of pharmaceuticals;
- (15) Pertaining to the dispensing of biological products.

**Source:** SDC 1939, § 27.1006; SL 1967, ch 102, § 7; SL 1973, ch 244, § 2; SL 1986, ch 302, § 111; SL 1990, ch 325, § 1; SL 1997, ch 216, § 2; SL 2004, ch 248, § 2; SL 2004, ch 249, § 1; SL 2012, ch 194, § 10; SL 2018, ch 231, § 2.

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36-11-12. Repealed by SL 1986, ch 302, § 112.

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**36-11-13. Unregistered practice of pharmacy as misdemeanor.**

It is a Class 2 misdemeanor for any person other than a pharmacist registered under the laws of South Dakota to engage in the practice of pharmacy except as provided by § [36-11-14](#).

**Source:** SDC 1939, § 27.1013; SL 1964, ch 86; SL 1967, ch 102, § 14; SL 1977, ch 190, § 166; SL 1993, ch 278, § 5.

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**36-11-14. Physicians and veterinarians unaffected by chapter.**

Nothing in this chapter applies to or in any manner interferes with the business of any physician, as a physician, or any licensed veterinarian, as a licensed veterinarian, or an optometrist, as a licensed optometrist, or prevent him from supplying, under his supervision, to his patients such drugs and medicines as may seem to him proper.

**Source:** SDC 1939, § 27.1013; SL 1964, ch 86; SL 1967, ch 102, § 14; SL 1986, ch 306, § 4.

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**36-11-15. Unregistered dispensing of drugs or operation of pharmacy as misdemeanor.**

Any person other than a registered pharmacist who compounds or dispenses drugs, medicines, or poisons, or who keeps a pharmacy or store for retailing or compounding medicines, or who takes, uses or exhibits the title of a registered pharmacist is guilty of a Class 2 misdemeanor.

**Source:** SDC 1939, § 27.9922; SL 1967, ch 102, § 21; SL 1977, ch 190, § 167.

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**36-11-16. Requirements for registration as pharmacist.**

Any person of good moral character and temperate habits, not less than eighteen years of age, who is a graduate of a college of pharmacy recognized and approved by the board, and who has had the necessary experience as determined by the board in the practice of pharmacy under a regularly licensed pharmacist in a pharmacy where physicians' prescriptions are compounded and who shall pass a satisfactory examination prescribed by the State Board of Pharmacy, shall be entitled to a certificate of registration as a licensed pharmacist. The board shall have the authority to allow credit for suitable military and research activities in the field of pharmacy as part of the experience requirement.

**Source:** SDC 1939, § 27.1007; SL 1967, ch 102, § 9; revised pursuant to SL 1972, ch 15, § 4; SL 2020, ch 168, § 7.

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**36-11-16.1. Criminal background investigation of applicants for licensure and licensees under disciplinary investigation--Fees.**

Each applicant for licensure as a pharmacist in this state shall submit to a state and federal criminal background investigation by means of fingerprint checks by the Division of Criminal Investigation and the Federal Bureau of Investigation. Upon application, the board shall submit completed fingerprint cards to the Division of Criminal Investigation. Upon completion of the criminal background check, the Division of Criminal Investigation shall forward to the board all information obtained as a result of the criminal background check. This information shall be obtained prior to permanent licensure of the applicant. The board may require a state and federal criminal background check for any licensee who is the subject of a disciplinary investigation by the board. Failure to submit or cooperate with the criminal background investigation is grounds for denial of an application or may result in revocation of a license. The applicant shall pay for any fees charged for the cost of fingerprinting or the criminal background investigation.

**Source:** SL 2012, ch 193, § 5.

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**36-11-17. Registration fee.**

Every person initially applying for a certificate of registration with the Board of Pharmacy as a registered pharmacist shall pay to the board with the application a fee, not to exceed thirty-five dollars, set by the board by rule promulgated pursuant to chapter [1-26](#).

**Source:** SDC 1939, § 27.1010; SL 1967, ch 102, § 10; SL 1988, ch 301, § 1; SL 2008, ch 191, § 25.

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**36-11-18. Examination of applicants for registration--Grant of certificates to qualified persons.**

It shall be the duty of the Board of Pharmacy to examine all applications for registration submitted in due form as provided in the rules and regulations of the board and to grant certificates of registration to such persons as may be entitled to the same under the provisions of this chapter.

**Source:** SDC 1939, § 27.1004; SL 1967, ch 102, § 5.

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### **36-11-19. Registration of applicants registered in other states--Fee.**

The Board of Pharmacy may in its discretion grant certificates of registration to such persons as shall furnish with their applications satisfactory proof that they have been registered by examination in some other state; provided that such other state required a degree of competency at the time such person was licensed at least equal to that required of licentiates in this state at that same time. The State Board of Pharmacy, in order to be informed, may, in determining the degree of fitness required by the several states' boards of pharmacy for granting license and reciprocal registration, join with other states' boards of pharmacy. Every person applying for registration pursuant to this section shall pay to the board upon application a fee, not to exceed one hundred fifty dollars, set by the board by rule promulgated pursuant to chapter [1-26](#).

**Source:** SDC 1939, § 27-.1007; SL 1967, ch 102, § 9; SL 1986, ch 302, § 114; SL 2008, ch 191, § 26.

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### **36-11-19.1. Authority of registered pharmacists.**

Registered pharmacists may:

- (1) Perform drug administration pursuant to a prescription drug order. The Board of Pharmacy shall establish standards for drug administration pursuant to chapter [1-26](#) with the approval of a committee composed of two persons appointed by the Board of Pharmacy, two persons appointed by the Board of Nursing and two persons appointed by the Board of Medical and Osteopathic Examiners;
- (2) Perform drug reviews;
- (3) Perform or participate in scientific or clinical drug or drug-related research as an investigator or in collaboration with other investigators;
- (4) Interpret and apply pharmacokinetic data and other pertinent laboratory data to design safe and effective drug dosage regimens;
- (5) Participate in drug and drug device selection pursuant to a prescription drug order;
- (6) Initiate or modify drug therapy by protocol or other legal authority established and approved within a licensed health care facility or by a practitioner authorized to prescribe drugs; and
- (7) Provide information on prescription drugs, which may include advising, consulting, and educating, as necessary or as required, patients, the public, and other health care providers on the rational, safe and cost-effective use of drugs, including therapeutic values, content, hazards and appropriate use.

**Source:** SL 1993, ch 278, § 2.

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### **36-11-19.2. Nonresident pharmacy defined.**

For purposes of §§ [36-11-19.2](#) to [36-11-19.9](#), inclusive, a nonresident pharmacy is any pharmacy located outside this state that:

- (1) Ships, mails, or delivers any dispensed drug to a resident in this state pursuant to a legally issued prescription; and

- (2) Provides to a resident of this state information on drugs or devices including advice relating to therapeutic values, potential hazards, and uses; or
- (3) Counsels pharmacy patients residing in this state concerning adverse and therapeutic effects of drugs.

**Source:** SL 1997, ch 217, § 1.

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**36-11-19.3. Requirements for licensure of nonresident pharmacy.**

Any nonresident pharmacy shall be licensed before conducting business in this state. The Board of Pharmacy shall issue a license to any nonresident pharmacy which meets the requirements of §§ [36-11-19.2](#) to [36-11-19.9](#), inclusive. In order to be licensed by the board to do business in this state, a nonresident pharmacy shall:

- (1) Be licensed and in good standing in the state in which its dispensing facilities are located;
- (2) Comply with all applicable laws, rules, and standards of that state and the United States, and if requested by the board, provide evidence that it has complied; and
- (3) Submit an application upon a form prescribed by the Board of Pharmacy and pay a fee set by the board.

The application shall include information on ownership and location of the pharmacy, the identity of licensed pharmacist in charge of the pharmacy, identity of licensed pharmacists who are providing services to patients residing in this state, and provide a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located. The board shall establish pursuant to chapter [1-26](#) the application fee, which may not be greater than that assessed resident pharmacies.

**Source:** SL 1997, ch 217, § 2.

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**36-11-19.4. Denial of nonresident pharmacy's application--Appeal.**

The board may approve, approve with conditions, or deny the application for licensure or renewal of licensure as a nonresident pharmacy based on information concerning the qualifications of the applicant provided in the application. An applicant may appeal the decision of the board regarding licensure or renewal of licensure pursuant to contested case procedure in chapter [1-26](#).

**Source:** SL 1997, ch 217, § 3.

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**36-11-19.5. Expiration and renewal of nonresident pharmacy license.**

Each nonresident pharmacy license expires on June thirtieth following the date of issue. The board shall mail an application for license renewal to each licensee before June first of each year. If application for renewal of the license accompanied by the annual license fee is not made before the expiration date, the existing license lapses on the date of expiration.

**Source:** SL 1997, ch 217, § 4.

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**36-11-19.6. Conduct causing denial, revocation, or suspension of nonresident pharmacy license--Contested case.**

The board may deny, revoke, or suspend a nonresident pharmacy registration for conduct which causes serious bodily injury or serious psychological injury to a resident of this state if the board has referred the matter to the regulatory or licensing agency in the state in which the nonresident pharmacy is located

and the regulatory or licensing agency fails to initiate an investigation within forty-five days after the referral. Any action taken to deny, revoke, or suspend a nonresident pharmacy registration is a contested case proceeding pursuant to chapter [1-26](#).

**Source:** SL 1997, ch 217, § 5.

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**[36-11-19.7. Nonresident pharmacy dispensing equivalent drug product or interchangeable biological product.](#)**

No nonresident pharmacy may dispense an equivalent drug product or an interchangeable biological product if a brand name has been prescribed, unless the dispensing is done in compliance with the laws of this state nor may dispense an equivalent drug product or an interchangeable biological product to a resident of this state without informing the patient of the selection and the right to refuse the product selected either by telephone or in writing.

**Source:** SL 1997, ch 217, § 6; SL 2018, ch 231, § 3.

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**[36-11-19.8. Recording patient information--Toll-free telephone service--Written information on new or changed prescriptions.](#)**

A nonresident pharmacy shall obtain, record, and maintain pertinent patient information. The pharmacy shall provide patients a written offer to consult and access to a toll-free telephone service to facilitate communications between the patient and the pharmacist at the pharmacy. The number of the toll-free telephone service shall be printed on a label affixed to each container of a prescription drug dispensed by the pharmacy to a patient. The toll-free telephone service shall be available for a minimum of six days a week and forty hours a week.

In addition, a nonresident pharmacy shall provide the patient written information about the medication on all new or changed prescriptions. The information shall include directions for storage and use, precautions and relevant warnings about drug interactions and common side effects, and directions for patient action if the patient misses a scheduled dose of the prescription.

**Source:** SL 1997, ch 217, § 7.

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**[36-11-19.9. Designation of resident agent for nonresident pharmacy.](#)**

A nonresident pharmacy shall designate a resident agent in this state for service of process. If an agent is not designated, the secretary of state of this state shall be considered to be its agent, upon whom may be served all legal process in any action or proceeding against the nonresident pharmacy. A copy of any service of process shall be mailed by certified mail, return receipt requested, postage prepaid, at the address the nonresident pharmacy has designated on its application for licensure. If any nonresident pharmacy is not licensed in this state, service on the secretary of state is sufficient service.

**Source:** SL 1997, ch 217, § 8.

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**[36-11-20. Suspension, revocation, or refusal of license--Grounds--Fraudulent registration void.](#)**

The Board of Pharmacy may, in compliance with chapter [1-26](#), suspend, revoke, or refuse to grant a license or certificate of registration to any person guilty of a felony or a misdemeanor involving moral turpitude, or who is addicted to the use of alcoholic liquors or narcotic drugs to such an extent as to render him unfit to practice pharmacy with reasonable skill and safety; and the board may, in compliance with chapter [1-26](#), revoke a license for like cause, or any license which has been procured by fraud or by false



representation. Any license or registration, or renewal thereof, obtained through fraud or by any fraudulent or false representations shall be void. The board may suspend, revoke or refuse to grant a license or certificate of registration to any person permitting or engaging in the unauthorized sale of legend or controlled drugs or substances or who the board finds to be in violation of any law, rule, or regulation governing pharmacists.

**Source:** SL 1967, ch 102, § 5; SL 1982, ch 275, § 1.

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36-11-20.1, 36-11-20.2. Repealed by SL 1996, ch 227, § 17.

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36-11-20.3 to 36-11-20.10. Repealed by SL 1996, ch 227, §§ 18 to 25.

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**36-11-21. Continuing validity of prior certificates.**

Nothing in this chapter shall be construed to invalidate any certificate of registration in force on July 1, 1967.

**Source:** SDC 1939, § 27.1007; SL 1967, ch 102, § 9.

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**36-11-22. Registration record maintained by board--Contents.**

The Board of Pharmacy shall keep a record of registration in which shall be entered the names and places of business of all persons registered under this chapter which records shall also specify such facts as such persons shall claim to justify their registration.

**Source:** SL 1967, ch 102, § 5.

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**36-11-23. Annual registry fee and renewal--Suspension of certificate for failure to renew--Reinstatement after suspension.**

Each pharmacist shall annually by October first each year, pay to the board a registry fee to be fixed by the board in compliance with chapter [1-26](#), not to exceed one hundred fifty dollars. Upon payment of the fee by a pharmacist, the Board of Pharmacy shall renew the pharmacist's certificate of registration. Any pharmacist who fails to pay the renewal fee by the due date is subject to suspension of certificate by the board in compliance with chapter [1-26](#). Any suspended certificate may be reinstated if all delinquent fees have been paid, plus a penalty of twenty- five dollars, and the Board of Pharmacy has approved the application for reinstatement.

**Source:** SDC 1939, § 27.1009; SL 1953, ch 121; SL 1967, ch 102, § 10; revised pursuant to SL 1972, ch 15, § 4; SL 1988, ch 301, § 2; SL 1996, ch 230, § 3; SL 2005, ch 199, § 35.

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**36-11-23.1. Continuing education program established.**

There is hereby established a program of continuing education for licensed pharmacists within this state.

**Source:** SL 1977, ch 296, § 1.

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**36-11-23.2. Rules relating to continuing education--Maximum annual requirement.**

The State Board of Pharmacy shall promulgate rules pertaining to continuing education of pharmacists. Such continuing education program shall not exceed twelve hours in length in any one year.

**Source:** SL 1977, ch 296, § 3; SL 1986, ch 302, § 113.

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**36-11-23.3. Continuing education required for relicensure.**

As of October 1, 1980, no active pharmacist shall be eligible for relicensure in this state unless the pharmacist has met the continuing education requirements established by the State Board of Pharmacy.

**Source:** SL 1977, ch 296, § 2.

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**36-11-23.4. Advisory council on continuing education.**

There is hereby established an advisory council to the State Board of Pharmacy consisting of two pharmacists appointed by the State Board of Pharmacy, two pharmacists appointed by the state college of pharmacy and four pharmacists appointed by the South Dakota Pharmacists Association who shall serve without compensation and whose duties shall be to advise the State Board of Pharmacy in the establishment and accreditation of programs of continuing education.

**Source:** SL 1977, ch 296, § 4.

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36-11-24. Repealed by SL 1970, ch 212, § 1.

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**36-11-25. Pharmacy intern certificates--Restrictions on practice.**

Pharmacy intern certificates may be issued by the Board of Pharmacy to persons who are gaining experience as a qualification for licensure as a registered pharmacist. Any pharmacy intern granted an intern certificate shall perform his internship pursuant to regulations which shall be promulgated by the Board of Pharmacy. Nothing in this section shall be construed as giving such pharmacy intern authority to fill any prescription, except under the supervision and in the presence of the registered pharmacist.

**Source:** SDC 1939, § 27.1008; SL 1955, ch 92; SL 1961, ch 130; SL 1967, ch 102, § 11; SL 1970, ch 212, § 2.

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**36-11-26. Board power to discipline registrant.**

If the Board of Pharmacy is satisfied that any person holding a certificate of registration is for any reason incompetent or disqualified to perform the duties of a registered pharmacist pursuant to § [36-11-20](#) or as contemplated by the provisions of this chapter, it may, in compliance with § [36-11-28](#):

- (1) Issue a reprimand to the registrant;
- (2) Place the registrant on probation and supervision;
- (3) Suspend the registrant's certificate until he completes a course of therapy, treatment, training, or any combination thereof;
- (4) Suspend the registrant's certificate for a fixed period; and
- (5) Revoke the registrant's certificate.

**Source:** SDC 1939, § 27.1011; SL 1959, ch 132; SL 1967, ch 102, § 12; SL 1982, ch 275, § 2; SL 1986, ch 311.

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36-11-27. Repealed by SL 1982, ch 275, § 3.

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**36-11-28. Procedure for revocation or suspension of certificate.**

A certificate of registration as a pharmacist shall not be revoked or suspended except after hearing before the Board of Pharmacy at which a majority of its members are present and in compliance with chapter [1-26](#).

**Source:** SDC 1939, § 27.1011; SL 1959, ch 132; SL 1967, ch 102, § 12; revised pursuant to SL 1972, ch 15, § 4.

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**[36-11-29. Appeal from revocation or suspension of certificate.](#)**

An appeal from the decision of the Board of Pharmacy may be taken as provided by chapter [1-26](#).

**Source:** SDC 1939, § 27.1011; SL 1959, ch 132; SL 1967, ch 102, § 12; revised pursuant to SL 1972, ch 15, § 4.

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**[36-11-30. Registration and permit required for operation of pharmacy--Violation as misdemeanor.](#)**

No pharmacy shall open or be kept open for transaction of business until it has been registered and a permit issued by the State Board of Pharmacy.

A violation of this section is a Class 2 misdemeanor. Each day of violation is a separate offense.

**Source:** SDC 1939, § 27.1012; SL 1967, ch 102, § 13; SL 1992, ch 158, § 82.

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**[36-11-31. Business name or advertising implying pharmacy prohibited unless registered--Violation as misdemeanor.](#)**

No person, copartnership or corporation may carry on, conduct, or transact business under a name which contains as a part thereof the term or words "drug department," "drugstore" or "pharmacy" or any term implying the operation of a pharmacy or drugstore, or in any manner by advertisement, circular, poster, sign or otherwise describe or refer to a place of business by the terms "drugstore" or "pharmacy" or any other term or words which may be applied to establishments where drugs, medicines, and poisons are usually dispensed or distributed, unless the place of business so conducted is a pharmacy duly authorized and registered by the State Board of Pharmacy. A violation of this section is a Class 2 misdemeanor.

**Source:** SDC 1939, § 27.1017; SL 1967, ch 102, § 17; SL 1992, ch 158, § 83.

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**[36-11-32. Pharmacy permit issued by board--Fee.](#)**

Upon a form prescribed by the State Board of Pharmacy and the payment of a fee, not to exceed two hundred dollars, set by the Board of Pharmacy in accordance with chapter [1-26](#), the State Board of Pharmacy shall issue to pharmacists in good standing, registered under the laws of this state, a permit to conduct a pharmacy.

**Source:** SDC 1939, § 27.1015; SL 1943, ch 105; SL 1953, ch 122; SL 1967, ch 102, § 15; SL 1975, ch 236; SL 1984, ch 251; SL 2008, ch 191, § 27.

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**[36-11-33. Institutional pharmacy permits--Scope of services provided--Minimum standards.](#)**

The Board of Pharmacy may issue to pharmacists in good standing a permit to conduct a part-time, limited, or conditional pharmacy in hospitals, nursing homes or related facilities provided that the pharmacy services are limited to patients. A permit to conduct a pharmacy, the merchandise and fixtures of which are owned by a person, firm, or corporation other than a registered pharmacist, upon said registered pharmacist

making application for a permit hereunder, may be issued and granted to the said registered pharmacist, on compliance with the provisions of this chapter, and with minimum standards as established by the board.

**Source:** SL 1967, ch 121, § 15.

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**36-11-34. Ownership or control by pharmacist required for pharmacy permit.**

No permit to conduct a pharmacy shall be issued to any pharmacist applicant unless such pharmacist applicant is owner, or part owner, of the merchandise and fixtures of the place of business for which such pharmacy registration is applied for, or unless application is made jointly with a registered pharmacist owner, or unless the nonpharmacist owner of the merchandise and fixtures of the place of business for which pharmacy registration is applied for, has made affidavit on a form prescribed by the state board of pharmacy delegating complete responsibility for the pharmaceutical services in said place of business to the pharmacist applicant.

**Source:** SDC 1939, § 27.1014; SL 1967, ch 102, § 15.

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**36-11-35. Pharmacy permit as legal registration--Expiration date.**

Each permit for a pharmacy shall constitute and signify a legal registration for the pharmacy to which it applies, and shall expire on the last day of June following the date of issue.

**Source:** SDC 1939, § 27.1015; SL 1943, ch 105; SL 1953, ch 122; SL 1967, ch 102, § 15.

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**36-11-36. Permit and certificate displayed in pharmacy.**

Each permit for a pharmacy, together with a certificate naming the pharmacist actively conducting said pharmacy, issued by the State Board of Pharmacy, which shall be a part of said permit, shall be exposed in a conspicuous place in the pharmacy to which it applies.

**Source:** SDC 1939, § 27.1015; SL 1943, ch 105; SL 1953, ch 122; SL 1967, ch 102, § 15.

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**36-11-37. Transfer of pharmacy permit to another pharmacist.**

Each permit for a pharmacy may be transferred to another pharmacist in good standing and registered under the laws of this state without the payment of an additional fee; provided an application for the transfer of said permit is made upon a form prescribed by the State Board of Pharmacy and filed with the secretary thereof not less than ten days before the transfer of such active management is made.

**Source:** SDC 1939, § 27.1015 as added by SL 1943, ch 105; SL 1953, ch 122; SL 1967, ch 102, § 15.

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**36-11-38. Permit void after death of pharmacist--Time allowed for transfer.**

In the event of the death of the pharmacist permittee, the pharmacy permit issued to the deceased under this chapter shall, within one hundred twenty days after the death of such permittee, become null and void unless transfer thereof, as provided in § [36-11-37](#), shall have been made within the said one hundred twenty day period.

**Source:** SDC 1939, § 27.1015 as added by SL 1943, ch 105; SL 1953, ch 122; SL 1967, ch 102, § 15.

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**36-11-39. Report to board of changes in location or ownership of pharmacy.**

The change of location of any pharmacy for which a permit has been issued from one municipality to another within this state, any change in the ownership of such pharmacy, or the cessation of business by such pharmacy shall be reported to the State Board of Pharmacy within ten days from such occurrence on forms prescribed by the State Board of Pharmacy.

**Source:** SDC 1939, § 27.1015 as added by SL 1943, ch 105; SL 1953, ch 122; SL 1967, ch 102, § 15.

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**36-11-40. Permit void on unreported transfer, change of location or change in management.**

Any permit issued under the provisions of § [36-11-32](#) shall be void if the active management of any pharmacy is changed without the transfer, as provided in § [36-11-37](#), of the permit therefor, or if the location of said pharmacy is changed without the same being reported as provided in § [36-11-39](#), or if the pharmacy is kept open for business after the permittee has ceased to be in active management of said pharmacy, and whenever the minimum requirements of this chapter and the Board of Pharmacy are no longer met.

**Source:** SDC 1939, § 27.1015 as added by SL 1943, ch 105; SL 1953, ch 122; SL 1967, ch 102, § 15.

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**36-11-41. Equipment, supplies and publications required for pharmacy permit.**

No permit may be issued under [36-11-32](#) unless:

- (1) The pharmacy is equipped with the pharmaceutical instruments and utensils prescribed by the State Board of Pharmacy, and shall possess a stock of pharmaceuticals adequate to serve the needs of the community in which the pharmacy is located; and
- (2) The pharmacy has on file at all times the publications and supplements of formularies and drug information prescribed by the board by rules promulgated pursuant to chapter [1-26](#).

**Source:** SDC 1939, § 27.1015 as added by SL 1943, ch 105; SL 1953, ch 122; SL 1967, ch 102, § 15; SL 1987, ch 271; SL 2003, ch 204, § 1.

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**36-11-42. Sanitary conditions required in pharmacy.**

Any permit issued under the provisions of § [36-11-32](#) shall be void and subject to cancellation by the State Board of Pharmacy, unless such pharmacy is maintained and operated in a clean and sanitary condition, free from unhealthful, foreign, or injurious contamination.

**Source:** SDC 1939, § 27.1015 as added by SL 1943, ch 105; SL 1953, ch 122; SL 1967, ch 102, § 15.

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**36-11-43. Code of professional ethics--Association recommendations considered--Employment rights not regulated--No basis for criminal prosecution.**

The Board of Pharmacy may, in the manner provided by chapter [1-26](#), adopt a code of professional ethics for pharmacists in this state in the practice of their profession. In adopting such code, or any amendments thereafter, the board will consider the recommendations of the South Dakota Pharmacists Association and the vote of its members, provided however, that any such code so adopted shall at no time contain any provision that would in any way restrain, prohibit or attempt to regulate the rights of any pharmacist to be employed in any pharmacy holding a valid pharmacy permit. Violation of the code of professional ethics shall not be the basis for criminal prosecution unless otherwise declared unlawful.

**Source:** SL 1967, ch 102, § 7 (h); SL 1972, ch 15, § 4.

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**36-11-44. Permitting unauthorized practice or false representation to secure registration as misdemeanor.**

Any registered pharmacist who permits the compounding or dispensing of prescriptions or the vending of drugs or poisons in his store or place of business, except under the personal supervision of a registered pharmacist, or any pharmacist who, while continuing in business, makes any false representations to procure registration for himself or any other person, is guilty of a Class 2 misdemeanor.

**Source:** SDC 1939, § 27.9923; SL 1967, ch 102, § 22; SL 1977, ch 190, § 168.

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36-11-45. Repealed by SL 1985, ch 300.

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**36-11-46. Dispensing of substandard drugs prohibited--Violation as misdemeanor.**

No person may compound, dispense, sell, or offer for sale, or cause to be compounded, dispensed, sold or offered for sale any medicine or preparation under or by a name recognized in the United States Pharmacopoeia or National Formulary, for internal or external use, which differs from the standard of strength, quality or purity as determined by the test laid down in the United States Pharmacopoeia or National Formulary, official at the time of such compounding, dispensing, sale, or offering for sale. A violation of this section is a Class 2 misdemeanor.

**Source:** SL 1967, ch 102, § 20 (b); SL 1978, ch 271, § 1; SL 1992, ch 158, § 84.

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**36-11-46.1. Dispensing equivalent drug products.**

A pharmacist dispensing a prescription drug order for a drug product prescribed by its brand name may select any equivalent drug product, if the manufacturer or distributor of the equivalent drug product holds, if applicable, either an approved new drug application or an approved abbreviated new drug application, unless other approval by law or from the Federal Food and Drug Administration is required.

**Source:** SL 1978, ch 271, § 3; SL 1993, ch 277, § 2.

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**36-11-46.2. Prescription prohibiting substitution--Requirements.**

A practitioner may prohibit a pharmacist from selecting an equivalent drug product or interchangeable biological product by handwriting on the prescription drug order the words, brand necessary, or words of similar meaning. The prohibition may not be preprinted or stamped on the prescription drug order. This selection does not preclude a reminder of the procedure required for the practitioner to prohibit selection by a pharmacist from being preprinted on the prescription drug order. If an oral prescription is given to a pharmacist, the practitioner or practitioner's authorized agent shall instruct the pharmacist if selection of an equivalent drug product or interchangeable biological product is prohibited. The pharmacist shall note the instructions on the file copy of the prescription drug order.

**Source:** SL 1978, ch 271, § 4; SL 1990, ch 306, § 2; SL 1993, ch 277, § 3; SL 2018, ch 231, § 4.

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**36-11-46.3. Notification to person receiving equivalent drug product or interchangeable biological product--Right of refusal.**

The pharmacist or the pharmacist's agent shall inform the person receiving the drug or biological product pursuant to the prescription drug order of the selection of an equivalent drug product or interchangeable biological product and of the person's right to refuse the product selected. A pharmacist

shall, upon request of the prescribing practitioner, provide information regarding substitutions of equivalent drug products.

**Source:** SL 1978, ch 271, § 5; SL 1990, ch 306, § 3; SL 1993, ch 277, § 4; SL 2018, ch 231, § 5.

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#### **36-11-46.4. Standards for selecting prescription drug.**

A pharmacist may not select a product unless it has been manufactured, labeled, or distributed by a manufacturer, labeler, or distributor who:

- (1) Marks capsules and tablets with an identification code or monogram;
- (2) Labels products with their expiration date;
- (3) Provides reasonable services to accept return goods that have reached their expiration date;
- (4) Maintains reasonable resources for product information;
- (5) Maintains recall capabilities for unsafe or defective drugs; and
- (6) Makes available therapeutic equivalency ratings.

**Source:** SL 1978, ch 271, § 6; SL 1990, ch 306, § 4; SL 1993, ch 277, § 5.

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#### **36-11-46.5. Liability for dispensing equivalent drug product or interchangeable biological product.**

A pharmacist who selects an equivalent drug product or interchangeable biological product pursuant to this chapter assumes no greater liability for selecting the dispensed drug or biological product than would be incurred in filling a prescription for a drug or biological product prescribed by its established, generic, or proper name.

**Source:** SL 1986, ch 309; SL 2018, ch 231, § 6.

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#### **36-11-46.6. Label to contain drug name--Form when generic equivalent selected--Contents of prescription files--Label information.**

The pharmacist shall, unless otherwise instructed by the prescriber, label the prescription container with the name of the dispensed drug. If the dispensed drug does not have a brand name, the prescription label shall indicate the generic name or the United States Pharmacopoeia pharmacy equivalent name of the drug dispensed. If a pharmacist selects a generically equivalent drug product for the brand name drug product prescribed, the prescription container label shall identify the generic name and may identify the brand name for which the selection is made. The dual identification allowed under this section shall take the form of the following statement on the prescription container label: "(generic name) Generic for (brand name)". The pharmacy file copy of each prescription shall include the brand name, if any, or the name of the manufacturer, labeler, or distributor of the drug product dispensed. The prescription container label shall include all information required by federal and state law or by rule promulgated by the board pursuant to chapter [1-26](#).

**Source:** SL 1990, ch 306, § 5; SL 1993, ch 278, § 6; SL 2001, ch 201, § 1.

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#### **36-11-46.7. Equivalent drug and biological product requirements not applicable to hospital patients.**

The requirements of §§ [36-11-46.1](#) to [36-11-46.3](#), inclusive, [36-11-46.6](#), and [36-11-46.9](#) to [36-11-46.11](#), inclusive, do not apply to an order to dispense a drug or biological product to a hospital patient.

**Source:** SL 1990, ch 306, § 6; SL 1993, ch 277, § 6; SL 2018, ch 231, § 7.

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**36-11-46.8. Cause of action for selection of equivalent drug product or interchangeable biological product.**

The selection of an equivalent drug product or interchangeable biological product does not, in itself, in the absence of willful misconduct or negligence, constitute a cause of action against the practitioner.

**Source:** SL 1993, ch 277, § 7; SL 2018, ch 231, § 8.

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**36-11-46.9. Dispensing interchangeable biological products.**

A pharmacist dispensing a prescription drug order for a biological product prescribed by its brand or proper name may select an interchangeable biological product of the prescribed product. Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through:

- (1) An interoperable electronic medical records system;
- (2) An electronic prescribing technology;
- (3) A pharmacist benefit management system; or
- (4) A pharmacy record.

**Source:** SL 2018, ch 231, § 9.

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**36-11-46.10. Notice to practitioner of biological product dispensed.**

Any entry into an electronic records system as described in § [36-11-46.9](#) is presumed to provide notice to the practitioner. Otherwise, the pharmacist shall communicate the biological product dispensed to the practitioner using facsimile, telephone, electronic transmission, or other prevailing means, if communication is not required where:

- (1) There is no interchangeable biological product approved by the U.S. Food and Drug Administration for the product prescribed; or
- (2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

**Source:** SL 2018, ch 231, § 10.

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**36-11-46.11. Labeling of prescription container for biological product.**

The pharmacist shall, unless otherwise instructed by the prescriber, label the prescription container with the name of the dispensed biological product. If the dispensed biological product does not have a brand name, the prescription label shall indicate the proper name of the biological product dispensed. If a pharmacist selects an interchangeable biological product for the brand name biological product prescribed, the prescription container label shall identify the proper name and may identify the brand name for which the selection is made. The dual identification allowed under this section shall take the form of the following statement on the prescription container label: (proper name) interchangeable with (brand name). The pharmacy file copy of each prescription shall include the brand name, if any, or the proper name, and the name of the manufacturer of the biological product dispensed. The prescription container label shall include all information required by federal and state law or by rule promulgated by the board pursuant to chapter [1-26](#).

**Source:** SL 2018, ch 231, § 11.



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36-11-47. Repealed by SL 1977, ch 190, § 170.

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**36-11-47.1. Posting of prescription drug prices authorized--Rules and regulations.**

The posting of prescription drug prices upon the premises of a duly licensed pharmacy department is hereby specifically authorized and shall not constitute "advertising of prescription prices" within the meaning of this chapter when performed in accordance with such rules and regulations as may be adopted by the State Board of Pharmacy to provide consumers with comparative pricing information.

**Source:** SL 1973, ch 244, § 5.

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**36-11-47.2. Refusal to quote prescription price as misdemeanor.**

It is a Class 2 misdemeanor for any pharmacist to refuse to quote the price of any prescription legend drug when said quote is requested by a person.

**Source:** SL 1975, ch 235; SL 1977, ch 190, § 171.

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**36-11-48. Grounds for suspension or revocation of pharmacy permit.**

The State Board of Pharmacy may suspend or revoke any permit obtained by false representations made in the application therefor, or when the pharmacy for which the permit shall be issued is kept open for the transaction of business without a registered pharmacist in charge thereof, or upon conviction of a violation of any law of this state or of the United States pertaining to the drug business or for the aiding or abetting in the violation of any such law.

**Source:** SDC 1939, § 27.1016; SL 1967, ch 102, § 16.

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**36-11-49. Procedure for revocation of pharmacy permit.**

Before any permit for a pharmacy shall be revoked chapter [1-26](#) shall be complied with. Two members of the board shall constitute a quorum and no permit shall be revoked except by a vote of two or more members of the State Board of Pharmacy.

**Source:** SDC 1939, § 27.1016; SL 1967, ch 102, § 16; revised pursuant to SL 1972, ch 15, § 4.

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**36-11-50. Appeal from cancellation of pharmacy permit.**

An appeal from the decision of the Board of Pharmacy may be taken as provided by chapter [1-26](#).

**Source:** SDC 1939, § 27.1016; SL 1967, ch 102, § 16; revised pursuant to SL 1972, ch 15, § 4.

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**36-11-51, 36-11-52. Repealed by SL 2012, ch 194, §§ 11, 12.**

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36-11-53 to 36-11-59. Repealed by SL 1997, ch 216, §§ 5 to 11.

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**36-11-60, 36-11-61. Repealed by SL 2012, ch 194, §§ 13, 14.**

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36-11-62. Repealed by SL 1992, ch 158, § 88.

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**36-11-63. Fees paid to secretary of board--Employment of personnel and payment of expenses from funds collected.**

All fees shall be paid to the secretary of the State Board of Pharmacy. Out of the funds collected the board may, pursuant to chapter [3-6D](#), employ agents, inspectors, and clerical assistance and pay expenses as may be necessary for the enforcement of the provisions of this chapter.

**Source:** SDC 1939, § 27.1015; SL 1943, ch 105; SL 1953, ch 122; SL 1967, ch 102, § 15; SL 1973, ch 23; SL 2018, ch 12, § 15.

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**[36-11-64. Employment of inspectors--Inspection of licensed establishments.](#)**

The Board of Pharmacy may employ inspectors of pharmacy. The members of the board and inspectors of pharmacy may inspect during business hours, all establishments required to be licensed under the authority of the board.

**Source:** SL 1967, ch 102, § 8.

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**[36-11-65. Injunction proceedings to prevent violations of chapter--Election of remedies.](#)**

Whenever the Board of Pharmacy believes, from evidence satisfactory to it, that any person is violating or about to violate any provisions of this chapter or any order or requirement of the board issued or promulgated pursuant to authority expressly granted the board by law, the board may bring an action in the name of the State of South Dakota against such person to enjoin such violation or any act in furtherance thereof. Such action shall be an alternate to criminal proceedings, and the commencement of one proceeding by the board constitutes an election. In such action an order or judgment may be entered awarding such temporary or permanent injunction as is proper.

**Source:** SL 1967, ch 102, § 24; SL 1978, ch 155, § 20.

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**[36-11-66. Severability of provisions.](#)**

If any provision of this chapter is declared unconstitutional or the applicability thereof to any person or circumstance is held invalid, the constitutionality of the remainder of the chapter and applicability thereof to other persons and circumstances shall not be affected thereby.

**Source:** SL 1967, ch 102, § 26.

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**[36-11-67. Participants in drug utilization review program immune from liability.](#)**

Pharmacists licensed under this chapter or physicians licensed under chapter [36-4](#) who participate on a drug utilization review program as defined in § [36-11-2](#) are individually or jointly not subject to and are immune from claim, suit, liability, damages, or any other recourse, civil or criminal, arising from any act or proceeding, decision or determination undertaken, performed or reached in good faith and without malice when acting individually or jointly in carrying out the responsibilities, authority, duties, powers and privileges of the program conferred upon them under any provisions of law or rule, good faith being presumed until proven otherwise, with malice required to be shown by the complainant.

**Source:** SL 1992, ch 270, § 2.

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**[36-11-68. Counseling patients and caregivers--Maintenance of patient records.](#)**

After receipt of a prescription drug order, the pharmacist shall offer to counsel each patient or caregiver who receives a prescribed drug or device from him on matters which in the exercise of the pharmacist's professional judgment the pharmacist deems significant. To this purpose, the pharmacist shall

make a reasonable effort to obtain, record, and maintain pertinent patient information. Before January 1, 1993, the board shall establish minimum standards by rules adopted pursuant to chapter [1-26](#) for counseling patients and caregivers and for maintenance of patient information.

Nothing in this section shall be construed to require a pharmacist to provide patient counseling for prescribed drugs:

- (1) Administered to an inpatient or resident of a health care facility;
- (2) Administered by a certified or licensed health professional to registered outpatients of a hospital;  
or
- (3) Provided in less than a seventy-two-hour supply to inpatients or outpatients as a part of the discharge process.

**Source:** SL 1992, ch 270, § 3.

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**[36-11-69](#). Release of patient information--Good faith required.**

Patient information may be released only in the following circumstances:

- (1) If it is authorized by the patient;
- (2) If it is requested by the board as part of an inspection or investigation of a pharmacy or pharmacist;
- (3) If, in the pharmacist's professional judgment, release to practitioners and other pharmacists is necessary to protect the patient's health and well-being; and
- (4) If other persons are authorized or required by law to obtain access to patient information.

A pharmacist or pharmacy is immune from civil liability for any action based on good faith release of patient information under this section.

**Source:** SL 1992, ch 270, § 4.

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**[36-11-70](#). Refusal to dispense medication.**

No pharmacist may be required to dispense medication if there is reason to believe that the medication would be used to:

- (1) Cause an abortion; or
- (2) Destroy an unborn child as defined in subdivision 22-1-2(50A); or
- (3) Cause the death of any person by means of an assisted suicide, euthanasia, or mercy killing.

No such refusal to dispense medication pursuant to this section may be the basis for any claim for damages against the pharmacist or the pharmacy of the pharmacist or the basis for any disciplinary, recriminatory, or discriminatory action against the pharmacist.

**Source:** SL 1998, ch 226, § 1.

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**[36-11-71](#). Central pharmacy, remote pharmacy, and telepharmacy practice defined.**

Terms as used in this section and § [36-11-72](#) mean:

- (1) "Central pharmacy," a pharmacy with one or more remote pharmacies in which all sites are connected via computer link, video link, and audio link. The central pharmacy may be retail or hospital-based;
- (2) "Remote pharmacy," a pharmacy staffed by a registered pharmacy technician with access to a central pharmacy with a registered pharmacist by computer link, video link, and audio link while open;
- (3) "Telepharmacy practice," the practice whereby a licensed pharmacist uses telecommunications technology to provide personalized, electronically documented, real-time pharmaceutical care

to patients at a remote pharmacy, including prescription dispensing and counseling, and to oversee and supervise remote pharmacy operations.

**Source:** SL 2007, ch 214, § 1.

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**36-11-72. Telepharmacy--Promulgation of rules.**

The board shall promulgate rules pursuant to chapter [1-26](#) to provide for the regulation of telepharmacy in the state. The rules shall include:

- (1) License requirements, including establishment of an annual license fee not to exceed two hundred fifty dollars;
- (2) Minimum structural, security, and equipment requirements for the remote pharmacy;
- (3) Minimum staffing requirements for the central pharmacy and remote pharmacy;
- (4) Record keeping requirements for the central pharmacy and remote pharmacy;
- (5) Establishment of policies and procedures for the daily operation of the remote pharmacy; and
- (6) Use of automated dispensing machines.

**Source:** SL 2007, ch 214, § 2.

## ARTICLE [20:51](#)

### PHARMACISTS

Chapter	
<a href="#">20:51:01</a>	Registration by examination.
<a href="#">20:51:02</a>	Internship requirements.
<a href="#">20:51:03</a>	Interns in clinical projects, Repealed.
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<a href="#">20:51:05</a>	Restricted professional practices.
<a href="#">20:51:06</a>	Pharmacy practice and registration.
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<a href="#">20:51:11</a>	Patent and proprietary medicines, Repealed.
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<a href="#">20:51:13</a>	Special restrictions.
<a href="#">20:51:14</a>	General administration.
<a href="#">20:51:15</a>	Pharmacies in hospitals, nursing facilities, or related facilities.
<a href="#">20:51:16</a>	Rules of professional conduct.
<a href="#">20:51:17</a>	Automated mechanical distribution devices.
<a href="#">20:51:18</a>	Posting of prescription drug prices, Repealed.
<a href="#">20:51:19</a>	Continuing education.
<a href="#">20:51:20</a>	Computer pharmacy.
<a href="#">20:51:21</a>	Unit dose systems.
<a href="#">20:51:22</a>	Support personnel.
<a href="#">20:51:23</a>	Transfer of prescription information.
<a href="#">20:51:24</a>	Patient record system.
<a href="#">20:51:25</a>	Patient counseling.
<a href="#">20:51:26</a>	Sterile products for home care patients, Repealed.
<a href="#">20:51:27</a>	Nonresident pharmacy registration.
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<a href="#">20:51:30</a>	Telepharmacy.
<a href="#">20:51:31</a>	Sterile compounding practices.
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<a href="#">20:51:34</a>	Contested case hearing procedures.
<a href="#">20:51:35</a>	Donated prescription drug and medical supply redispensing program

### CHAPTER 20:51:01

#### REGISTRATION BY EXAMINATION

Section	
20:51:01:01	Application for registration.
20:51:01:02	Experience required.
20:51:01:03	Application requirements.
20:51:01:04	Examination.
20:51:01:05	Repealed.

20:51:01:06	Repealed.
20:51:01:07	Repealed.
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.

**20:51:01:01. Application for registration.** An applicant for registration as a pharmacist by examination shall apply on forms provided by the board and provide all requested information on or with the application.

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

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

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

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

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

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

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

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

**Cross-References:**

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

Required hours, § 20:51:02:13.

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

- (1) The certificate of registration fee of \$35;
- (2) A photo of the applicant that is at least 2¼ by 3¼ inches in size with the applicant's signature in ink on the back;
- (3) A list of the applicant's practical experience on a form provided by or approved by the board;
- (4) A transcript showing graduation from a college of pharmacy approved by the American Council on Pharmaceutical Education; and
- (5) A government-issued form of photo identification.

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

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

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

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

**20:51:01:04. Examination.** An applicant for registration by examination shall successfully complete the North American Pharmacist Licensure Examination (NAPLEX) and the Multistate Jurisprudence Examination (MPJE), South Dakota edition. A total scaled score of not less than 75 is required to pass each examination.

**Source:** SL 1975, ch 16, § 1; 10 SDR 117, effective May 8, 1984; 12 SDR 178, effective May 11, 1986; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**20:51:01:10. Application requirements for graduates from colleges of pharmacy located outside the United States.** Any applicant who is a graduate of a school or college of pharmacy located outside of the United States must submit the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification

awarded by the National Association of Boards of Pharmacy (NABP). The FPGEC certification includes the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English (TSE), or the Internet-based TOEFL iBT as a prerequisite to taking the licensure examinations.

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

**Source:** 9 SDR 171, effective July 12, 1983; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 18 SDR 95, effective November 25, 1991; 22 SDR 133, effective April 25, 1996; 36 SDR 21, effective August 17, 2009.

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

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

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

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

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

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

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

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

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

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

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

## CHAPTER 20:51:02

### INTERNSHIP REQUIREMENTS

#### Section

20:51:02:01	Definitions.
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.
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:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**20:51:02:05. Renewal of certificate.** Each pharmacy intern shall apply for renewal of his or her certificate before October 1 each year. A pharmacy intern who desires to continue in the practice of pharmacy in South Dakota shall file with the board an application in such form and containing such facts as the board may require for renewal of the certificate. The board shall issue a certificate to the applicant if the board finds that the applicant has continued his or her pharmacy education in accordance with the rules of the board and is entitled to continue in the practice of pharmacy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**20:51:02:11. Supervising pharmacist requirements.** A registered pharmacist who agrees to supervise the practical experience of a registered pharmacy intern must certify this on a form provided by the board and agree to abide by the South Dakota pharmacy law and the rules of the South Dakota Board of Pharmacy. A pharmacist must be in continuous contact with and actually giving instructions to the intern during all professional activities of the entire internship. Interns may receive written or verbal prescriptions if the pharmacist reviews and makes the necessary professional determinations about the medication order, including the name of the drug, its strength and dosage, directions for use, and the number of allowable refills.

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

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

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

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

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

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

**Source:** 31 SDR 35, effective September 19, 2004; 36 SDR 21, effective August 17, 2009; 47 SDR 42, effective October 12, 2020.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**20:51:02:14. Credit given for military and research activities.** The Board of Pharmacy may allow up to 400 hours of intern credit for suitable military and research activities in the field of pharmacy as part of the experience requirement.

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

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

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

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

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

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

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

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

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

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

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

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

- (1) Revoke a registration;
- (2) Suspend a registration until further order of the board or for a specified period; or
- (3) Prohibit permanently, until further order of the board, or for a specified period, the engaging in specified procedures, methods, or acts.

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

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

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

## **CHAPTER 20:51:03**

### **INTERNS IN CLINICAL PROJECTS** (Repealed. 22 SDR 133, effective April 25, 1996)

## **CHAPTER 20:51:04**

### **REGISTRATION BY RECIPROCITY**

#### Section

20:51:04:01	Application.
20:51:04:02	Qualifications for reciprocity.
20:51:04:03	Reciprocity requirements.
20:51:04:04	Application requirements.
20:51:04:05	Appearance before board.
20:51:04:06	Repealed.
20:51:04:07	Repealed.
20:51:04:08	Certificates of reciprocity identified by letter R.
20:51:04:09	Repealed.

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

**Source:** SL 1975, ch 16, § 1; 6 SDR 103, effective May 5, 1980; 12 SDR 86, effective November 27, 1985; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 36 SDR 21, effective August 17, 2009.

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

**Law Implemented:** SDCL 36-11-19.

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

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

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

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

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

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

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

**Law Implemented:** SDCL 36-11-19.

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

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

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

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

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

**Law Implemented:** SDCL 36-11-19.

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

(1) The application fee of \$150;

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

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

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

**Law Implemented:** SDCL 36-11-19.

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

**Source:** SL 1975, ch 16, § 1; 10 SDR 117, effective May 8, 1984; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 36 SDR 21, effective August 17, 2009.

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

**Law Implemented:** SDCL 36-11-19.

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

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

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

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

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

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

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

**Law Implemented:** SDCL 36-11-19.

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

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

## CHAPTER 20:51:05

### RESTRICTED PROFESSIONAL PRACTICES

#### Section

20:51:05:00	Definitions.
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.
20:51:05:15	Controlled drug to be dispensed only by 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 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.
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) which is controlled under the provisions of SDCL chapter 34-20B and is listed in SDCL 34-20B-11 to 34-20B-26, inclusive.

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**20:51:05:15. Controlled drug to be dispensed only by prescription.** No pharmacist may dispense a controlled drug unless the controlled drug is dispensed pursuant to the prescription of a practitioner licensed

to prescribe controlled drugs. A pharmacist shall exercise sound professional judgment with respect to the legitimacy of prescription orders. Any facsimile transmission of a Schedule II controlled drug prescription must comply with the requirements of § 44:58:08:18.03. A prescription must be dated and signed on the date issued. The prescription must bear the name and address of the patient and the name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner. Where an oral prescription for a schedule II controlled drug is not permitted, a prescription order must be written in ink or typewritten and manually dated and signed by the practitioner or issued and signed electronically where permissible by law.

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

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

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

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

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

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

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

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

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

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

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

**20:51:05:18. Partial filling of prescription for Schedule II controlled drug.** A pharmacist may partially fill a prescription for a Schedule II controlled drug according to the procedure set out in §§ 44:58:08:18 and 44:58:08:18.01.

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

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

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

**20:51:05:19. Prescription required to dispense Schedule III or IV controlled drug -- Refill restricted.** No pharmacist may dispense a Schedule III or IV controlled drug without a written, oral, or electronic prescription. A prescription by the prescriber may be delivered to a pharmacist by handwritten order, facsimile, or electronic equipment where permissible by law. The pharmacist may refill the prescription, if so authorized on the prescription, up to five times within six months after the date of issue. The partial dispensing of refills may not exceed the total amount authorized on the prescription. Each refill shall be entered on the back of the prescription or captured electronically and shall indicate the quantity dispensed, date refilled, and the initials or name of the dispensing pharmacist. After six months or the dispensing of all authorized refills, whichever comes first, a new controlled drug prescription is required either orally, in writing, or electronically where permissible by law from the prescriber. Any prescription

renewed by the prescriber shall be considered a new and separate prescription, assigned a new serial number, and subject to the restrictions in this section.

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

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

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

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

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

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

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

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

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

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

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

**20:51:05:21. Labeling of prescription container for controlled or noncontrolled legend drug.** A pharmacist filling a prescription for a controlled or noncontrolled legend drug shall attach to the container a label showing the date, the name, address, and telephone number of the pharmacy, the serial number of the prescription, the name of the prescriber, the name of the patient, and the directions for use, precautions, if any, the name, strength, and quantity of the drug, and the initials of the dispensing pharmacist. The prescription label for controlled drugs must comply with the label requirements of § 44:58:08:20, including the transfer auxiliary label warning.

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

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

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

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

**20:51:05:22. Distribution of drugs to other practitioners.** A registered pharmacy is authorized to distribute up to five percent of its controlled drugs and legend drugs to a practitioner registered to prescribe, dispense, or distribute such drugs in the course of professional practice or to other registered pharmacies to meet temporary inventory shortages.

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

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

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

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

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

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

(3) The dialysate or dialysis devices are delivered only upon receipt of a prescription order issued by a licensed practitioner and only if an order from a licensed pharmacy is transmitted to the manufacturer or the manufacturer's agent.

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

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

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

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

## CHAPTER 20:51:06

### PHARMACY PRACTICE AND REGISTRATION

#### Section

20:51:06:01	Application for pharmacy permit.
20:51:06:02	Ownership or control by pharmacist required.
20:51:06:02.01	Pharmacist-in-charge -- Defined, duties.
20:51:06:03	Renewal required each year.
20:51:06:04	False application grounds for suspending or revoking.
20:51:06:05	Must be registered in order to advertise pharmacy name.
20:51:06:06	Transfer of pharmacy registration.
20:51:06:07	Changes in ownership or location must be reported to secretary.
20:51:06:08	Valid permit must be displayed.
20:51:06:09	Permit expires 120 days after death of pharmacist.

20:51:06:10 Provisions for pharmacist temporary absence from pharmacy.  
20:51:06:11 Pharmacy requirements for nonpharmacist owners.  
20:51:06:12 Pharmacy requirements for pharmacist owners.  
20:51:06:13 Repealed.

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

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

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

**Law Implemented:** SDCL 36-11-32.

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

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

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

**Law Implemented:** SDCL 36-11-32.

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

The pharmacist-in-charge shall:

- (1) Be employed or contracted for pharmacy services at the pharmacy so licensed;
- (2) Establish policy and procedure for the pharmacy;
- (3) Supervise all pharmacy employees; and
- (4) Establish recordkeeping systems for the purchase, safekeeping, storage, compounding, sale, and return of drugs.

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

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

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

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

**20:51:06:03. Renewal required each year.** Application for the renewal of a permit to conduct a pharmacy shall be filed with the secretary of the Board of Pharmacy before July 1 each year. The fee set by the Board of Pharmacy shall accompany the application. Applications for opening and conducting a new pharmacy in South Dakota shall be filed with the secretary of the Board of Pharmacy at least 30 days before

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

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

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

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

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

**Law Implemented:** SDCL 36-11-32.

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

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

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

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

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

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

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

**Law Implemented:** SDCL 36-11-31.

**20:51:06:06. Transfer of pharmacy registration.** Each permit to conduct a pharmacy may be transferred to another pharmacist registered under the laws of this state, without payment of an additional fee; provided, an application for the transfer is made and the same is filed with the secretary of the Board of Pharmacy no less than ten days before the transfer of such active management is made. Any application for transfer made at a later date than ten days before the transfer of such active management is made shall be accomplished by the fee as set by the Board of Pharmacy for permit to conduct a pharmacy and such application for transfer shall be approved by the members of the Board of Pharmacy before permit to conduct a pharmacy is issued by the secretary of the Board of Pharmacy on such application.

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

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

**Law Implemented:** SDCL 36-11-37.

**20:51:06:07. Changes in ownership or location must be reported to secretary.** Any change in the location of a pharmacy, or any change in the ownership of the merchandise and fixtures of a pharmacy, or the cessation of business as a pharmacy, shall be reported to the secretary of the Board of Pharmacy within ten days of such occurrence. The pharmacist permittee shall be held responsible for reporting such changes to the Board of Pharmacy.

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

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

**Law Implemented:** SDCL 36-11-39.

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

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

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

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

**20:51:06:09. Permit expires 120 days after death of pharmacist.** Except in the event of the death of the pharmacist permittee, a permit to conduct a pharmacy is void when the holder of the permit ceases to be in active management of the pharmacy. When a pharmacist permittee dies, the pharmacy for which the pharmacist held a permit to conduct may not be kept open for the transaction of business without a pharmacist on duty and in charge. A permit to conduct a pharmacy in the name of a pharmacist who is deceased shall within 120 days after the death of the permittee become void, unless transfer of the permit has been made within the 120-day period to a pharmacist owner or to an employee pharmacist manager for whom an affidavit has been filed by a nonpharmacist owner or owners of the merchandise and fixtures of the pharmacy.

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

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

**Law Implemented:** SDCL 36-11-38.

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

- (1) A space or unrestricted floor area where general merchandise is sold, or offered for sale; and
- (2) A restricted drug area where only packaged drugs, medicines and poisons are displayed and offered for sale; and
- (3) A prescription department, and where facilities not less than eight feet high are maintained within such pharmacy for closing and isolating such restricted drug area and prescription department from the unrestricted floor area where general merchandise is sold.

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

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

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

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

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

- (1) A space or unrestricted floor area where general merchandise is sold or offered for sale;
- (2) A restricted floor area where only packaged drugs, medicines, and poisons are displayed and offered for sale; and
- (3) A prescription department,

the pharmacist permittee shall require the nonpharmacist employer to maintain on the premises a prescription department and restricted floor area that is surrounded by a continuous partition or wall not less than 3/8 inch in thickness extending from the floor to the permanent ceiling, containing doors capable of being securely locked for closing and isolating the prescription department and restricting the drug area from any unrestricted floor area where general merchandise is sold or offered for sale. The pharmacist permittee may not leave the pharmacy department in charge of the nonpharmacist employer until the pharmacist permittee has first closed and locked all entrances to the prescription department.

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

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

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

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

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

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

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

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

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

## CHAPTER 20:51:07

### MINIMUM EQUIPMENT REQUIREMENTS

#### Section

20:51:07:01 Pharmacy must comply with all public health regulations.

20:51:07:02 Repealed.

20:51:07:03 Minimum equipment requirements.

20:51:07:04 Publication and reference library.



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

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

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

**Law Implemented:** SDCL 36-11-42.

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

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

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

- (1) A balance with a delicacy of not less than 1/10 grain;
- (2) Prescription equipment of the kind and quality that will enable the pharmacist to meet all prescription requirements;
- (3) A poison register;
- (4) A supply of labels, including poison labels;
- (5) Permanent file for all prescriptions;
- (6) Locked space for narcotics and dangerous drugs;
- (7) A supply of standard grade chemicals and pharmaceuticals adequate to meet the needs in the location; and
- (8) Refrigerated storage space for biologicals and drugs affected by extreme temperatures.

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

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

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

**20:51:07:04. Publication and reference library.** Each pharmacy shall maintain the latest copy of South Dakota pharmacy laws and rules and the telephone number of the nearest poison control center. Pharmaceutical reference publications may be printed or computer-accessed. At least one general pharmaceutical information reference must be a printed copy. Additional reference material shall be maintained and shall include, at a minimum, one current reference from three of the following categories, including access to period updates:

- (1) Patient information references such as:
  - (a) *USP-DI*, Volume II (Advice for the Patient) by MicroMedex;
  - (b) *Professional Guide to Patient Drug Facts* by Facts and Comparisons;
- (2) References on drug interactions such as:
  - (a) *Hansten and Horn's Drug Interaction*;
  - (b) *Drug Interactions Facts* by Facts & Comparisons;
  - (c) *Trissel's Handbook on Injectable Drugs*, ASHP;
  - (d) *Trissel's TM 2 Clinical Pharmaceutics Database*;
- (3) General information reference such as:

- (a) *Facts and Comparisons*;
  - (b) *USP-DI*, Volume I;
  - (c) *Gold Standard*;
  - (d) *American Hospital Formulary Service*;
  - (e) *Lexi-Comp's Drug Information Handbook*;
- (4) A drug equivalency reference such as:
- (a) *Approved Drug Products with Therapeutic Equivalence Evaluations* (orange book);
  - (b) *USP Dispensing Information*, Volume III;
- (5) A reference on natural or herbal medicines such as:
- (a) *Natural Medicines - Comprehensive Database*;
  - (b) *The Review of Natural Products*.

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

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

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

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

## CHAPTER 20:51:08

### SELF-SERVICE RESTRICTIONS

Section

20:51:08:01	Repealed.
20:51:08:02	Repealed.
20:51:08:03	Repealed.
20:51:08:04	Repealed.
20:51:08:05	Repealed.
20:51:08:06	Repealed.
20:51:08:07	Repealed.
20:51:08:08	Repealed.
20:51:08:09	Repealed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## CHAPTER 20:51:09

### NONPRESCRIPTION DRUGS

#### Section

20:51:09:01	Repealed.
20:51:09:02	Repealed.
20:51:09:03	Repealed.
20:51:09:04	Repealed.
20:51:09:05	Repealed.
20:51:09:06	Repealed.
20:51:09:07	Repealed.
20:51:09:08	Repealed.
20:51:09:09	Repealed

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## **CHAPTER 20:51:10**

### **POISONS**

#### Section

20:51:10:01	Repealed.
20:51:10:02	Repealed.
20:51:10:03	Repealed.
20:51:10:04	Repealed.
20:51:10:05	Repealed.
20:51:10:06	Repealed.
20:51:10:07	Repealed.
20:51:10:08	Repealed.

20:51:10:09 Repealed.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**CHAPTER 20:51:11**

**PATENT AND PROPRIETARY MEDICINES**  
(Repealed. 12 SDR 86, effective November 27, 1985)

**CHAPTER 20:51:12**

**WHOLESALE DRUGS AND MEDICINES**  
(Repealed. 12 SDR 86, effective November 27, 1985)

**CHAPTER 20:51:13**

## SPECIAL RESTRICTIONS

### Section

20:51:13:01	Repealed.
20:51:13:02	Return of unused drugs.
20:51:13:02.01	Return of unused unit dose drugs by patients in hospice programs, nursing facilities, or assisted living facilities.
20:51:13:02.02	Repealed.
20:51:13:02.03	Redispensing unit dose drugs returned from hospice programs, nursing facilities, or assisted living facilities.
20:51:13:02.04	Repackaging drugs from prescription container.
20:51:13:03	Free choice of pharmacies.
20:51:13:04	Splitting fees or rebates prohibited.

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

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

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

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

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

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

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

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

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

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

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

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

(a) Name and strength of the medication;

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

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

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

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

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

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

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

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

(9) The drugs are not controlled drugs.

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

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

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

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

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

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

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

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

(1) Drugs may not be removed and repackaged from the returned unit dose package prior to redispensing;

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

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

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

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

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

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

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

- (1) Date received;
- (2) Name of drug;
- (3) Strength;
- (4) Quantity;
- (5) Expiration date;
- (6) Lot number;
- (7) Manufacturer; and
- (8) National Drug Code (NDC).

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

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

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

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

"NOTICE TO THE PUBLIC

FREE CHOICE OF PHARMACIES

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

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

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

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

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

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

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

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



## CHAPTER 20:51:14

### GENERAL ADMINISTRATION

#### Section

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

**20:51:14:01. Annual certificate renewal.** The fee for annual certificate renewal is \$125. Certificates expire on September 30 following issuance and must be renewed annually by October 1.

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

**General Authority:** SDCL 36-11-23.

**Law Implemented:** SDCL 36-11-23.

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

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

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

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

**20:51:14:04. Equivalent drug products.** An equivalent drug product is a drug product that is considered to be pharmaceutically equivalent to a drug product that contains the same active ingredient(s) as determined by the Food and Drug Administration in **Approved Drug Products with Therapeutic Equivalence Evaluations**, 19<sup>th</sup> 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).

**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**, 19<sup>th</sup> Edition, U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, 1999. Copies may be obtained from Superintendent of Documents, U.S. Government Printing Office, PO Box 371954, Pittsburgh, PA 15250-7954; cost \$78.

## CHAPTER 20:51:15

### PHARMACIES IN HOSPITALS, NURSING FACILITIES, OR RELATED FACILITIES

Section	
20:51:15:01	Definition and general provisions.
20:51:15:02	Pharmaceutical services supervised by pharmacist.
20:51:15:03	Central area to be licensed as a pharmacy.
20:51:15:04	Dispensing limited to pharmacist.
20:51:15:05	Transferring drugs from original containers limited to pharmacists.
20:51:15:06	Removing a single dose from prescription container.
20:51:15:07	Preparing a solution.
20:51:15:08	Medication floor stocks.
20:51:15:09	Filling or refilling of nursing station containers limited to pharmacists.
20:51:15:10	Registration and renewal.
20:51:15:11	Schedule of attendance by pharmacist.
20:51:15:12	Supervision of drugs located in areas other than pharmacy.
20:51:15:13	Access to pharmacy -- Records.
20:51:15:14	Pharmacy must be in a separate room.
20:51:15:15	Pharmacist controls emergency drugs in health care facilities.
20:51:15:15.01	Pharmacist controls emergency kit in nursing facility.
20:51:15:16	Minimum standards for pharmacy service.
20:51:15:17	Repealed.

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

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

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

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

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

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

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

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

(5) "Dispensing," includes, but is not limited to, issuing to a patient, or to a person acting on a patient's behalf one or more unit doses of medication in a suitable container with appropriate labeling. Dispensing affects one or many patients. Dispensing, while including compounding, also includes the act of packaging a

drug or medication either from a bulk container, or as a result of compounding, in a container other than the original and labeling the new container with all required information;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**20:51:15:07. Preparing a solution.** The preparation of a solution by a licensed nurse for injection by a licensed nurse is considered a step in administration of medication.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**20:51:15:15.01. Pharmacist controls emergency kit in nursing facility.** A registered pharmacist may provide to a nursing facility a limited quantity of controlled legend drugs pursuant to § 44:04:08:07.01 and a limited amount of noncontrolled legend drugs and nonprescription drugs, for emergency and supportive

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

The provider pharmacist shall comply with the following requirements:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## CHAPTER 20:51:16

### RULES OF PROFESSIONAL CONDUCT

#### Section

20:51:16:01	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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**General Authority:** SDCL 36-11-43.

**Law Implemented:** SDCL 36-11-43.

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

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

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

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

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

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

**General Authority:** SDCL 36-11-43.

**Law Implemented:** SDCL 36-11-43.

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

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

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

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

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

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

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



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

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

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

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

**General Authority:** SDCL 36-11-43.

**Law Implemented:** SDCL 36-11-43.

## CHAPTER 20:51:17

### AUTOMATED MECHANICAL DISTRIBUTION DEVICES

#### Section

- 20:51:17:01 Definitions.
- 20:51:17:01.01 Approval for use of automated mechanical distribution device.
- 20:51:17:01.02 Pharmacist shall review first-dose prescription drug order -- Exception.
- 20:51:17:02 Procedure for distributing drugs in automated mechanical distribution device.

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

(1) "Automated mechanical distribution device," a mechanical device that delivers a drug or drug device other than by administration or dispensing and uses automated data processing technology to do the following:

- (a) Limit access of stocked drugs or drug devices to only authorized personnel;
- (b) Record identity of all personnel who have access to drugs or drug devices stocked within the device; and
- (c) Document both stocking and removal transactions;

(2) "Health care facility," any state licensed hospital, nursing facility, or related facility that offers supervised care of the sick or injured;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (a) The name of the person stocking the drug or medicine;
- (b) The name, quantity, and strength of the drug or medicine; and
- (c) The date of stocking;

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

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

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

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

- (a) The patient's name and the location within the hospital;
- (b) The name of the person withdrawing the drug or medicine;
- (c) The name, quantity, and strength of the drug or medicine; and
- (d) The date of issue;

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

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

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

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

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

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

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

**Reference:** Pages 10, 11, 12, 13, 1786, and 1787, **The United States Pharmacopeia, Twenty-third Revision - The National Formulary, Eighteenth Edition**, January 1, 1995, published by the United States Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852. Photocopies of pages 10, 11, 12, 13, 1786, and 1787 may be obtained without charge from the State Board of Pharmacy, 4305 S. Louise Avenue, Suite 104, Sioux Falls, SD 57106.

## CHAPTER 20:51:18

### POSTING OF PRESCRIPTION DRUG PRICES

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

## CHAPTER 20:51:19

### CONTINUING EDUCATION

#### Section

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

20:51:19:06	Continuing education from other states.
20:51:19:07	Newly licensed registrants.
20:51:19:08	Different ways of obtaining accredited continuing education hours.
20:51:19:09	Sponsors defined.
20:51:19:10	Program approval.
20:51:19:11	Forms required for continuing education sponsors.
20:51:19:12	Program changes.
20:51:19:13	Frequency of participation.
20:51:19:14	Attendance by board or council members.
20:51:19:15	Sponsors' records.
20:51:19:16	Sponsor to provide list of pharmacists attending program.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**General Authority:** SDCL 36-11-23.2.

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

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

**Source:** 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.  
**General Authority:** SDCL 36-11-10, 36-11-11.  
**Law Implemented:** SDCL 36-11-23.2.

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

**Source:** 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986; 16 SDR 98, effective December 3, 1989.  
**General Authority:** SDCL 36-11-10, 36-11-11.  
**Law Implemented:** SDCL 36-11-23.2.

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

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

**20:51:19:06. Continuing education from other states.** The Board of Pharmacy may accept comparable continuing education hours approved by other state boards of pharmacy and the South Dakota Board of Pharmacy.

**Source:** 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.  
**General Authority:** SDCL 36-11-10, 36-11-11.  
**Law Implemented:** SDCL 36-11-23.2.

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

**Source:** 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.  
**General Authority:** SDCL 36-11-10, 36-11-11.  
**Law Implemented:** SDCL 36-11-23.2.

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

- (1) Cassette and audio visual presentation;
- (2) In-company professional seminars;
- (3) Accredited school of pharmacy continuing education programs;
- (4) Post graduate courses in pharmaceutical sciences;
- (5) Correspondence courses;
- (6) Programs granted continuing education credit by other states;
- (7) Continuing education television series;
- (8) Programs sponsored by professional groups in public health provider services;
- (9) Professional society and association sponsored programs;
- (10) Study groups.

**Source:** 4 SDR 54, effective February 26, 1978; 12 SDR 151, 12 SDR 155, effective July 1, 1986.  
**General Authority:** SDCL 36-11-10, 36-11-11.  
**Law Implemented:** SDCL 36-11-23.2.

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

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

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

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

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

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

Each program evaluated must be supported by backup material, such as a brochure, a critique of material covered, a script, or a cassette or book for a correspondence course.

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

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

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

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

- (1) Name of sponsor and address;
- (2) Name of person in charge;
- (3) Location of program;
- (4) Estimated number of pharmacists participating;
- (5) General title of program;
- (6) Type program: Cassette, seminar, post graduate course, correspondence course, CETV program, programs sponsored by public health providers, professional society and association programs, programs granted continuing education credit by other states who reciprocate continuing education hours with South Dakota;
- (7) How program objectives will be met;
- (8) Estimated contact time;
- (9) How attendance or participation will be proven;
- (10) How certificates will be awarded;
- (11) Copy of examination, if utilized.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**General Authority:** SDCL 36-11-23.2.

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

## CHAPTER 20:51:20

### COMPUTER PHARMACY

#### Section

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

**20:51:20:01. Input of drug information into electronic data processing to be by pharmacist or under supervision of pharmacist.** When electronic data processing equipment is employed by any pharmacy, input of drug information shall be performed only by a pharmacist or under the immediate and personal supervision of a pharmacist. The pharmacist must certify the accuracy of the information to be entered and verify the prescription order at the time of entry. The identity of the pharmacist must be carried in the record.

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

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

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

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

- (1) Guarantee the confidentiality of the information contained in the data bank;
- (2) Be capable of producing a hard-copy daily summary of controlled substance transactions;
- (3) Provide on-line retrieval of original prescription order information for those prescription orders which are currently authorized for refilling;
- (4) Be capable of recording and carrying in the record all dates of refills of any prescription and the initials of the pharmacist. This shall meet the requirements of § 20:51:05:06;
- (5) Be capable of producing a patient profile indicating all drugs being taken and the date of refills of these prescriptions; and
- (6) Be capable of being reconstructed in the event of a computer malfunction or accident resulting in destruction of the data bank.

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

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

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

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

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

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

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

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

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

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

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

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

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

## CHAPTER 20:51:21

### UNIT DOSE SYSTEMS



Section	
20:51:21:01	Definitions.
20:51:21:01.01	Prepackaging and repackaging.
20:51:21:02	Transferred.
20:51:21:03	Pharmacist to interpret original order of practitioner.
20:51:21:04	Repealed.
20:51:21:05	Labeling of unit dose package -- Relabeling of unit dose system.
20:51:21:05.01	Recall of unit dose package.
20:51:21:05.02	Manufacturer packaging.
20:51:21:06	Pharmacist to maintain drug profile.
20:51:21:07	Pharmacist to be responsible for delivery of medications to healthcare facility.

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

- (1) "Automated mechanical distribution device," see § 20:51:17:01 for definition and use;
- (2) "Container," that which holds the drug and is or may be in direct contact with the drug without interacting chemically or physically affecting the drug placed in it so as to alter the strength, quality, or purity of the drug beyond the official compendium requirements;
- (3) "Customized patient medication package," a package that contains two or more drugs per compartment;
- (4) "Prepackage," to prepare a drug in a container for dispensing, prior to the receipt of an order. Such packaging may be in a unit dose, single dose, or unit of issue package for use in a unit dose dispensing system, in a container suitable for a traditional dispensing system, or in a customized patient medication package;
- (5) "Repackage," to prepare a unit dose, single dose, unit of issue package, customized patient medication package, or traditional dispensing system package for dispensing pursuant to an existing order;
- (6) "Sealed unit dose container," a container that holds the drug in a hermetically sealed compartment to reduce the drug's exposure to moisture, air, and tampering until the time of administration;
- (7) "Traditional dispensing system," a drug package system in which individual doses are not packaged in unit dose packages or unit of issue packages;
- (8) "Unit dose," a single dose of a drug in an individually sealed, labeled container ready for administration to a particular patient by the prescribed route at the prescribed time;
- (9) "Unit dose distribution system," a drug distribution system that is in a pharmacy outlet, hospital, or other healthcare facility and uses unit dose packages, or unit of issue packages, labeled in accordance with § 20:51:21:05 and preserves the identity of the drug until the time of administration;
- (10) "Unit dose package," an individual package that contains one single unit dose of a drug packaged by a manufacturer or a pharmacy and preserves the integrity and identity of the drug from the point of packaging to the point of administration; and
- (11) "Unit of issue package," a package that provides multiple units of the same drug doses, each separated in a medication card or other specifically designed container.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**20:51:21:05. Labeling of unit dose package -- Relabeling of unit dose system.** Unit dose packages shall be labeled with the name of the drug and its strength. Labeling of the package with the drug lot number or expiration date is optional.

After any change in dosage or administration schedule, the pharmacy shall relabel the unit dose system no later than the next medication exchange.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

## CHAPTER 20:51:22

### SUPPORT PERSONNEL

#### Section

20:51:22:00	Repealed.
20:51:22:01	Repealed.
20:51:22:02	Repealed.
20:51:22:03	Repealed.
20:51:22:04	Repealed.
20:51:22:05	Support personnel.

**20:51:22:00. Definitions.** Repealed.

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

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

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

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

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

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

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

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

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

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

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

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

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

## CHAPTER 20:51:23

### TRANSFER OF PRESCRIPTION INFORMATION

#### Section

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

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

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

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

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

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

**20:51:23:02. Requirements of transferring pharmacist.** The pharmacist transferring the prescription information shall:

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

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

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

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

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

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

**20:51:23:03. Requirements of receiving pharmacist.** The pharmacist receiving the transferred prescription information shall:

- (1) Write the word "transfer" on the face of the transferred prescription; and
- (2) Record on the transferred prescription the following information:

- (a) The original date of issuance and the date of dispensing, if different from date of issuance;
  - (b) The original prescription number and the number of refills authorized on the original prescription;
  - (c) The number of valid refills remaining and the date of the last refill;
  - (d) The name and address of the pharmacy from which the prescription information is transferred;
- and
- (e) The name of the pharmacist transferring the prescription information.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (a) The name and address of the hospital pharmacy;
- (b) The hospital prescription number;
- (c) The quantity dispensed;
- (d) The date of dispensing; and
- (e) The name of the pharmacist dispensing the medication.

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

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

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

## CHAPTER 20:51:24

### PATIENT RECORD SYSTEM

#### Section

20:51:24:01	Transitory patient defined.
20:51:24:02	Patient record system.
20:51:24:03	Reasonable effort to obtain information.
20:51:24:04	Maintenance of records.

**20:51:24:01. Transitory patient defined.** A transitory patient is a patient that the pharmacist determines will have prescription drug orders filled at the pharmacy on a one-time basis or no more than once each year. If a pharmacist determines from information provided by a patient or caregiver that the patient is a transitory patient, the pharmacist may forego the requirement to record and maintain information.

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

**General Authority:** SDCL 36-11-68.

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

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

- (1) The full name of the patient for whom the drug or drug device is intended;
- (2) The address and telephone number of the patient;
- (3) The patient's age or date of birth;
- (4) The patient's gender;
- (5) A list of all prescription drugs or drug devices obtained by the patient at the pharmacy maintaining the patient record during the one-year period immediately preceding the most recent entry, showing the prescription number, name and strength of the drug or drug device, the quantity and date received, and the name of the practitioner;
- (6) Any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient;
- (7) The identity of any other drugs, including over-the-counter drugs, or drug devices currently being used by the patient which may relate to prospective drug review; and
- (8) Comments of the pharmacist relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

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

**General Authority:** SDCL 36-11-68.

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

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

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

**General Authority:** SDCL 36-11-68.

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

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

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

**General Authority:** SDCL 36-11-68.

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

## CHAPTER 20:51:25

### PATIENT COUNSELING

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

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

- (1) "Adverse medical result," a clinically significant undesirable effect experienced by a patient as a result of a course of drug therapy;
- (2) "Caregiver," a person who provides care for a friend, family member, or patient.

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

**General Authority:** SDCL 36-11-68.

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

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

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

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

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

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

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

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

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

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

(9) Clinical abuse or misuse.

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



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

**General Authority:** SDCL 36-11-68.

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

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

- (1) The name and description of the drug;
- (2) The dosage form, dose, route of administration, and duration of drug therapy;
- (3) The intended use of the drug and its expected action;
- (4) Special directions and precautions for preparation, administration, and use by the patient;
- (5) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
- (6) Techniques for self-monitoring drug therapy;
- (7) Storage requirements;
- (8) Prescription refill information;
- (9) Action to be taken if a dose is missed; and
- (10) The pharmacist's comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

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

**General Authority:** SDCL 36-11-68.

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

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

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

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

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

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

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

**General Authority:** SDCL 36-11-68.

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

**20:51:25:05. Alternative forms of patient information.** Alternative forms of patient information include written information leaflets, pictogram labels, video programs, or information generated by electronic

data processing equipment. When used to replace oral counseling, alternative forms of patient information shall advise the patient or caregiver that the pharmacist may be contacted for consultation in person at the pharmacy, by toll-free telephone, or by collect telephone call. Alternative forms of patient information may also be used to supplement patient counseling.

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

**General Authority:** SDCL 36-11-68.

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

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

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

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

**General Authority:** SDCL 36-11-68.

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

#### CHAPTER 20:51:26

#### STERILE PRODUCTS FOR HOME CARE PATIENTS

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

#### CHAPTER 20:51:27

#### NONRESIDENT PHARMACY REGISTRATION

##### Section

20:51:27:01	Definitions.
20:51:27:02	Application form.
20:51:27:03	Application fee.
20:51:27:04	Report of change in ownership or location.

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

- (1) "Home state," the state in which the dispensing facilities of a nonresident pharmacy are located.

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

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

**Law Implemented:** SDCL 36-11-19.3.

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

- (1) Evidence of licensure in good standing in the nonresident pharmacy's home state;
- (2) A description of any disciplinary action against the nonresident pharmacy in the home state or any other state within the last three years and the resolution of any such action; and

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

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

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

**Law Implemented:** SDCL 36-11-19.3.

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

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

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

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

**20:51:27:04. Report of change in ownership or location.** The pharmacist in charge of a nonresident pharmacy shall report any changes in the location of the nonresident pharmacy, any change in the ownership of the merchandise and fixtures of a nonresident pharmacy, or the cessation of business as a nonresident pharmacy to the secretary of the Board of Pharmacy within ten days after the occurrence. The license of a nonresident pharmacy is not transferable to a new ownership. Any new ownership of a nonresident pharmacy must apply for licensure pursuant to § 20:51:27:02.

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

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

**Law Implemented:** 36-11-19.3.

## CHAPTER 20:51:28

### ADMINISTRATION OF INFLUENZA IMMUNIZATIONS

#### Section

20:51:28:01	Authority to administer influenza immunizations.
20:51:28:01.01	Authority to administer immunizations.
20:51:28:02	Qualifications for authorization to administer immunizations.
20:51:28:02.01	Qualifications for interns to administer immunizations.
20:51:28:03	Repealed.
20:51:28:04	Training program requirements.
20:51:28:05	Record keeping and reporting requirements.
20:51:28:06	Confidentiality of records maintained.
20:51:28:07	Renewal of authorization to administer immunizations.

**20:51:28:01. Authority to administer influenza immunizations.** A pharmacist may administer influenza immunizations to eligible patients 18 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.

**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. Qualifications for authorization to administer immunizations.** The board may authorize a pharmacist who:

- (1) Is licensed to practice pharmacy in this state;
- (2) Has completed an approved training program; and
- (3) Is certified in cardiopulmonary resuscitation.

**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.

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

- (1) Is registered as a pharmacy intern in this state;
- (2) Has successfully completed an approved training program;
- (3) Is certified in cardiopulmonary resuscitation; and
- (4) Is directly supervised by a pharmacist who has a current authorization to administer immunizations in this state.

**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.

**20:51:28:03. Standards for approval of influenza immunization training programs.** Repealed.

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

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

- (1) Basic immunology and the human immune response;
- (2) Mechanics of immunity, adverse effects, dose, and administration schedule of available vaccines;
- (3) Response to an emergency situation as a result of the administration of an immunization;
- (4) Administration of injections; and
- (5) Record keeping and reporting requirements as set forth in § 20:51:28:05.

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

**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.

**20:51:28:05. Record keeping and reporting requirements.** A pharmacist authorized under this chapter to administer immunizations shall maintain in the pharmacy, administered for a minimum of five years:

- (1) The name, address, and date of birth of each patient who received an immunization;

- (2) The date of administration and site of the injection;
- (3) The name, dose, manufacturer's lot number, and expiration date of the vaccine;
- (4) The name and address of the patient's primary health care provider, as identified by the patient;
- (5) The name of the person administering the immunization;
- (6) A record of any consultation or other professional information provided to the patient; and
- (7) The name and date of the Vaccine Information Sheet provided to the patient.

The pharmacy must report all administrations of immunizations to the South Dakota Immunization Information System within 14 days of the immunization. The required records as set forth in this section are open to inspection by the board and must be made available upon the board's request.

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

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

**Source:** 29 SDR 37, effective September 26, 2002; 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, 36-11-69.

**20:51:28:07. Renewal of authorization to administer immunizations.** The authorization to administer immunizations must be renewed on or before September 30. A pharmacist desiring to renew the authorization shall attest to the following:

- (1) The pharmacist is certified in cardiopulmonary resuscitation; and
- (2) The pharmacist has completed one hour of continuing education related to immunizations.

The board may audit for compliance with the renewal requirements of this section.

**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.

## CHAPTER 20:51:29

### REGISTERED PHARMACY TECHNICIANS

Section	
20:51:29:00	Definitions.
20:51:29:01	Purpose of registration.
20:51:29:02	Registration required.
20:51:29:03	Original application.
20:51:29:04	College or vocational based training program.
20:51:29:05	Exemptions from registration.
20:51:29:06	Certification of pharmacy technicians.
20:51:29:07	Registration application form.
20:51:29:08	Declaration of current impairment or limitations.
20:51:29:09	Felony or misdemeanor crimes.
20:51:29:10	Sworn signature.
20:51:29:11	Registration renewal.
20:51:29:12	Registration fee.

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

**20:51:29:00. Definitions.**

- (1) "Board" or "board of pharmacy," as defined in SDCL 36-11-2(2);
- (2) "Pharmacist," as defined in SDCL 36-11-2(18);
- (3) "Pharmacist intern," as defined in § 20:51:02:01;
- (4) "Registered pharmacy technician," as defined in SDCL 36-11-2(22A);
- (5) "Pharmacy technician-in-training," an individual who is registered with the board to receive on-the-job training in a licensed pharmacy for preparation for registration as a pharmacy technician.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**20:51:29:06. Certification of pharmacy technicians.** The national certification of pharmacy technicians is required. Effective July 1, 2014, the board shall not renew the registration of a pharmacy technician who was initially registered after July 1, 2011, unless the pharmacy technician is nationally certified and has passed a board-approved pharmacy technician certification examination that is accredited by the National Commission for Certifying Agencies (NCCA).

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

**Source:** 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:07. Registration application form.** The application form for registration as a pharmacy technician shall include the following:

- (1) Information sufficient to identify the applicant including name, address, phone number, date of birth, gender, and social security number;
- (2) Work experience; and
- (3) Current and past places of employment.

**Source:** 31 SDR 35, effective September 19, 2004.  
**General Authority:** SDCL 36-11-11(1), 36-11-11(14).  
**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:08. Declaration of current impairment or limitations.** The applicant shall declare any current use of drugs, alcohol, or other chemical substances that in any way impairs or limits the applicant's ability to perform the duties of a pharmacy technician with reasonable skill and safety.

**Source:** 31 SDR 35, effective September 19, 2004.  
**General Authority:** SDCL 36-11-11(1), 36-11-11(14).  
**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:09. Felony or misdemeanor crimes.** The applicant shall declare any history of being charged, convicted, found guilty of or entering a plea of guilty or no contest to a felony or misdemeanor crime other than minor traffic violations with fines under \$100.

**Source:** 31 SDR 35, effective September 19, 2004.  
**General Authority:** SDCL 36-11-11(1), 36-11-11(14).  
**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:10. Sworn signature.** The applicant shall sign the application under penalty of perjury and shall submit it to the board.

**Source:** 31 SDR 35, effective September 19, 2004.  
**General Authority:** SDCL 36-11-11(1), 36-11-11(14).  
**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:11. Registration renewal.** The registration of a pharmacy technician expires on October 31 each year following initial registration.

Effective July 1, 2014, the board shall not renew the registration of a pharmacy technician who was initially registered after July 1, 2011, or who was initially registered prior to that date but did not maintain continuous registration, unless the individual provides the board with evidence of completion of one of the following:

(1) A pharmacy technician training program offered by a board-approved, accredited vocational/technical institution or college;

(2) A pharmacy technician training program accredited by a board-approved, national organization that accredits pharmacy technician training programs;

(3) A pharmacy technician training program provided by a branch of the United States armed forces or Public Health Service; or

(4) An employer-based pharmacy technician training program that includes a minimum total of 480 hours in a one-year period to include both theoretical and practical instruction. An employer utilizing such a program must develop and regularly update a technician training manual that must be available for board inspection upon request. The employer must also supply a pharmacy technician who completes the training program with evidence of completion. The employer-based pharmacy technician training program must include written guidelines, policies, and procedures that define the specific tasks the technician will be expected to perform.

**Source:** 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012.



**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:12. Registration fee.** The fee for initial registration is \$25. The renewal fee for the registration is \$25. Fees shall be paid at the time the new application or the renewal application is submitted. Fee payment shall be in the form of a personal check, certified or cashier check, or money order payable to the Board of Pharmacy.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:13. Timeliness of initial application or renewal application.** An application for initial or renewal application may be denied if not received within the applicable period specified in § 20:51:29:03 for new applicants or by the expiration date of the renewal registration. Any registration not renewed before its expiration date is delinquent. An individual who continues employment as a pharmacy technician without a current registration may be subject to disciplinary sanctions as provided in § 20:51:29:27.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:14. Registration certification.** The pharmacy technician shall maintain the original certificate of registration as a pharmacy technician issued by the board. The pharmacist-in-charge (§ 20:51:06:02.01) of each pharmacy utilizing a pharmacy technician is responsible for verifying that any technician working in the pharmacy is registered and compliant with all rules of this chapter. Any violation by the technician may be grounds for disciplinary action against the pharmacist-in-charge.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:15. Notification to the board.** Within ten days of any change of the technician's name, address, or pharmacy employment status, a pharmacy technician shall report that change to the board.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:16. Training and utilization of pharmacy technicians.** Notwithstanding the fact that a pharmacy technician has completed a training program as specified in § 20:51:29:11, it is the responsibility of the pharmacist-in-charge of a pharmacy to ensure that a technician receives adequate training in the tasks performed by pharmacy technicians working at that pharmacy. Any pharmacy utilizing a pharmacy technician shall develop, implement, and periodically review written policies and procedures for training and utilizing pharmacy technicians appropriate to the practice of pharmacy at that pharmacy. Each pharmacy shall specify in its policies the frequency of review. Each pharmacy shall document and maintain each technician's training for the duration of employment. The pharmacy shall make its policies and procedures and documentation of technician training available for inspection by the board.

**Source:** 31 SDR 35, effective September 19, 2004; 38 SDR 121, effective January 17, 2012.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:17. Identification of pharmacy technicians.** A pharmacy technician shall wear a visible identification badge while on duty that clearly identifies the person as a pharmacy technician and includes the technician's first name.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:18. Misrepresentation prohibited.** A pharmacy technician may not represent himself or herself in any manner as a pharmacist.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:19. Ratio.** The ratio of pharmacy technicians to pharmacists that may be on duty in a pharmacy at a given time is three technicians for every pharmacist. A pharmacy intern does not count in this ratio (§ 20:51:02:11.01).

**Source:** 31 SDR 35, effective September 19, 2004; 42 SDR 19, effective August 19, 2015.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:19.01. Exception to ratio for mail service pharmacy.** Repealed.

**Source:** 33 SDR 73, effective November 6, 2006; 36 SDR 21, effective August 17, 2009; repealed, 42 SDR 19, effective August 19, 2015.

**20:51:29:19.02. Exception to ratio for hospital, mail order, and long-term care pharmacy.** The maximum ratio of pharmacy technicians to pharmacists that may be on duty in a hospital, mail order, and long-term care pharmacy will be determined by the pharmacist in charge. However, all of the following requirements must be met:

- (1) Medication is dispensed pursuant to a legal prescription;
- (2) The technology includes tablet or product imaging and or bar code scanning, or both, to insure accuracy in the prescription filling process;
- (3) A role-based access software automation system that places stop points within the prescription filling process is used, which requires a pharmacist's intervention before allowing the prescription to move to the next step in the prescription dispensing process;
- (4) Pharmacy software that screens and detects drug allergies, identifies drug interactions, and checks age appropriate dosage ranges is used;
- (5) A pharmacist reviews clinically significant computer warnings of drug interactions, therapy duplications, and contraindications;
- (6) Electronic surveillance technology is used to control access or to provide continuous monitoring of all areas where drugs are stored or dispensed or both;
- (7) All non-pharmacist personnel who input patient drug information into a computer or whose duties include receiving, packaging, shipping of drugs, or who have access to any areas where drugs are dispensed are registered as pharmacy technicians and meet the requirements in chapter 20:51:29;

(8) In hospital and long-term care pharmacies, nursing personnel in facilities served by the pharmacy have telephone access to a pharmacist 24 hours a day, 7 days a week. In mail order pharmacies, a patient has access to a pharmacist 24 hours a day, 7 days a week on a dedicated pharmacist staff line;

(9) Drug information, both electronic and hard copy, is readily available to pharmacists;

(10) A quality assurance program that identifies and evaluates dispensing errors, accompanied by a continuous quality improvement program that assures very high dispensing accuracy rates in place;

(11) There are written policies and procedures for all pharmacy functions -- clerical, supportive, technical, and clinical;

(12) There are written policies and procedures for training personnel, including on-going training programs for all personnel and documentation of that training for each employee;

(13) There is a strict monitoring program designed to prevent diversion of controlled substances. This includes perpetual inventory of all schedule II controlled drugs as well as selected high-risk schedule III, IV, and V drugs. Routine audits are conducted to review purchases versus dispensing of controlled drugs to deter and detect diversion.

**Source:** 36 SDR 21, effective August 17, 2009; 42 SDR 19, effective August 19, 2015.

**General Authority:** SDCL 36-11-11(1)(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:20. Delegation and supervision of technical functions.** A pharmacist may delegate technical dispensing functions to a pharmacy technician, but only if the pharmacist is on site supervising the delegated functions performed. The pharmacist shall provide and document the final verification for the accuracy, validity, completeness, and appropriateness of the patient's prescription or medication order prior to the delivery of the medication to the patient or the patient's representative.

The physical presence requirement of the pharmacist does not apply when utilizing an automated dispensing device approved by the board. After proper checking and verification with the physician orders by the pharmacist, the technician may replace medications to the automated dispensing device that have been checked by the pharmacist. The pharmacist is not required to accompany the technician when placing medications into the automated dispensing device. The automated dispensing device must be capable of printing out a record of medications filled by the technician. The record shall be checked and verified by the pharmacist daily.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:21. Technical functions.** At the discretion of the supervising pharmacist, technical functions which may be delegated to a pharmacy technician include the following:

(1) Performing packaging, manipulative, or repetitive tasks relating to the processing of a prescription or medication order in a licensed pharmacy;

(2) Accepting prescription refill authorization communicated to a pharmacy by a prescriber, or by the prescriber's agent;

(3) Contacting prescribers to obtain prescription refill authorization;

(4) Collecting pertinent patient information;

(5) Inspecting drug supplies provided and controlled by a South Dakota licensed pharmacy, including drug supplies maintained in an automated mechanical dispensing device, emergency medical room, ambulance vehicle, long-term care facility, a hospital nursing unit, or a hospice facility;

(6) Assisting the pharmacist with the preparation of medications for administration to the patient topically, by injection, or other approved methods.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:22. Tasks a pharmacy technician may not perform.** A pharmacy technician may not:

(1) Provide the final verification for the accuracy, validity, completeness, or appropriateness of a filled prescription or medication order;

(2) Conduct prospective drug use review or evaluate a patient's medication record for purposes identified in § 20:51:25:02;

(3) Provide final verification of automated dispensing medication fill records for accuracy and completeness;

(4) Make decisions that require a pharmacist's professional judgment such as interpreting new orders, applying information, or making product selection for drugs that are substitutable;

(5) Accept new oral prescription medication orders communicated to the pharmacy by a prescriber or the prescriber's agent; or

(6) Open, keep open, or provide pharmaceutical services from a pharmacy without a pharmacist being present as provided in §§ 20:51:06:11, 20:51:15:02, and 20:51:15:04.

A violation of this section constitutes illegal conduct or practice and may be grounds for disciplinary action as provided in § 20:51:29:27.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:23. Misrepresentative deeds.** A pharmacy technician may not make any statement tending to deceive, misrepresent, or mislead anyone, or be a party to or an accessory to any fraudulent or deceitful practice or transaction in a pharmacy or in the operation or conduct of a pharmacy.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:24. Confidentiality.** In the absence of express written consent from the patient or written order or direction of a court, except where the best interests of the patient require, a pharmacy technician may not divulge or reveal to any person other than the patient or the patient's authorized representative, the prescriber, or other licensed practitioner then caring for the patient, a licensed pharmacist or a person duly authorized by law to receive such information, any of the following:

- (1) The contents of any prescription drug order or medication or the therapeutic effect thereof or the nature of professional pharmaceutical services rendered to a patient;
- (2) The nature, extent, or degree of illness suffered by any patient; or
- (3) Any medical information furnished by the prescriber.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:25. Illegal/unethical behavior.** A pharmacy technician may not exhibit illegal/unethical behavior in connection with the technician's pharmacy employment. Illegal/unethical behavior includes the following acts: verbal or physical abuse, coercion, intimidation, harassment, sexual advances, threats, degradation of character, profanity, indecent or obscene conduct, and theft. A violation of this section may be grounds for disciplinary action as provided in § 20:51:29:27.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:26. Denial of registration.** The board may deny an application for registration as a pharmacy technician for any violation of the laws of this state, another state, or the United States relating to prescription drugs, controlled substances, or nonprescription drugs (or for any violation of this chapter).

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

**20:51:29:27. Sanctions.** The board may impose the following disciplinary sanctions for violations of this chapter:

- (1) Revoke a pharmacy technician registration;
- (2) Suspend a pharmacy technician registration until further order of the board or for a specified period;
- (3) Not renew of a pharmacy technician registration;
- (4) Prohibit permanently, until further order of the board, or for a specified period, the engaging in specified procedures, methods, or acts;
- (5) Impose a probationary period;
- (6) Order a physical or mental examination;
- (7) Issue a citation and warning.

**Source:** 31 SDR 35, effective September 19, 2004.

**General Authority:** SDCL 36-11-11(1), 36-11-11(14).

**Law Implemented:** SDCL 36-11-11(14).

## CHAPTER 20:51:30

### TELEPHARMACY

#### Section

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20:51:30:18	Use of automated mechanical dispensing device.

**20:51:30:01. Definitions.** Terms used in this chapter mean:

- (1) "Automated mechanical distribution device," as defined in § 20:51:17:01;
- (2) "Central pharmacy," as defined in SDCL 36-11-71(1);
- (3) "Remote pharmacy," as defined in SDCL 36-11-71(2);
- (4) "Telepharmacy practice," as defined in SDCL 36-11-71(3).

**Source:** 35 SDR 183, effective February 2, 2009.

**General Authority:** SDCL 36-11-11(1).

**Law Implemented:** SDCL 36-11-11(1),(4),(5), 36-11-71.

**20:51:30:02. Application for remote pharmacy site.** No remote pharmacy may be established, operated, or maintained unless the board issues a license. An application for licensure to establish, operate, or maintain a remote pharmacy shall be made on a form provided by the board. The applicant shall submit an initial license fee of \$200 and provide a set of blueprints and documentation showing that all requirements of this chapter have been met. The applicant shall demonstrate to the board that there is limited or no access to pharmacy services in the community. When considering whether to approve an application, the board shall consider the needs of the community. The board shall approve or disapprove an application within 60 days of receipt.

**Source:** 35 SDR 183, effective February 2, 2009.

**General Authority:** SDCL 36-11-11(1), 36-11-72(1).

**Law Implemented:** SDCL 36-11-72(1).

**20:51:30:03. Ownership or control by pharmacist required.** The board may not issue a permit to conduct a remote pharmacy to any pharmacist applicant unless such pharmacist applicant is an owner, or part owner, of the place of business from which the pharmacist will practice telepharmacy, or unless the non-pharmacist owner of the place of business from which the pharmacist will practice telepharmacy files an affidavit on a form prescribed by the board delegating full and complete authority to the pharmacist applicant to be in active management of the place of business for the license year ending June 30.

**Source:** 35 SDR 183, effective February 2, 2009.

**General Authority:** SDCL 36-11-11(1), 36-11-72(1).

**Law Implemented:** SDCL 36-11-34, 36-11-72.

**20:51:30:04. Board inspection.** No remote pharmacy may provide pharmacy services until the board has inspected the remote pharmacy for minimum equipment, size, security, and sanitation standards as set forth in § 20:51:07:01 and found the remote pharmacy to be in compliance with such standards.

**Source:** 35 SDR 183, effective February 2, 2009.  
**General Authority:** SDCL 36-11-11(1), 36-11-72(1).  
**Law Implemented:** SDCL 36-11-71, 36-11-72.

**20:51:30:05. License renewal.** A remote pharmacy license expires on June 30 of each year and may be renewed annually by filing an application provided by the board. The renewal fee is \$200.

**Source:** 35 SDR 183, effective February 2, 2009.  
**General Authority:** SDCL 36-11-72(1).  
**Law Implemented:** SDCL 36-11-72(1).

**20:51:30:06. License required.** Any pharmacy licensed by the board may operate a remote pharmacy in South Dakota. The remote pharmacy is considered an extension of the central pharmacy. However, the remote pharmacy must have its own license as a pharmacy.

**Source:** 35 SDR 183, effective February 2, 2009.  
**General Authority:** SDCL 36-11-72(1).  
**Law Implemented:** SDCL 36-11-72(1).

**20:51:30:07. Audiovisual link.** There must be a continuously accessible, two-way audiovisual link between the central pharmacy and the remote pharmacy. The transmission of information through the computer link must make information available to the central pharmacy and the remote pharmacy simultaneously. The video camera used for the certification of prescriptions must be of sufficient quality and resolution so that the certifying pharmacist can visually identify the markings on tablets and capsules. A second camera is required to meet security needs if the camera used to certify prescriptions is not able to monitor activities in other parts of the remote site.

**Source:** 35 SDR 183, effective February 2, 2009.  
**General Authority:** SDCL 36-11-11(1), 36-11-72(2).  
**Law Implemented:** SDCL 36-11-72(2).

**20:51:30:08. Remote pharmacy identification sign.** Each remote site shall display a sign easily viewable by customers stating "This business is a remote pharmacy, supervised by a pharmacist located at (*insert name of pharmacy and address*)".

**Source:** 35 SDR 183, effective February 2, 2009.  
**General Authority:** SDCL 36-11-11(1), 36-11-72(2),(5).  
**Law Implemented:** SDCL 36-11-72(2),(5).

**20:51:30:09. Restricted area posted.** The remote pharmacy dispensing area shall be posted as a restricted area. Only pharmacy technicians or pharmacy interns employed directly and involved in processing prescriptions are permitted in the dispensing area. There must be restricted access to the restricted area. The security system at the remote pharmacy must allow for tracking of each entry into the pharmacy. The pharmacist-in-charge shall review the log of entries at least weekly.

**Source:** 35 SDR 183, effective February 2, 2009.  
**General Authority:** SDCL 36-11-11(1), 36-11-72(2),(5).  
**Law Implemented:** SDCL 36-11-72(2),(5).

**20:51:30:10. Toll-free telephone number.** The remote pharmacy shall provide a toll-free telephone number that patients and prescribers may use to contact the central pharmacy. The telephone number shall be printed on the label of each prescription container.

**Source:** 35 SDR 183, effective February 2, 2009.  
**General Authority:** SDCL 36-11-11(1), 36-11-72(2),(5).  
**Law Implemented:** SDCL 36-11-72(2),(5).

**20:51:30:11. Pharmacist staffing requirements.** Any pharmacist performing services in support of a remote pharmacy, whether those services are performed at the central pharmacy or the remote pharmacy, must be licensed by the board. A copy of the pharmacist's license must be posted in any remote pharmacy to which the pharmacist provides services.

**Source:** 35 SDR 183, effective February 2, 2009.  
**General Authority:** SDCL 36-11-11(1), 36-11-13, 36-11-72(3).  
**Law Implemented:** SDCL 36-11-72(3).

**20:51:30:12. Technician and intern staffing requirements.** Each remote pharmacy must be staffed with South Dakota registered pharmacy technicians or interns. A pharmacy technician working at a remote pharmacy shall have a minimum of 2000 hours of experience as a registered pharmacy technician in accordance with chapter 20:51:29 and shall be certified through one of the certification programs recognized by the board. An intern working at a remote pharmacy shall have a minimum of 500 hours of experience as a registered pharmacy intern in accordance with chapter 20:51:02.

**Source:** 35 SDR 183, effective February 2, 2009.  
**General Authority:** SDCL 36-11-11(1), 36-11-72(3).  
**Law Implemented:** SDCL 36-11-72(3).

**20:51:30:13. Pharmacist-to-technician ratio.** The pharmacist on duty at a central pharmacy may supervise no more than the number of technicians allowed in accordance with § 20:51:29:19. The total number of allowed technicians may be divided between the central pharmacy and the remote pharmacy in any manner. However, each remote pharmacy must have at least one pharmacy technician or pharmacy intern on duty when it is open.

**Source:** 35 SDR 183, effective February 2, 2009.  
**General Authority:** SDCL 36-11-11(1), 36-11-72(3).  
**Law Implemented:** SDCL 36-11-72(3).

**20:51:30:14. Prescription workload.** Any central pharmacy providing telepharmacy services shall provide pharmacist staffing to meet the prescription workload of both the central pharmacy and the remote pharmacy.

**Source:** 35 SDR 183, effective February 2, 2009.  
**General Authority:** SDCL 36-11-11(1), 36-11-72(3).  
**Law Implemented:** SDCL 36-11-72(3).

**20:51:30:15. Requirements for prescription orders.** Only a registered pharmacist may take a verbal prescription order. A pharmacy technician at the remote pharmacy may not accept verbal orders for new prescriptions, but may accept written orders. A written order for a new prescription may be entered at the central pharmacy or the remote pharmacy. The pharmacist must approve or override all drug utilization review alerts.

**Source:** 35 SDR 183, effective February 2, 2009.  
**General Authority:** SDCL 36-11-11(1), 36-11-72(5).  
**Law Implemented:** SDCL 36-11-72(5).

**20:51:30:16. Requirements for operation.** The following requirements must be adhered to when operating a remote pharmacy:



(1) The remote pharmacy may only be open if a computer link, video link, and audio link with the central pharmacy are functioning properly. If any link is not functioning properly, the remote pharmacy must be closed unless a pharmacist is working at the remote pharmacy;

(2) No remote pharmacy may be open when the central pharmacy is closed, unless a licensed pharmacist is working at the remote pharmacy;

(3) Any prescription filled at the remote pharmacy must be profiled, reviewed, and interpreted by a pharmacist at the central pharmacy before the prescription is dispensed;

(4) Any remotely dispensed prescriptions must have a label properly prepared in accordance with § 20:51:05:21 attached to the final drug container before the pharmacist certifies the dispensing process. This prescription certification process must be done in real time. All prescription certification must be documented in the computer record. The computer must be capable of carrying the initials of the technician preparing the prescription and the pharmacist verifying the prescription. Verification is required for both new prescriptions and refills;

(5) When the patient receives a prescription, the pharmacist must use audiovisual communication to counsel the patient regarding use of the prescription being dispensed. Counseling is required only for new prescriptions. The pharmacist must meet the counseling standards in accordance with § 20:51:25:04;

(6) The remote pharmacy must maintain a log, signed by the patient, that documents a patient's refusal for counseling by the pharmacist.

**Source:** 35 SDR 183, effective February 2, 2009.

**General Authority:** SDCL 36-11-11(1), 36-11-72(2),(3),(4),(5).

**Law Implemented:** SDCL 36-11-72(2),(3),(4),(5).

**20:51:30:17. Routine quality assurance required.** The pharmacist-in-charge must adhere to the following procedures:

(1) An inspection of the remote pharmacy shall be conducted by a licensed pharmacist at weekly intervals or more if deemed necessary. Inspection must be documented and kept on file at the remote pharmacy and available upon request by the board;

(2) Implement and conduct a quality assurance plan that provides for on-going review of dispensing errors, with appropriate action taken, if necessary, to assure patient safety;

(3) Verify controlled substance prescriptions for both accuracy and legitimacy of the original prescription by the pharmacist-in-charge or a designated pharmacist during weekly inspection visits;

(4) Maintain records of all controlled substances stocked by the remote pharmacy through a daily perpetual inventory. Controlled substance perpetual inventory records must be available for inspection by the board's inspectors. A remote pharmacy stocking controlled drugs must be registered by the Drug Enforcement Administration and South Dakota Department of Health;

(5) Conduct an inventory of all controlled substances at least monthly to verify accuracy.

**Source:** 35 SDR 183, effective February 2, 2009.

**General Authority:** SDCL 36-11-11(1), 36-11-72(4),(5).

**Law Implemented:** SDCL 36-11-72(4),(5).

**20:51:30:18. Use of automated mechanical dispensing device.** If the remote pharmacy uses an automated mechanical dispensing device, the stocking and loading of this device must either be checked by a pharmacist, prior to use, or employ a secure bar coding system or its equivalent. Policies and procedures consistent with § 20:51:17:02 regarding the operation of the automated mechanical distribution system must be developed and submitted to the board for consideration. After approval, these policies and procedures must be available at both the central pharmacy and the remote pharmacy.

**Source:** 35 SDR 183, effective February 2, 2009.

**General Authority:** SDCL 36-11-11(1),(6), 36-11-72(6).

**Law Implemented:** SDCL 36-11-11(6), 36-11-72(6).

## CHAPTER 20:51:31

### STERILE COMPOUNDING PRACTICES

#### Section

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20:51:31:02	Standards and procedures.
20:51:31:03	Manual required.
20:51:31:04	Physical environment requirements for sterile products.
20:51:31:05	Requirement for primary engineering control device or room.
20:51:31:06	Placement of primary engineering control device.
20:51:31:07	Compounding aseptic isolator (CAI).
20:51:31:08	Exception for placement of CAI.
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20:51:31:11	Cleaning, maintenance, and supplies.
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20:51:31:19	Low-risk preparations.
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20:51:31:22	Immediate-use preparations.
20:51:31:23	Utilization of single-dose and multiple-dose containers.
20:51:31:24	Utilization of proprietary bag and vial systems.
20:51:31:25	Sterilization methods.
20:51:31:26	Media-fill testing by personnel.
20:51:31:27	Environmental monitoring requirements.
20:51:31:28	Storage and delivery of sterile preparations.
20:51:31:29	Additional requirements for preparation of hazardous drugs.
20:51:31:30	Responsibilities for patient care.
20:51:31:31	Patient or caregiver education and training.

**20:51:31:01. Definitions.** Terms used in this chapter mean:

(1) "Ante area," an ISO Class 8 or superior area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, preparation labeling, and other high-particulate generating activities;

(2) "Aseptic preparation," the technique involving procedures designed to preclude contamination by microorganisms during processing;

(3) "Batch preparation," compounding or repackaging of multiple units, in a single process, by the same operator;

(4) "Beyond-use date," the date or time following compounding after which the preparation may not be stored, transported, or used. The beyond-use date is determined from the date or time compounding of the preparation is completed;

(5) "Biological safety cabinet, Class II" or "BSC," a ventilated cabinet having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection;

(6) "Buffer area," a clean room or area where the primary engineering control device is physically located and in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class;

(7) "Compounding," the constitution, reconstitution, combination, dilution, or another process causing a change in the form, composition, or strength of any ingredient or any other attribute of a product;

(8) "Compounding aseptic isolator" or "CAI," a form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations;

(9) "Critical site," a location that includes any component or fluid pathway surfaces (such as injection ports) or openings (such as opened ampoules or needle hubs) exposed and at risk of direct contact with air, moisture, or touch contamination;

(10) "Hazardous drug," a pharmaceutical that is antineoplastic, carcinogenic, mutagenic, or teratogenic;

(11) "HEPA filter," a high efficiency particulate air filter where air is forced through in a uniform flow and 99.97 percent of all particles three-tenths (0.3) microns or larger are removed;

(12) "High-risk preparation," a sterile preparation that is compounded from nonsterile ingredients; that is compounded with nonsterile components, containers, or equipment and requires terminal sterilization; or that meets the conditions of § 20:51:31:21;

(13) "ISO (International Organization for Standardization) Classification of Particulate Matter in Room Air," limits in particles of 0.5 microns or larger in diameter per cubic foot of air:

(a) ISO Class 5, less than 100 particles per cubic foot;

(b) ISO Class 7, less than 10,000 per cubic foot; and

(c) ISO Class 8, less than 100,000 per cubic foot;

(14) "Laminar airflow workbench," or "LAFW," an apparatus designed to provide an ISO Class 5 environment for the preparation of sterile products that uses air circulation in a defined direction that passes through a HEPA filter to remove the initial particles and the particles generated within the controlled environment;

(15) "Low-risk preparation," a sterile preparation that is compounded with sterile equipment, sterile ingredients, and sterile contact surfaces or that meets the conditions of § 20:51:31:19;

(16) "Medium-risk preparation," a sterile preparation that is compounded with sterile equipment, sterile ingredients, and sterile contact surfaces and involves complex or numerous manipulations of a sterile product or that meets the conditions of § 20:51:31:20;

(17) "Media-fill test" or "MFT," a test used to validate aseptic technique of compounding personnel or of processes and to ensure that the processes used are able to produce a sterile product without microbial contamination;

(18) "Multiple-dose container," a multiple-unit container for articles or preparations intended for parenteral administration only usually containing antimicrobial preservatives;

(19) "Negative pressure room," a room that is at a lower pressure compared to adjacent spaces, creating a new airflow into the room;

(20) "Positive pressure room," a room that is at a higher pressure compared to adjacent spaces, creating a net airflow out of the room;

(21) "Preparation" or "compounded sterile preparation," a sterile drug or nutrient that is compounded in a licensed pharmacy or other health care-related facility pursuant to the order of a licensed prescriber, which preparation may or may not contain sterile products;

(22) "Product," a commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA; and

(23) "Sterile compounding," the aseptic processing in a clean air environment of any pharmaceutical including the following preparations that are required to be sterile when they are administered to patients: baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, and suspensions), aqueous bronchial and nasal inhalations, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1),(3),(4), and (5).

**Law Implemented:** SDCL 36-11-11, 36-11-41.

**20:51:31:02. Standards and procedures.** The standards and procedures outlined in this chapter apply to pharmacy practice when a preparation:

(1) Is prepared according to the manufacturer's labeled instructions and requires other manipulations that expose the original contents to potential contamination;

(2) Contains nonsterile ingredients or employs nonsterile components or devices that must be sterilized before administration; or

(3) Is a biologic, diagnostic, drug, or nutrient that possesses characteristics of either subdivision (1) or (2) of this section and includes the following preparations that are required to be sterile when they are administered to patients: baths and soaks for live organs and tissues, injections, aqueous bronchial and nasal inhalations, irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1) and (4).

**Law Implemented:** SDCL 36-11-11.

**20:51:31:03. Manual required.** Each pharmacy shall prepare, implement, maintain, and adhere to a written policy and procedure manual for the compounding, dispensing, administration, storage, and use of sterile preparations. The manual shall be available for inspection by the board. The manual shall address the following:

- (1) Responsibilities of compounding personnel;
- (2) Personnel training and testing;
- (3) Competency practices and assessment of compounding personnel;
- (4) Quality assurance as described in § 20:51:31:12;
- (5) Proper use and deployment of environmental controls;
- (6) Gowning and garbing practices;
- (7) Inspection of finished products, labeling, storage, and transfer to final use areas for storage or use;
- (8) Introduction of supplies and products into the compounding area; and
- (9) The formulation, process for compounding, beyond-use dating, and storage requirements for each routinely compounded sterile preparation.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1) and (4).

**Law Implemented:** SDCL 36-11-11.

**20:51:31:04. Physical environment requirements for sterile products.** The pharmacy shall have a designated area for compounding sterile preparations with entry restricted to designated personnel. The area shall be used only for sterile compounding. The area shall be structurally isolated from other areas and shall be designed to avoid unnecessary traffic and airflow disturbances. The area shall be of sufficient size to accommodate at least one primary engineering control device and to provide for the storage of drugs and supplies under appropriate temperature, light, moisture, sanitation, ventilation, and security conditions.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1), (3), and (4).

**Law Implemented:** SDCL 36-11-11.

**20:51:31:05. Requirement for primary engineering control device or room.** The primary engineering control device or room shall be capable of maintaining at least ISO Class 5 air quality in the area where critical objects are exposed and critical activities are performed. The device shall be capable of maintaining ISO Class 5 air quality during normal activity. A primary engineering control device includes, but is not limited to, a horizontal or vertical laminar airflow workbench or CAI.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1), (4), and (5).

**Law Implemented:** SDCL 36-11-11, 36-11-41.

**20:51:31:06. Placement of primary engineering control device.** The primary engineering control device shall be placed in a room where HEPA filters are employed and the air quality is maintained at ISO Class 7. This area shall have cleanable, non-shedding, smooth surfaces; all junctures shall be covered; and all cracks and crevices shall be caulked. The ceiling shall be impervious and hydrophobic. The room may not contain any drains or sinks. Only the furniture, equipment, supplies, and other material required for compounding activities to be performed shall be brought into the room. Such items brought into the room shall be cleaned and disinfected. Placement in rooms of objects and devices not essential to the compounding process is dictated by the measured effect of those objects and devices on the required environmental quality of air atmospheres and surfaces.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1), (4), and (5).

**Law Implemented:** SDCL 36-11-11, 36-11-41.

**20:51:31:07. Compounding aseptic isolator (CAI).** A CAI is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer process. Air exchange into the isolator from the surrounding environment should not occur unless it has first passed through a microbially retentive filter, HEPA minimum.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1), (4), and (5).

**Law Implemented:** SDCL 36-11-11, 36-11-41.

**20:51:31:08. Exception for placement of CAI.** The CAI shall be placed in an ISO Class 7 room unless the CAI meets each of the following conditions:

(1) The CAI provides isolation from the room and maintains ISO Class 5 conditions when ingredients, components, and devices are transferred into and out of the CAI during the preparation process; and

(2) The manufacturer provides documentation verifying that the CAI meets the standard in subdivision (1) when the CAI is located in an environment inferior to ISO Class 7.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1), (4), and (5).

**Law Implemented:** SDCL 36-11-11, 36-11-41.

**20:51:31:09. Ante area requirements.** An ante area shall be located adjacent to the buffer area and maintained at ISO Class 8 air quality. If the ante area is adjacent to a negative pressure room, then the ante area must maintain ISO Class 7 air quality.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1), (4), and (5).

**Law Implemented:** SDCL 36-11-11, 36-11-41.

**20:51:31:10. Delayed implementation.** A pharmacy whose sterile compounding area is in substantial compliance with the physical and structural requirements of this chapter may engage in the compounding of sterile preparations pursuant to the practice standards established by this chapter. However, any pharmacy engaged in the compounding of sterile preparations shall, no later than December 31, 2011, complete any necessary changes or improvements to the sterile compounding area to ensure compliance with the physical and structural requirements of this chapter.

Any pharmacy that commences operation after December 31, 2010, or any new construction or remodeling of a pharmacy sterile compounding area completed after December 31, 2010, shall comply with the physical and structural requirements of this chapter.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1), (4), and (5)

**Law Implemented:** SDCL 36-11-11, 36-11-41.

**20:51:31:11. Cleaning, maintenance, and supplies.** The pharmacy shall have the following appropriate equipment and supplies and documented procedures for maintaining an environment suitable for the aseptic processing of sterile preparations:

(1) Required supplies and equipment shall include the following:

(a) Appropriate attire, including non-shedding coveralls or gowns, head and facial covers, face masks, appropriate gloves, and shoe covers; and

(b) A sink with hot and cold running water, with soap available for the purpose of hand and forearm scrubs, which shall be located convenient to the area used for compounding sterile preparations but outside the room; and

(2) Documented procedures shall include the following:

(a) Specific cleaning procedures and frequencies for each compounding area involved;

(b) A list of approved cleaning agents for each procedure;

(c) A written plan and schedule for the evaluation of airborne microorganisms in each controlled air environment (e.g., LAFW, barrier isolators, room, and ante area);

(d) Equipment calibration and monitoring of proper function of equipment, apparatus, and devices used to compound sterile preparations, in accordance with § 20:51:31:25; and

(e) An appropriate cleansing and garbing procedure. Coveralls and gowns may be hung outside the entry of the room and reused for one shift, if the coveralls and gowns are not visibly soiled and have not been worn during the compounding of hazardous drugs.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1), (3), and (5)

**Law Implemented:** SDCL 36-11-11, 36-11-41, 36-11-42.

**20:51:31:12. Additional records required.** In addition to records required in § 20:51:24:02, the pharmacy shall maintain records of lot numbers of the components used in compounding sterile products if:

(1) The preparation will be dispensed to a home care patient; or

(2) Non-sterile ingredients are used in preparing high risk sterile products.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1) and (4).

**Law Implemented:** SDCL 36-11-11.

**20:51:31:13. Quality assurance.** The pharmacy shall establish, implement, and document an ongoing quality assurance program in order to maintain and improve facilities, equipment, personnel performance, and the provision of patient care. The two portions of the quality assurance program are as follows:

(1) Monitoring facilities, equipment, and personnel performance, which shall include the following:

(a) Methods for verification of automated compounding devices for parenteral nutrition compounding;

(b) Methods for sampling finished preparations to ensure that the pharmacy is capable of consistently preparing sterile preparations that meet appropriate risk level specifications and to ensure product integrity;

(c) Procedures for inspection of all prescription orders, written compounding procedures, preparation records, and materials used to compound at all contamination risk levels, to ensure accuracy of ingredients, aseptic mixing, sterilizing, packaging, labeling, and expected physical appearance of the finished preparation;

(d) Procedures for visual inspection of preparations to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling;

(e) Procedures for review of all orders and packages of ingredients to ensure that the correct ingredients and quantity of ingredients were compounded;

(f) Methods for routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality;

(g) Methods for ensuring personnel qualifications, training, and performance, including periodic performance of applicable MFT procedures;

(h) Procedures for visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments; and

(i) Methods for establishing beyond-use dates of preparation;

(2) Monitoring patient care, which shall include the following:

(a) Utilizing specific procedures for recording, filing, and evaluating reports of adverse events and the quality of preparation identified in the adverse event;

(b) Utilizing written policies and procedures that include specific procedures or instructions for receiving, acknowledging, and dating the receipt of products;

(c) Reviewing documented patient or caregiver education and training required pursuant to § 20:51:31:31;

(d) Ensuring that a qualified pharmacist is available and accessible at all times to respond to the questions and needs of other health professionals, the patient, or the patient's caregiver; and

(e) Identifying activities and processes that are deemed high-risk, high-volume, or problem-prone and providing effective corrective actions to remedy these activities and processes.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1), 36-11-68.

**Law Implemented:** SDCL 36-11-11.

**20:51:31:14. Pharmacist responsibilities.** Each pharmacy shall have a pharmacist responsible for ensuring that:

(1) Preparations are accurately identified, measured, diluted, and mixed and are correctly sterilized, packaged, sealed, labeled, stored, dispensed, and distributed;

(2) Cleanliness is maintained, including preservation of the sterile environment during the compounding process;

(3) Beyond-use dates are established based on direct testing or extrapolation from reliable literature sources. The pharmacy shall maintain written justification of the chosen beyond-use date or, if a written statement is not available, a maximum 24-hour expiration shall be used;

(4) Equipment, apparatus, and devices used to compound a preparation are consistently capable of operating properly and within acceptable tolerance limits;



(5) Procedures are followed for measuring, mixing, diluting, sterilizing, packaging, and labeling of the specific preparation;

(6) Packaging selection is appropriate to preserve the sterility and strength of the preparation; and

(7) All functions performed by non-pharmacists are verified by the pharmacist before the preparation is dispensed to the patient. Pharmacist verification of a preparation shall include visual inspection of labeling, physical integrity, and expected appearance, including final fill amount.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1), 36-11-41, 36-11-46.6.

**Law Implemented:** SDCL 36-11-11.

**20:51:31:15. Training documentation.** Documentation of training shall verify that compounding personnel are able to adequately complete the following activities:

- (1) Perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces;
- (2) Select and appropriately don protective garb;
- (3) Maintain or achieve sterility of preparations in ISO Class 5 primary engineering control devices;
- (4) Identify, weigh, and measure ingredients;
- (5) Manipulate sterile products aseptically, sterilize high-risk preparations, and label preparations; and
- (6) Protect personnel and compounding environments from contamination by hazardous drugs.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1).

**Law Implemented:** SDCL 36-11-11.

**20:51:31:16. Reference requirements.** The pharmacy shall have current reference materials related to sterile products and preparations. References may be printed or computer-accessed. In addition to meeting the requirements set forth in § 20:51:07:04, any pharmacy involved in sterile compounding shall maintain a minimum of one current reference, including access to current periodic updates, from each of the following categories:

- (1) An injectable drug compatibility reference; and
- (2) If the pharmacy is compounding hazardous drugs, a reference related to hazardous drugs.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1) and (9).

**Law Implemented:** SDCL 36-11-11.

**20:51:31:17. Labeling requirements.** A pharmacist shall label containers as follows:

(1) At the time of delivery, a patient-specific dispensing container used for a preparation shall bear a label with at least the following information:

- (a) Name and quantity of all contents;
- (b) Patient's name;
- (c) For home care patient prescriptions, unique serial number or prescription number;
- (d) Preparer's and reviewing pharmacist's initials or unique identifiers;
- (e) Stability (beyond-use date) as set forth in the pharmacy's policy and procedure manual (unless the contents will be used within 24 hours of preparation);
- (f) The prescribed flow rate in ml/hr, if applicable; and
- (g) Auxiliary labels as needed;

(2) Each container of a batch preparation that is compounded in anticipation of later dispensing shall bear a label with at least the following information:

- (a) Name and quantity of all contents;
- (b) Internal code to identify the date and time of preparation and the preparer's and reviewing pharmacist's initials or unique identifiers;
- (c) Stability (beyond-use date) as set forth in the pharmacy's policy and procedure manual; and
- (d) Auxiliary labels as needed.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1) and (12), 36-11-46.6.

**Law Implemented:** SDCL 36-11-11.

**20:51:31:18. Microbial contamination risk levels.** A pharmacist shall assign each preparation the appropriate risk level--low, medium, or high--according to the corresponding probability of contaminating a preparation with microbial contamination such as microbial organisms, spores, and endotoxins, and chemical and physical contamination such as foreign chemicals and physical matter.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1), (3), and (5).

**Law Implemented:** SDCL 36-11-11.

**20:51:31:19. Low-risk preparations.** Any preparation compounded under all of the following conditions is at a low risk of contamination:

(1) The preparations are compounded with aseptic manipulations entirely within ISO Class 5 or superior air quality using only sterile ingredients, products, components, and devices;

(2) The compounding involves only transferring, measuring, and mixing no more than three commercially manufactured sterile products and entries into one container (e.g., bag, vial) of sterile product to make the preparation;

(3) Manipulations are limited to aseptically opening ampoules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, containers of other sterile products, and containers for storage and dispensing.

If a low risk preparation does not pass a sterility test but is properly stored before administration, the preparation may be stored under the following conditions and time period restrictions:

- (a) At controlled room temperature for 48 hours;
- (b) At a cold temperature for 14 days; or
- (c) In a solid-frozen state at minus 20 degrees Celsius or colder for 45 days.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2(3), 36-11-11(1).

**Law Implemented:** SDCL 36-11-11.

**Examples:** The single-volume transfer of sterile dosage forms from ampoules, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. When ampoules are employed, solution content shall be passed through a sterile filter to remove any particles. The manual measuring and mixing of no more than three manufactured products including an infusion or diluent solution to compound drug admixtures and nutritional solutions.

**20:51:31:20. Medium-risk preparations.** Any preparation compounded aseptically under low-risk conditions with one or more of the following additional conditions is at a medium risk of contamination:

(1) Multiple individual or small doses of sterile products are combined or pooled to prepare a sterile preparation for administration either to multiple patients or to one patient on multiple occasions;

(2) The compounding process includes complex aseptic manipulations other than the single-volume transfer;

(3) The compounding process requires an unusually long duration, such as that required to complete dissolution or homogeneous mixing.

If a medium-risk preparation does not pass a sterility test but is properly stored before administration, the preparation may be stored under the following conditions and time period restrictions:

(a) At controlled room temperature for 30 hours;

(b) At a cold temperature for 9 days; or

(c) In a solid-frozen state at minus 20 degrees Celsius or colder for 45 days.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2(3), 36-11-11(1)

**Law Implemented:** SDCL 36-11-11.

**Examples:** Examples of medium-risk compounding include:

(1) Compounding total parenteral nutrition fluids, using manual or automated devices and involving multiple injections, detachments, or attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container;

(2) Filling reservoirs of injection or infusion devices with more than three sterile drug products and evacuating air from those reservoirs before dispensing the filled device; and

(3) Transferring volumes from multiple ampoules or vials into one or more final sterile containers.

**20:51:31:21. High-risk preparations.** Any preparation that is either contaminated or likely to become contaminated with infectious microorganisms when compounded under any of the following conditions is at a high risk of contamination:

(1) Nonsterile ingredients, including manufactured products not intended for sterile use, are incorporated or a nonsterile device is used in the compounding process before terminal sterilization;

(2) Sterile contents of commercially manufactured products, preparations that lack effective antimicrobial preservatives, and sterile surfaces of devices and containers intended for the preparation, transfer, sterilization, and packaging of preparations are exposed to air quality inferior to ISO Class 5 for more than one hour;

(3) Nonsterile procedures such as weighing and mixing in air quality inferior to ISO Class 7 are performed before sterilization, compounding personnel are not properly garbed and gloved, or water-containing preparations are stored for more than six hours;

(4) The chemical purity and content strength of bulk ingredients, whether the ingredients are in opened or unopened packages, are not verified by examination of labeling and documentation of suppliers or by direct determination.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2(3), 36-11-11(1).

**Law Implemented:** SDCL 36-11-11.

**20:51:31:22. Immediate-use preparations.** For the purpose of emergency or immediate patient care, a pharmacy is exempt from requirements described in this chapter for low- and medium-risk preparations if all of the following criteria are met:

(1) Only simple aseptic measuring and transfer manipulations are performed with not more than three sterile commercial drug products including an infusion or diluent solution;

(2) Unless required for the preparation, the compounding procedure occurs continuously without delays or interruptions and does not exceed one hour;

(3) At no point during preparation are critical surfaces and ingredients of the preparation directly exposed to contact contamination, such as human touch, cosmetic flakes or particulates, blood, human body substances (e.g., nasal and oral excretions and secretions), and nonsterile inanimate sources;

(4) Unless immediately and completely administered by the person who prepared it, or immediate and complete administration is witnessed by the preparer, the compounded sterile preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact beyond-use date and time; and

(5) Administration begins not later than two hours after compounding of the preparation has begun. If administration has not begun within two hours after compounding of the preparation has begun, the preparation is promptly and safely discarded. Immediate-use preparations may not be stored for later use.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2(3), 36-11-11(1).

**Law Implemented:** SDCL 36-11-11.

**20:51:31:23. Utilization of single-dose and multiple-dose containers.** Any pharmacy utilizing single-dose and multiple-dose containers in sterile compounding shall comply with the following requirements:

(1) Single-dose containers that are opened or needle-punctured shall be used within one hour if opened in air quality conditions inferior to ISO Class 5;

(2) Single-dose vials that are continuously exposed to ISO Class 5 air shall be used within six hours after initial needle puncture;

(3) Opened single-dose ampoules may not be stored for any period of time under any air quality conditions;

(4) Multiple-dose containers that are entered or opened shall be used within 28 days of initial entry or opening unless otherwise specified by the manufacturer; and

(5) Multiple-dose and single-dose sterile products may not be combined for use as multiple-dose applications.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1).

**Law Implemented:** SDCL 36-11-11.

**20:51:31:24. Utilization of proprietary bag and vial systems.** A pharmacy shall follow the manufacturer's instructions for sterility, storage, and beyond-use times for attached and activated container pairs of drug products for intravascular administration.

**Source:** 36 SDR 100, effective December 14, 2009.  
**General Authority:** SDCL 36-11-2.2, 36-11-11(1).  
**Law Implemented:** SDCL 36-11-11.

**20:51:31:25. Sterilization methods.** The pharmacist shall select the sterilization method that complies with the standards identified in United States Pharmacopoeia, Chapter 797.

**Source:** 36 SDR 100, effective December 14, 2009.  
**General Authority:** SDCL 36-11-2.2, 36-11-11(1).  
**Law Implemented:** SDCL 36-11-11.

**Reference: The United States Pharmacopoeia, Thirtieth Revision - The National Formulary, Twenty-Fifth Edition,** May 1, 2007, page 337, published by the United States Pharmacopoeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, Maryland 20852. Cost: \$800.

**20:51:31:26. Media-fill testing by personnel.** The pharmacy shall develop, maintain, and implement written procedures that include media-fill testing by personnel authorized to compound preparations. The tests shall be performed without interruption in an ISO Class 5 environment under conditions that closely simulate the stressful conditions encountered during compounding of the specific risk level preparations for which the test is intended. The pharmacy shall maintain records of media-fill testing performed, and results of testing procedures shall be available to the board. Compounding personnel whose media-fill test vials result in gross microbial colonization shall be immediately reinstructed and reevaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

Each person authorized to compound low-risk and medium-risk preparations shall annually perform a successful MFT procedure.

Each person authorized to compound high-risk preparations shall semiannually perform a successful MFT procedure.

**Source:** 36 SDR 100, effective December 14, 2009.  
**General Authority:** SDCL 36-11-2.2, 36-11-11(1).  
**Law Implemented:** SDCL 36-11-11.

**20:51:31:27. Environmental monitoring requirements.** Each pharmacy shall meet the following environmental requirements:

(1) All buffer areas, laminar airflow workbenches, and barrier isolators shall be certified for operational efficiency at least every six months and whenever the device or room is relocated or altered or whenever major service to the facility is performed. Inspection and certification records shall be maintained for two years from the date of certification; and

(2) The pharmacy shall establish written procedures appropriate for the risk level preparations compounded by the pharmacy. The procedures shall include environmental testing, end testing, and evaluation of validation results of the following:

- (a) Microbial sampling of air within the primary engineering control devices, buffer areas, and ante areas is required every six months; and
- (b) Unidirectional air flow shall be maintained and validated.

**Source:** 36 SDR 100, effective December 14, 2009.  
**General Authority:** SDCL 36-11-2.2, 36-11-11(1).  
**Law Implemented:** SDCL 36-11-11.

**Note:** It is recommended that this be done using a pressure gauge or a velocity meter installed between the buffer area and ante area. In absence of a pressure gauge or velocity meter, unidirectional flow and velocity should be tested and documented semi-annually at the time of hood and room certification.

**20:51:31:28. Storage and delivery of sterile preparations.** The pharmacy is responsible for proper packaging, labeling, handling, transport, and storage of preparations compounded and dispensed by the pharmacy and for education, training, and supervision of pharmacy and non-pharmacy personnel responsible for such functions. The pharmacy shall establish, maintain, and implement written policies and procedures to ensure product quality and packaging integrity until the preparation is administered. The policies and procedures shall address:

(1) Storage areas -- Controlled temperature storage areas within the pharmacy shall be monitored at least once daily and the results documented on a temperature log. Temperature-sensing mechanisms shall be suitably placed within the storage space to accurately reflect the area's temperature;

(2) Packaging, handling, and transport, including:

(a) Instruction in proper hand washing, aseptic techniques, site care, and change of administration sets to ensure the quality and sterility of the preparation;

(b) Special requirements for those products and techniques for the pharmacy that compounds or prepares products or devices or uses techniques where in-line filtration, automated infusion control devices, or replenishment of drug products into reservoirs of portable infusion pumps is required;

(c) Provisions for the return to the pharmacy of unused preparations for appropriate disposition. Unused preparations may be redispensed only if the continuing quality and sterility of the preparation can be fully ensured. To avoid contamination of the ISO Class 5 containment area (hood), any returned preparation may not be placed in the containment area unless properly decontaminated. The pharmacist is the sole authority for determining whether a preparation that was not administered as originally intended may be used for an alternate patient or under alternate conditions; and

(d) Handling of hazardous preparations shall identify safeguards intended to maintain the integrity of the preparations and to minimize the exposure potential of these products to the environment and to personnel who have contact with the products.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1).

**Law Implemented:** SDCL 36-11-11.

**20:51:31:29. Additional requirements for preparation of hazardous drugs.** Hazardous drugs may only be prepared for administration under conditions that protect pharmacy personnel in the preparation area. The following requirements shall be met by pharmacies that prepare hazardous drugs:

(1) The pharmacist shall prepare policies and procedures to identify requirements for storage and handling of hazardous drugs to prevent contamination and personnel exposure;

(2) Preparations containing hazardous drugs shall be labeled on the primary container and placed in an overwrap bag that is also properly labeled. Prepared doses of dispensed hazardous drugs shall be labeled and distributed in a manner to minimize the risk of accidental rupture of the primary container. Proper labeling shall include any necessary precautions;

(3) All hazardous drugs shall be compounded in a vertical flow Class II or Class III biological safety cabinet or in a compounding aseptic isolator containment and control device with biohazard control capabilities;

(a) The ISO Class 5 BSC or CAI shall be placed in a contained environment where air pressure is negative and where the ISO Class 5 BSC or CAI is appropriately vented to the outside of the building;

(b) If the pharmacy compounds fewer than five preparations per week in a BSC or CAI and uses a closed system vial transfer device to compound the preparations, the BSC or CAI may be located in a positive pressure room;

(4) Personnel compounding hazardous drugs shall wear proper protective apparel in accordance with documented procedures. Protective apparel may include disposable, non-shedding coveralls or gowns with tight cuffs, face masks, eye protection, hair covers, double gloves, and shoe covers;

(5) Proper safety and containment techniques for compounding hazardous drugs shall be used in conjunction with the aseptic techniques required for processing sterile preparations;

(6) All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur before personnel prepare or handle hazardous preparations and shall be verified and documented for each person at least annually;

(7) Disposal of hazardous waste shall comply with all applicable local, state, and federal requirements; and

(8) Each pharmacy shall develop, maintain, implement, and adhere to written procedures for handling both major and minor spills of hazardous drugs. The procedures shall be maintained with the policies and procedures required in § 20:51:31:03.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1) and (5).

**Law Implemented:** SDCL 36-11-11.

**20:51:31:30. Responsibilities for patient care.** Pharmacies that provide sterile products to the patient in the home environment shall:

(1) Be knowledgeable of the roles of the physician, patient, pharmacy, and home health care provider related to delivery of care and the monitoring of the patients;

(2) Have a pharmacist accessible at all times to respond to a patient's and other health professional's questions and needs;

(3) Use the clinical and laboratory data of each patient to monitor initial and ongoing drug therapy. If the pharmacist does not have access to the data, the name of the health care provider assuming responsibility for monitoring drug therapy shall be documented in the patient's profile; and

(4) Report to the prescribing physician any knowledge of unexpected or untoward response to drug therapy.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1) and (12), 36-11-68.

**Law Implemented:** SDCL 36-11-11.

**20:51:31:31. Patient or caregiver education and training.** If sterile products are provided to the patient in the home environment, the pharmacist, in conjunction with nursing or medical personnel, shall verify and document the patient's or caregiver's training and competence in managing therapy.

**Source:** 36 SDR 100, effective December 14, 2009.

**General Authority:** SDCL 36-11-2.2, 36-11-11(1) and (12), 36-11-68.

**Law Implemented:** SDCL 36-11-11.

## CHAPTER 20:51:32

### PRESCRIPTION DRUG MONITORING PROGRAM

#### Section

20:51:32:01	Definitions.
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20:51:32:11	Data retention.

**20:51:32:01. Definitions.** Terms defined in SDCL 34-20E-1 have the same meaning in this article.

**Source:** 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 34-20E-20.

**Law Implemented:** SDCL 34-20E-1, 34-20E-20.

**20:51:32:02. Data submission.** Each dispenser may submit the data to the central repository using any electronic device compatible with the board's receiving device or the receiving device of the board's contracted vendor every 24 hours or by midnight of the next business day after dispensing. The data submitted to the central repository may be on electronic media approved by the board accompanied by a transmittal form identifying the dispenser submitting the electronic media, the number of prescription records included on the media, and the individual submitting the media.

If the dispenser does not have an automated recordkeeping system capable of producing an electronic report of the required data in the format established by the American Society for Automation in Pharmacy (ASAP), the dispenser may request a waiver from the electronic reporting requirement from the board.

If the board grants a waiver from the electronic reporting requirement, then the dispenser shall comply with an alternative method of reporting the data as determined by the board, such as submitting the required data on a form approved by the board.

**Source:** 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 34-20E-20.

**Law Implemented:** SDCL 34-20E-2, 34-20E-3, 34-20E-20(1).

**20:51:32:03. Data elements.** The information submitted for each prescription shall include the following items:

- (1) Dispenser name and identification number;
- (2) Date prescription filled;
- (3) Prescription number;



- (4) Prescription is new or is a refill;
- (5) Identification code for drug dispensed;
- (6) Quantity dispensed;
- (7) Day's supply dispensed;
- (8) Number of refills ordered;
- (9) Patient name;
- (10) Patient address;
- (11) Patient date of birth;
- (12) Patient gender;
- (13) Prescriber identification number;
- (14) Date prescription issued by the prescriber;
- (15) Pharmacy phone number;
- (16) Code identifying type of payment;
- (17) Prescriber last name;
- (18) Prescriber first name; and
- (19) Prescriber phone number.

**Source:** 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 34-20E-20(2).

**Law Implemented:** SDCL 34-20E-2, 34-20E-3, 34-20E-20(2).

**20:51:32:04. Access to data.** Healthcare practitioners authorized to prescribe or dispense controlled substances may request on-line access to the data for the purpose of providing patient health care. A healthcare practitioner authorized to prescribe may designate one or more persons who are licensed or registered with the respective regulatory board to serve as a delegate. Prior to being granted access to program information, a practitioner or delegate shall submit a request for registration and program access. The board will verify the licensure status of the practitioner or delegate with the appropriate licensing authority. In the case of integration, as defined in SDCL subdivision 34-20E-1(9), the board may allow an entity's credentialing process to verify licensure status. The program safeguards to protect the privacy of the data include a secure login and password for the practitioners authorized to access the data.

The board shall conduct regular reviews of data access by practitioners to identify possible violations of law or breach of professional standards that may have occurred. Whenever such information is identified, the board will notify the appropriate professional licensing, certification or regulatory agency or entity, and provide information necessary for an investigation.

**Source:** 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 34-20E-20(4).

**Law Implemented:** SDCL 34-20E-7(1), 34-20E-12, 34-20E-20(4).

**20:51:32:05. Disclosure of data.** Each request for information from the central repository must be submitted on a form or electronic platform provided by the board and may be mailed, faxed, or submitted electronically to the board office. The information may be mailed, faxed or submitted electronically to the individual requesting the profile, and marked "confidential".

A prescriber or dispenser may request patient information electronically or in writing if the request:

- (1) Is signed or submitted on an electronic platform by the prescriber, delegate, or dispenser requesting the information and includes the business name and address;
  - (2) Includes the patient's name, date of birth, purpose of the request, and the date range for the profile;
- and
- (3) Includes a statement indicating a prescriber or a dispenser and patient relationship exists.

**Source:** 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 34-20E-20(4).

**Law Implemented:** SDCL 34-20E-5, 34-20E-7(1).

**20:51:32:06. Disclosure of data -- Individual.** An individual or the individual's agent, authorized in writing, may request prescription information of the individual or the individual's minor child.

The individual requesting the prescription information or an authorized agent of the individual shall submit a signed, written request on a form provided by the board for records of the individual's prescriptions reported to the program.

The individual or agent will be required to present a current government-issued photo identification at the time of delivery of the request.

An individual who is unable to personally deliver the request to the board office may submit a request by mail or a commercial delivery service. The request shall comply with the provisions above, a copy of the current government issued photo identification shall be enclosed, and the signature of the requesting individual shall be notarized.

**Source:** 37 SDR 214, effective May 30, 2011.

**General Authority:** SDCL 34-20E-20.

**Law Implemented:** SDCL 34-20E-7(2), 34-20E-20(4).

**20:51:32:07. Disclosure of data -- Regulatory board.** A state board or regulatory agency with appropriate authority may request information electronically or in writing.

The request shall include a statement of its purpose and authority, the name and license number of the individual, the date range requested, and the specific reasons for the request.

The request shall be signed or submitted electronically by the authorized agent and include the mailing address for the board or agency.

**Source:** 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 34-20E-20.

**Law Implemented:** SDCL 34-20E-7(3), 34-20E-20(4).

**20:51:32:08. Disclosure of data -- Law enforcement.** A local, state, and federal law enforcement or prosecutorial official engaged in the enforcement of laws related to controlled substances may request information for the purpose of an investigation or prosecution of the drug-related activity or probation or parole compliance of an individual. The board shall verify the status of the law enforcement or prosecutorial official with the appropriate authority.

The electronic or written request shall include the individual's name and date of birth, the date range requested, and the specific reasons for the request, that must be approved by the board prior to the release of the information.

The request shall be signed by the authorized official and include that person's mailing address.

**Source:** 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 34-20E-20(4).

**Law Implemented:** SDCL 34-20E-7(4), 34-20E-20(4).

**20:51:32:09. Disclosure of data -- Court orders.** The board shall provide program information in response to court orders and warrants. The board shall provide program information in response to court issued subpoenas.

**Source:** 37 SDR 214, effective May 30, 2011.  
**General Authority:** SDCL 34-20E-20(4).  
**Law Implemented:** SDCL 34-20E-7(7), 34-20E-20(4).

**20:51:32:10. Disclosure of data -- Other entities.** Other designated entities may request profiles or information as identified in SDCL 34-20E-7.

The request shall include the date range requested, the specific reasons for the request, and the individual's name and birth date if applicable.

The request shall be signed by the authorized individual and include that person's mailing address.

**Source:** 37 SDR 214, effective May 30, 2011; 45 SDR 86, effective December 24, 2018.  
**General Authority:** SDCL 34-20E-20(4).  
**Law Implemented:** SDCL 34-20E-7(5)(6)(8) and (9).

**20:51:32:11. Data retention.** All dispenser records of prescriptions reported to the program shall be retained by the board for a period of three years following the date of the record. All records of access to or query of program information shall be retained by the board for a period of three years following the date of the record. At least semiannually, all program information identified as exceeding that three-year period shall be deleted from the program and discarded in a manner to maintain the confidentiality of the program information and data. Statistical data and reports from which all personally identifiable information has been removed or which do not contain personally identifiable information may be retained by the board for historical purposes.

**Source:** 37 SDR 214, effective May 30, 2011.  
**General Authority:** SDCL 34-20E-20.  
**Law Implemented:** SDCL 34-20E-20(2)(4) and (5).

## CHAPTER 20:51:33

### COMPLAINT PROCEDURES

Section	
20:51:33:01	Applicability.
20:51:33:02	Complaints.
20:51:33:03	Investigations.
20:51:33:04	Completion of complaint investigation.
20:51:33:05	Status of complainant.
20:51:33:06	Effect of failure to renew during investigation.

**20:51:33:01. Applicability.** The following procedure applies to complaints about holders of the licenses, permits, registrations, or certificates regulated by the Board of Pharmacy.

**Source:** 45 SDR 86, effective December 24, 2018.  
**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).  
**Law Implemented:** SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26, 36-11-28, 36-11-29, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48, 36-11-49, 36-11-65, 36-11A-14.

**20:51:33:02. Complaints.** The executive secretary may initiate an investigation based on a written complaint. Any person filing a complaint shall submit the complaint in writing to the executive secretary. A complaint is not a public record. The executive secretary shall dismiss any complaint that concerns matters over which the board does not have jurisdiction, and shall notify the complainant of that action. The executive secretary may also initiate an investigation upon reasonable suspicion that a licensee or registrant is in violation of any applicable standard for professional conduct.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26, 36-11-28, 36-11-29, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48, 36-11-49, 36-11-65, 36-11A-14.

**20:51:33:03. Investigations.** The executive secretary shall initiate an investigation of a complaint by notifying the license, registration, or certificate holder of the complaint and obtaining a response to the complaint. If the executive secretary determines that the complaint concerns compliance with licensing standards and requirements, the executive shall investigate the complaint. The notice shall be in writing and shall include a statement that the licensure, licensee, or registrant is entitled to due process rights, including the right to notice and an opportunity to be heard and to be represented by counsel. The executive secretary may appoint a board member to assist in the investigation.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26, 36-11-28, 36-11-29, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48, 36-11-49, 36-11-65, 36-11A-14.

**20:51:33:04. Completion of complaint investigation.** Upon completion of a complaint investigation, the executive secretary may:

- (1) Dismiss the complaint as unsubstantiated or requiring no further action. Dismissal of a complaint is not a public record;
- (2) Issue a letter of concern, that shall be placed in the licensee's or registrant's permanent records. A letter of concern is not a public record;
- (3) Recommend the board issue the licensee or registrant a public reprimand;
- (4) Recommend the board re-open and modify the license to include compliance with specified terms and conditions; or
- (5) Recommend the board suspend or revoke the license.

If the executive secretary recommends issuance of a public reprimand, re-opening and modification, or suspension or revocation of the license, registration, or certificate held by the licensee or registrant, the executive secretary shall notify the licensee or registrant of the right to contest the recommendation. If contested, the executive secretary shall issue a petition for hearing that sets out the recommendation and the reasons for the recommendation and initiates a contested case hearing. A copy of the petition for hearing shall be sent to the licensee or registrant. The executive secretary and licensee or registrant may enter into a settlement agreement concerning the recommendation to be made to the board.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26, 36-11-28, 36-11-29, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48, 36-11-49, 36-11-65, 36-11A-14.

**20:51:33:05. Status of complainant.** The complainant is not a party to any contested case hearing resulting from the executive secretary's investigation of a complaint, although the complainant may be called as a witness in the hearing. The executive secretary shall notify a complainant of any public final agency action taken as a result of a complaint.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26, 36-11-28, 36-11-29, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48, 36-11-49, 36-11-65, 36-11A-14.

**20:51:33:06. Effect of failure to renew during investigation.** The holder of a license, registration, or certificate may choose not to renew the license, registration, or certificate after a complaint investigation has been initiated by the executive secretary. A failure to renew after an investigation has been initiated shall be reported as "withdrawn under investigation" in the board's permanent license files and in any national databases to which the board is required to report licensure action.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-1, 36-11-13, 36-11-15, 36-11-16.1, 36-11-19.4, 36-11-19.6, 36-11-20, 36-11-23.3, 36-11-26, 36-11-28, 36-11-29, 36-11-30, 36-11-31, 36-11-44, 36-11-46, 36-11-48, 36-11-49, 36-11-65, 36-11A-14.

## CHAPTER 20:51:34

### CONTESTED CASE HEARING PROCEDURES

#### Section

20:51:34:01	Applicability.
20:51:34:02	Petitions for hearing.
20:51:34:03	Filing of petitions for hearing.
20:51:34:04	Scheduling of hearing.
20:51:34:05	Hearing procedure.
20:51:34:06	Final board decision.
20:51:34:07	Notice of decision.
20:51:34:08	Assessment of costs of disciplinary hearings.
20:51:34:09	Board member conflict of interest.
20:51:34:10	Board member potential conflict of interest.

**20:51:34:01. Applicability.** The following procedure applies to contested case proceedings for license, registration, or certificate applications and to disciplinary proceedings before the Board of Pharmacy.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11 (1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-28, 36-11A-45.

**20:51:34:02. Petitions for hearing.** An applicant for a license, registration, or certificate issued by the board may file a petition for hearing at any time during the processing of an application. The executive secretary may file a petition for hearing to initiate a disciplinary proceeding against a licensee or registrant. A petition for hearing shall be signed by the petitioner and contain the following information: the name and address of the applicant, licensee, or registrant; the basis for the request for hearing; recitation of the

applicable statutes or regulations under which the petitioner is requesting board action; and the relief requested by the petitioner.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-28, 36-11A-45.

**20:51:34:03. Filing of petitions for hearing.** All petitions for hearing shall be filed with the executive secretary, who shall maintain the record of contested case proceedings held before the board.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-28, 36-11A-45.

**20:51:34:04. Scheduling of hearing.** Upon receipt of a petition for hearing, the board president may appoint an examiner to conduct the contested case hearing, or may schedule the contested case hearing before the board, as authorized by applicable statutes.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-28, 36-11A-45.

**20:51:34:05. Hearing procedure.** Contested case hearings shall be conducted in accordance with SDCL chapter 1-26. The parties to a hearing are the executive secretary and the applicant, licensee or registrant. A board member who has participated in any investigation of the matter before the board shall be disqualified from all deliberations and decisions.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-28, 36-11A-45.

**20:51:34:06. Final board decision.** If the board hears the proceeding, the board shall issue a final decision and require the parties to submit proposed findings of fact and conclusions of law for consideration at the board's next meeting. If a hearing examiner hears the proceeding, the examiner shall issue a proposed decision including findings of fact and conclusions of law. The examiner shall serve the proposed decision upon the board and the parties. The board may request that the parties appear before the board to present oral arguments and objections to the examiner's proposed decision. The board shall issue a final decision and accept, reject, or modify the findings, conclusions, and decisions of the examiner.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-28, 36-11A-45.

**20:51:34:07. Notice of decision.** The board shall issue a notice of decision, accompanied by the final board decision and findings of fact and conclusions of law, to the applicant, licensee, or registrant and executive secretary.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-28, 36-11A-45.

**20:51:34:08. Assessment of costs of disciplinary hearings.** The board may assess the costs associated with a contested case proceeding resulting in disciplinary action, against a licensee or registrant upon motion by the executive secretary. If requesting the assessment of costs, the executive secretary shall

present a statement of costs to the board or hearing examiner at the time the board or hearing examiner submits proposed findings of fact and conclusions of law.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-28, 36-11A-14, 36-11A-45.

**20:51:34:09. Board member conflict of interest.** A board member may not participate in a contested case proceeding or disciplinary action if the board member:

(1) Is personally related to a party involved in the contested case proceeding or disciplinary action by two degrees of consanguinity;

(2) Has a direct financial interest in a party involved in the contested case proceeding or disciplinary action through employment or by contract;

(3) Directly supervises and is responsible for peer review of a party involved in the contested case proceeding or disciplinary action; or

(4) Has a spouse who has a direct financial interest in or directly contracts with a party involved in the contested case proceeding or disciplinary action. If a conflict of interest exists, the member shall make an oral statement of recusal on the record at the initiation of the hearing.

A recused member may not participate in board discussions or decision-making regarding that contested case proceeding or disciplinary action.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-28, 36-11A-14, 36-11A-45.

**20:51:34:10. Board member potential conflict of interest.** A potential conflict of interest is an indirect financial interest, or a personal relationship or another interest in a party involved in a contested case proceeding or disciplinary action that is different from that of the general public, and that a reasonable person would believe might result in bias or prejudice. A board member shall disclose any potential conflict of interest in a contested case proceeding or disciplinary action on the record at the initiation of the hearing, or during the hearing, if the board member becomes aware of the existence of a potential conflict of interest at that time. Upon the board's own motion or the motion of a party, and considering the rule of necessity if maintenance of a quorum is an issue, the board may recuse a member with a potential conflict of interest if the board determines that the potential conflict of interest raises an unacceptable risk of bias or prejudice in the contested case proceeding or disciplinary action.

**Source:** 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11-11(1)(2)(3)(10) and (13).

**Law Implemented:** SDCL 36-11-28, 36-11A-14, 36-11A-45.

## CHAPTER 20:51:35

### DONATED PRESCRIPTION DRUG AND MEDICAL SUPPLY REDISPENSING PROGRAM

Section

20:51:35:01 Definitions.

20:51:35:02 Eligibility criteria for participating pharmacies.

20:51:35:03 Criteria for donating and accepting donated prescription drugs and supplies. 20:51:35:04 Prescription drugs which may not be donated or accepted.

20:51:35:05	Inspecting and documenting donated prescription drugs and supplies.
20:51:35:06	Acceptance, storage, and destruction of donated prescription drugs and supplies.
20:51:35:07	Return or destruction of donated controlled substances.
20:51:35:08	Recalls.
20:51:35:09	Criteria for dispensing donated prescription drugs and supplies.
20:51:35:10	Acceptance form for individuals to receive donated prescription drugs and supplies.
20:51:35:11	Handling fee.

**20:51:35:01. Definitions.** Terms defined in SDCL 34-20H-1 have the same meaning when used in this chapter.

Terms used in this chapter mean:

- (1) "Board," South Dakota Board of Pharmacy as defined in SDCL 36-11-2(3);
- (2) "Controlled substance," the substances described, defined, or provided in SDCL 34-20B-11 to 34-20B-26, inclusive;
- (3) "Donor," any natural person or entity legally authorized to possess drugs with a license or permit in good standing in the state in which it is located, and government agencies and entities that are federally authorized to possess drugs;
- (4) "Eligible patient," an indigent, uninsured, or underinsured person;
- (5) "Health care facility," a:
  - (a) Facility licensed pursuant to SDCL chapter 34-12; or
  - (b) Similar licensed facility located in another state;
- (6) "Health care professional," a:
  - (a) Physician licensed pursuant to SDCL chapter 36-4;
  - (b) Certified nurse practitioner or certified nurse midwife licensed pursuant to SDCL chapter 36-9A;
  - (c) Physician assistant licensed pursuant to SDCL chapter 36-4A;
  - (d) Dentist licensed pursuant to SDCL chapter 36-6A;
  - (e) Optometrist licensed pursuant to SDCL chapter 36-7;
  - (f) Podiatrist licensed pursuant to SDCL chapter 36-8; or
  - (g) Pharmacist licensed pursuant to SDCL chapter 36-11;
- (7) "Indigent individual," any person who does not have sufficient money, credit, or insurance to pay for prescribed medication;
- (8) "Pharmacist-in-charge," as defined in § 20:51:06:02.01;
- (9) "Prescription Drugs," legend drugs as defined in SDCL 34-20B-28.1; and
- (10) "Program," the donated prescription drug and medical supply redispensing program established by the board pursuant to SDCL chapter 34-20H.

**Source:** 49 SDR 51, effective November 27, 2022.

**General Authority:** SDCL 34-20H-7.

**Law Implemented:** SDCL 34-20H-7.

Cross Reference: Drugs and Substances Control, SDCL chapter 34-20B.

**20:51:35:02.** Eligibility criteria for participating pharmacies. Participation in the program is voluntary. In order to participate, a pharmacy must:

- (1) Comply with all applicable federal and state laws and hold an active, nonrestricted, board-issued license in good standing; and
- (2) Submit on a form provided by the board:
  - (a) The pharmacy name, street address, telephone number, and board-issued license number;
  - (b) The name and license number of the pharmacist-in-charge as defined in § 20:51:06:02.01; and



(c) A statement, signed and dated by the pharmacist-in-charge, indicating that the pharmacy meets the eligibility requirements under this section and that all pharmacists shall comply with the requirements of this chapter.

A pharmacy may withdraw from participation in the program at any time by providing written notice to the board on a form prescribed by the board.

**Source:** 49 SDR 51, effective November 27, 2022.

**General Authority:** SDCL 34-20H-7(2)(5).

**Law Implemented:** SDCL 34-20H-4.

**20:51:35:03.** Criteria for donating and accepting donated prescription drugs and supplies. A participating pharmacy may only accept the following donations from natural persons eighteen years or older or entities, who are in lawful possession of the donation:

(1) A prescription drug that:

(a) Is in its original sealed and tamper-evident packaging. However, a drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit package is not opened;

(b) Has packaging containing the lot number and expiration date of the drug. If the lot number is not retrievable, all specified medications must be destroyed in the event of a recall;

(c) Has an expiration date that is more than six months after the date the drug was donated. A donated prescription drug bearing an expiration date that is six months or less after the date the prescription drug was donated may be accepted and distributed if the drug is in high demand and can be dispensed for use prior to the drug's expiration date;

(d) Has no physical signs of tampering, misbranding, deterioration or adulteration, whether to the drug itself or its packaging, and there is no reason to otherwise believe that the drug is adulterated; and

(e) If the drug has not been continually under the control of a health care professional, a pharmacy, or other legally authorized entity allowed to possess prescription drugs, the participating pharmacy must collect a donation form that is signed by the donor or that person's authorized representative attesting to the manufacturer's recommended proper storage of the prescription drug; and

(2) A medical supply that is:

(a) In its original, unopened, sealed packaging; and

(b) Not adulterated or misbranded.

**Source:** 49 SDR 51, effective November 27, 2022.

**General Authority:** SDCL 34-20H-7(2)(3)(5).

**Law Implemented:** SDCL 34-20H-2.

**20:51:35:04.** Prescription drugs which may not be donated or accepted. In addition to the grounds for donation rejection in SDCL 34-20H-2, no prescription drug that requires storage temperatures other than normal room temperature, as specified by the manufacturer, may be donated or accepted except a drug donated directly from a drug manufacturer or other entity authorized to possess prescription drugs.

**Source:** 49 SDR 51, effective November 27, 2022.

**General Authority:** SDCL 34-20H-7(2).

**Law Implemented:** SDCL 34-20H-2, 34-20H-4(1).

**20:51:35:05.** Inspecting and documenting donated prescription drugs and supplies. A pharmacist-in-charge designated pharmacist at the participating pharmacy shall inspect a donated prescription drug or medical supply to determine, to the extent reasonably possible, that the drug or supply is not adulterated or misbranded, is safe and suitable for dispensing, and is not ineligible. The pharmacist who inspects the drug or supply shall sign the donor form stating the above. If a participating pharmacy receives a drug or medical supply from another participating pharmacy, the receiving participating pharmacy does not need to reinspect

the drug or supply when receiving a copy of the donor form with the inspection information. The transfer of the drug or supply from one participating pharmacy to another must be documented in both the receiving and the donating pharmacy.

After inspecting donated prescription drugs and medical supplies, the participating pharmacy must inventory and document the donation in the board's program database.

**Source:** 49 SDR 51, effective November 27, 2022.

**General Authority:** SDCL 34-20H-4(3), 34-20H-7(2)(3)(5).

**Law Implemented:** SDCL 34-20H-2, 34-20H-4(3), 34-20H-9.

**20:51:35:06.** Acceptance, storage, and destruction of donated prescription drugs and supplies. A participating pharmacy shall store a donated drug or medical supply in a storage area under environmental conditions appropriate for the drug or supply being stored. Donated prescription drugs and medical supplies may not be stored with nondonated inventory.

When a donated prescription drug or medical supply is not inspected immediately upon receipt, a participating pharmacy must quarantine the donation until it has been inspected and approved for dispensing under the program.

A participating pharmacy shall destroy donations that are not suitable for dispensing and make a record of the destruction.

Prescription drugs and medical supplies may be donated on the premises of a participating pharmacy to a person designated by the pharmacy. A drop box may not be used to deliver or accept donations.

**Source:** 49 SDR 51, effective November 27, 2022.

**General Authority:** SDCL 34-20H-7(2)(3).

**Law Implemented:** SDCL 34-20H-3, 34-20H-4(1).

**20:51:35:07.** Return or destruction of donated controlled substances. A controlled substance may not be accepted for donation. A controlled substance submitted for donation must be returned immediately to the donor or the donor's representative who provided the controlled substance. In the event that a controlled substance enters the participating pharmacy and it is not practicable to return the controlled substance to the donor or the donor's representative due to an inability to identify the donor or the donor's representative or due to the refusal by the donor or the donor's representative to receive them, the abandoned controlled substance must be documented and destroyed rendering the chemical compound to be non-retrievable per 21 C.F.R. § 1300.05(b), in effect on April 1, 2021. A pharmacist or other person with authority to dispense controlled substances shall destroy the controlled substance. Another employee of the participating pharmacy shall witness the destruction.

**Source:** 49 SDR 51, effective November 27, 2022.

**General Authority:** SDCL 34-20H-7(2)(3).

**Law Implemented:** SDCL 34-20H-2, 34-20H-3.

**20:51:35:08.** Recalls. If a participating pharmacy receives a recall notification, the pharmacy shall perform a uniform destruction of the recalled, donated prescription drug or medical supply and complete the destruction information form for the drug or medical supply destroyed. If a recalled drug or recalled medical supply has been dispensed, the participating pharmacy shall immediately notify the recipient of the recalled drug or supply pursuant to established pharmacy recall procedures. The participating pharmacy shall remove the recalled prescription drug or supply from the program database.

**Source:** 49 SDR 51, effective November 27, 2022.

**General Authority:** SDCL 34-20H-7(2)(5).

**Law Implemented:** SDCL 34-20H-4(1), 34-20H-9.

**20:51:35:09.** Criteria for dispensing donated prescription drugs and supplies. A donated drug or medical supply may be dispensed only if:

- (1) The drug or supply is prescribed by a health care professional for use by an eligible patient and is dispensed by a licensed pharmacist in a participating pharmacy;
- (2) The participating pharmacy dispenses to an individual requesting a drug or supply through the program as follows, in descending order of priority:
  - (a) An indigent individual;
  - (b) An individual who has no active third-party prescription drug reimbursement coverage for the drug or medical supply prescribed; and
  - (c) Any other individual;
- (3) The participating pharmacy dispenses the donated prescription drug or supply in compliance with all applicable federal and state laws and regulations for dispensing prescription drugs and supplies;
- (4) The participating pharmacy dispensing the prescription drug or medical supply removes the original donor's identification and the name of the dispensing pharmacy from the package prior to dispensing the drug or supply; and
- (5) The participating pharmacy documents the dispensing in the board's program database.

**Source:** 49 SDR 51, effective November 27, 2022.

**General Authority:** SDCL 34-20H-7(1)(2)(3).

**Law Implemented:** SDCL 34-20H-4(1), 34-20H-7(1), 34-20H-3.

**20:51:35:10.** Acceptance form for individuals to receive donated prescription drugs and supplies. An individual who requests and receives a prescription drug or medical supply from the program shall, prior to receipt of the drug or medical supply, sign an acceptance form attesting that:

- (1) The individual is an eligible patient;
- (2) The individual acknowledges that the drug or supply has been donated; and
- (3) The individual waives the requirement for child-resistant packaging, if applicable.

**Source:** 49 SDR 51, effective November 27, 2022.

**General Authority:** SDCL 34-20H-7(2)(5).

**Law Implemented:** SDCL 34-20H-7(1)(a)(b).

**20:51:35:11.** Handling fee. A participating pharmacy may charge the recipient of a donated drug or medical supply a handling fee, not to exceed twenty-five dollars, to cover mailing, handling, or dispensing costs. A prescription drug or medical supply dispensed through the program is not eligible for reimbursement under any insurance or medical assistance program.

**Source:** 49 SDR 51, effective November 27, 2022.

**General Authority:** SDCL 34-20H-7(4).

**Law Implemented:** SDCL 34-20H-6.

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## CHAPTER 36-11A

### WHOLESALE DRUG DISTRIBUTORS

- [36-11A-1](#) Definitions .
- [36-11A-1.1](#) Trading partner defined.
- [36-11A-1.2](#) Transaction defined.
- [36-11A-1.3](#) Transaction information defined.
- [36-11A-1.4](#) Transaction statement defined.
- [36-11A-2](#) Distribution defined.
- [36-11A-3](#) Repealed .
- [36-11A-4](#) Pharmacy distributor defined.
- [36-11A-4.1](#) License required for wholesale distributors, outsourcing facilities, and third-party logistics providers.
- [36-11A-4.2](#) Prior registration and inspection by FDA required for certain outsourcing facilities.
- [36-11A-5](#) Purchase of drug from other source restricted--Penalty.
- [36-11A-6](#) Drug sample or drug coupon--Sale, purchase, trade or counterfeit prohibited--Distribution restricted--Penalty.
- [36-11A-7](#) Wholesale distribution without license prohibited--License unnecessary for agent or employee of licensed distributor--Violation as felony.
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- [36-11A-38](#) Accounts for purchase of prescription drugs.
- [36-11A-39](#), 36-11A-40. Repealed.
- [36-11A-41](#) Confirmation of receipt of transaction information, transaction history, and transaction statement.
- [36-11A-42](#), 36-11A-43. Repealed.
- [36-11A-44](#) Retention of transaction files--Inspection.
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### **36-11A-1. Definitions.**

Terms used in this chapter mean:

- (1) Repealed by SL 2017, ch 174, § 1;
- (2) "Board," the Board of Pharmacy;
- (3) "Chain pharmacy warehouse," a physical location for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of such drugs to a group of chain pharmacies that have the same common ownership and control;
- (4) "Co-licensed partner," a party that, with another party or parties, has the right to engage in the manufacturing or marketing, or both, of a co-licensed product;
- (5) "Co-licensed product," a prescription drug in which two or more parties have the right to engage in the manufacturing or marketing, or both, of a drug consistent with the United States Food and Drug Administration's implementation of the Prescription Drug Marketing Act (21 C.F.R. Parts 203 and 205);
- (6) "DSCSA," the Drug Supply Chain Security Act as included as Part II of the Federal Drug Quality and Security Act of 2013;
- (7) "Drug," "prescription drug," any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices required by federal law or federal regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to § 503(b) of the Federal Food, Drug and Cosmetic Act;
- (8) "Drug coupon," a form which may be redeemed at no cost or at reduced cost for a prescription drug;
- (9) "Drug Enforcement Administration," the Drug Enforcement Administration of the United States Department of Justice;
- (10) "Drug sample," a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug;
- (11) "Facility," a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale;
- (12) "Licensee," any wholesale drug distributor licensed pursuant to the provisions of this chapter;
- (13) "Manufacturer," as defined by the DSCSA;
- (14) "Out-of-state wholesale drug distributor," a wholesale drug distributor with no physical facilities located in this state;
- (15) "Outsourcing facility," a facility that is engaged in compounding of nonpatient specific sterile and nonsterile drugs that complies with § 503(b) of the Federal Food, Drug and Cosmetic Act

as of January 1, 2017, and is registered and inspected by the United States Food and Drug Administration;

- (16) "Pharmacy," a place licensed by the board under chapter [36-11](#) in which prescription drugs are sold;
- (17) "Repackage," repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug excluding that completed by the pharmacist responsible for dispensing the drug to the patient;
- (18) "Repackager," a person who repackages;
- (19) "Sterile pharmaceutical," any dosage form of a drug, including parenterals, such as injectables, surgical irrigants, and ophthalmics, devoid of viable microorganisms;
- (20) "Third-party logistics provider," an entity that provides or coordinates warehousing, distribution, or other services on behalf of a manufacturer, wholesale distributor, or dispenser as defined in the DSCSA, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition;
- (21) "Transaction history," a statement, in paper or electronic form, that includes the transaction information of each prior transaction going back to the manufacturer of the product.

**Source:** SL 1991, ch 307, § 1; SL 2007, ch 215, § 1; SL 2017, ch 174, § 1.

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#### **36-11A-1.1. Trading partner defined.**

As used in this chapter, the term, trading partner, means:

- (1) A manufacturer, repackager, wholesale distributor, or dispenser from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct ownership of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct ownership of a product; or
- (2) A third-party logistics provider from whom a manufacturer, repackager, wholesale distributor, or dispenser accepts direct possession of a product or to whom a manufacturer, repackager, wholesale distributor, or dispenser transfers direct possession of a product.

**Source:** SL 2017, ch 174, § 2.

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#### **36-11A-1.2. Transaction defined.**

As used in this chapter, the term, transaction, means the transfer of product between trading partners in which a change of ownership occurs. The term does not include:

- (1) Intracompany distribution of any product between members of an affiliate or within a manufacturer;
- (2) The distribution of a product among hospitals or other health systems that are under common control;
- (3) The distribution of a product for emergency medical reasons, including a public health emergency declaration pursuant to state or federal law;
- (4) The dispensing of a product pursuant to a prescription;
- (5) The distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with state and federal law;
- (6) The distribution of blood or blood components intended for transfusion;
- (7) The distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

- (8) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by state and federal law;
- (9) The distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;
- (10) A combination product that is:
  - (a) A product composed of a device and one or more other regulated components, such as a drug or device, biologic or device, or drug, device or biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
  - (b) Two or more separate products packaged together in a single package or as a unit and composed of a drug and device or a device and biological product; or
  - (c) Two or more finished medical devices plus one or more drug or biological products that are packaged together in what is referred to as a medical convenience kit as described in subdivision (11);
- (11) The distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user if:
  - (a) The medical convenience kit is assembled in an establishment that is registered with the United States Food and Drug Administration as a device manufacturer;
  - (b) The medical convenience kit does not contain a federally scheduled controlled substance;
  - (c) In the case of a medical convenience kit that includes a product, the person who manufactured the kit purchased the product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer, and does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and
  - (d) In the case of a medical convenience kit that includes a product, the product is an intravenous solution intended for the replenishment of fluids and electrolytes; a product intended to maintain the equilibrium of water and minerals in the body; a product intended for irrigation or reconstitution; an anesthetic; an anticoagulant; a vasopressor; or a sympathomimetic;
- (12) The distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);
- (13) The distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;
- (14) The distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;
- (15) The distribution of a medical gas; or
- (16) The distribution or sale of any licensed biologic product that meets the definition of device under federal law.

**Source:** SL 2017, ch 174, § 3.

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**36-11A-1.3. Transaction information defined.**



As used in this chapter, the term, transaction information, means the proprietary or established name or names of the product, the strength and dosage form of the product, the national drug code number of the product, the container size, the number of containers, the lot number of the product, the transaction date, the shipment date, if more than twenty-four hours after the transaction date, the business name and address of the transferring person, and the business name and address of the transferee person.

**Source:** SL 2017, ch 174, § 4.

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#### **36-11A-1.4. Transaction statement defined.**

As used in this chapter, the term, transaction statement, means a statement, in paper or electronic form, that the entity transferring ownership in a transaction:

- (1) Is authorized under federal law;
- (2) Received the product from a person who is authorized as required under federal law;
- (3) Received the transaction information and transaction statement from the prior owner of the product, as required by federal law;
- (4) Did not knowingly ship a suspect or illegitimate product;
- (5) Had systems and processes in place to comply with verification requirements outlined in federal law;
- (6) Did not knowingly provide false transaction information; and
- (7) Did not knowingly alter the transaction history.

**Source:** SL 2017, ch 174, § 5.

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#### **36-11A-2. Distribution defined.**

As used in this chapter, the term, distribution, means the sale, purchase, trade, delivery, handling, storage, or receipt of a product. The term does not include:

- (1) Intracompany sales between any division, subsidiary, parent or otherwise affiliated or related company under the common ownership and control of a corporate entity;
- (2) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
- (3) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug by a charitable organization described in § 501(c)(3) of the Internal Revenue Code of 1954, as amended through December 18, 2015, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
- (4) The sale, purchase or trade of a drug or an offer to sell, purchase or trade a drug among hospitals or other health care entities that are under common control;
- (5) The sale, purchase or trade of a drug, or an offer to sell, purchase or trade a drug, for emergency medical reasons;
- (6) The sale, purchase or trade of a drug, an offer to sell, purchase or trade a drug, or the dispensing of a drug pursuant to a prescription;
- (7) The transfer of drugs by a pharmacy to another pharmacy to alleviate a temporary shortage;
- (8) The distribution of drug samples by manufacturers' representatives or distributors' representatives;
- (9) The sale, purchase, or trade of blood and blood components intended for transfusion;
- (10) The sale, purchase, or trade of a drug to an individual under any form of insurance or an employee medical benefit program pursuant to a prescription; or
- (11) The logistics and warehouse services provided by a third-party logistics provider.

**Source:** SL 1991, ch 307, § 2; SL 2017, ch 174, § 7.

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36-11A-3. Repealed by SL 2007, ch 215, § 29.

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**36-11A-4. Pharmacy distributor defined.**

A pharmacy distributor is any pharmacy or hospital pharmacy that is engaged in the delivery or distribution of prescription drugs either to another pharmacy or to another person or entity, including to a wholesale drug distributor as defined in § [36-11A-3](#), that is engaged in the delivery or distribution of prescription drugs and who is involved in the actual, constructive, or attempted transfer of a drug in this state to other than the ultimate consumer, if the financial value of the drugs so delivered or distributed is equivalent to at least five percent of the total gross sales of the pharmacy.

**Source:** SL 1991, ch 307, § 4.

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**36-11A-4.1. License required for wholesale distributors, outsourcing facilities, and third-party logistics providers.**

Each wholesale distributor and outsourcing facility located within or outside of the state that provides services to outlets within the state, shall be licensed annually by the board. Each third-party logistics provider located in this state shall be licensed by the board.

**Source:** SL 2017, ch 174, § 6.

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**36-11A-4.2. Prior registration and inspection by FDA required for certain outsourcing facilities.**

No outsourcing facility engaged in compounding of nonpatient specific sterile and nonsterile drugs may become licensed by the board without first obtaining a registration and inspection by the United States Food and Drug Administration, and paying the license fee set by the board in rules promulgated pursuant to chapter [1-26](#). The fee may not exceed two hundred dollars.

**Source:** SL 2017, ch 174, § 8.

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**36-11A-5. Purchase of drug from other source restricted--Penalty.**

No person, other than a consumer or patient, may knowingly purchase or receive a prescription drug from any source other than a drug distributor or pharmacy licensed by the board under this chapter or chapter [36-11](#), as applicable.

Any person who violates this section is guilty of a Class 1 misdemeanor for the first conviction and a Class 6 felony for any subsequent conviction.

**Source:** SL 1991, ch 307, §§ 5, 20; SL 2017, ch 174, § 9.

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**36-11A-6. Drug sample or drug coupon--Sale, purchase, trade or counterfeit prohibited--Distribution restricted--Penalty.**

No person may sell, purchase, or trade a prescription drug sample or offer to sell, purchase, or trade a drug sample or a drug coupon. No person may counterfeit such a coupon. No person may distribute drug samples except as provided in § 503(d) of the Federal Food, Drug and Cosmetic Act, as amended through January 1, 1991.

Any person who violates this section is guilty of a Class 1 misdemeanor for the first conviction and a Class 6 felony for any subsequent conviction.

**Source:** SL 1991, ch 307, §§ 6, 20.

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**36-11A-7. Wholesale distribution without license prohibited--License unnecessary for agent or employee of licensed distributor--Violation as felony.**

No person or distribution outlet may engage in the wholesale distribution of prescription drugs in this state unless that person or outlet is licensed by the board as a drug distributor in accordance with the minimum standards, conditions and terms set forth in this chapter and in rules adopted pursuant to chapter [1-26](#).

An agent or employee of a licensed drug distributor need not seek licensure under this chapter and may lawfully possess prescription drugs when the agent or employee is acting in the usual course of business or employment.

Any person who violates this section is guilty of a Class 6 felony.

**Source:** SL 1991, ch 307, §§ 7, 20; SL 2017, ch 174, § 10.

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**36-11A-8. Application for license.**

An applicant for licensure as a wholesale distributor shall apply annually to the board on a form provided by the board. The application shall be accompanied by a license fee set by the board. The fee may not exceed two hundred fifty dollars. All financial statements or related information submitted by applicants shall be treated as confidential materials.

**Source:** SL 1991, ch 307, § 8.

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**36-11A-9. Separate license required for each facility owned or operated by same business entity.**

The board may require a separate license for each facility directly or indirectly owned or operated by the same business entity within this state or for a parent entity with divisions, subsidiaries, or affiliate companies within this state if operations are conducted at more than one location and joint ownership and control exists among all the entities.

**Source:** SL 1991, ch 307, § 9.

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**36-11A-10. Temporary licenses.**

The board may grant temporary licensure when a wholesale drug distributor first applies for a license to operate within this state. Temporary licenses remain valid until the board approves or denies the license or for ninety days, whichever occurs first.

**Source:** SL 1991, ch 307, § 10.

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**36-11A-11. Out-of-state distributor--License--Application--Violation as felony.**

No out-of-state wholesale drug distributor may conduct business in this state without first obtaining a license from the board and paying the license fee set by the board. Application for an out-of-state wholesale drug distributor license under this section shall be made on a form provided by the board. Each person acting as a principal or agent for an out-of-state wholesale drug distributor to sell or distribute drugs in this state shall obtain a license unless the distributor has obtained a license pursuant to this chapter. Out-of-state wholesale drug distributors may obtain the license required by this chapter on the basis of reciprocity if the out-of-state wholesale drug distributor possesses a valid license granted by another state

pursuant to standards comparable to those in this state and the other state extends reciprocal treatment under its laws to wholesale drug distributors of this state.

Any person who violates this section is guilty of a Class 6 felony.

**Source:** SL 1991, ch 307, §§ 11, 20.

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**36-11A-12. Approval or denial of application or renewal--Appeal.**

The board may approve, approve with conditions, or deny the application for licensure or renewal of licensure as a wholesale distributor based on information concerning the qualifications of the applicant provided in the application. No license to engage in wholesale drug distribution may be issued or renewed unless the applicant agrees to operate and satisfies the board that it operates in a manner prescribed by federal law, this chapter and the rules adopted by the board.

An applicant may appeal the decision of the board regarding licensure or renewal of licensure pursuant to contested case procedures in chapter [1-26](#).

**Source:** SL 1991, ch 307, § 12.

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**36-11A-13. Expiration and renewal of license.**

Each wholesale drug distributor license expires on December thirty-first following the date of issue. The board shall provide an application for license renewal to each licensee before December first of each year. If application for renewal of the license accompanied by the annual license fee is not made before the expiration date, the existing license lapses on the date of expiration.

**Source:** SL 1991, ch 307, § 13; SL 2017, ch 174, § 11.

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**36-11A-14. Promulgation of rules.**

The board shall promulgate rules, pursuant to chapter [1-26](#), pertaining to:

- (1) Application procedures and information required for initial application and for renewal of license;
- (2) Treatment of confidential materials;
- (3) Qualification of applicants;
- (4) Temporary licensure;
- (5) Licensure by reciprocity;
- (6) Annual license fee;
- (7) Requirements for storing and handling prescription drugs;
- (8) Record keeping;
- (9) Liability insurance;
- (10) Security systems and procedures;
- (11) Personnel;
- (12) Policies and procedures;
- (13) Inspection of incoming and outgoing product shipments by licensees;
- (14) Conduct of inspections by the board; and
- (15) Due process.

**Source:** SL 1991, ch 307, § 14; SL 2017, ch 174, § 12.

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36-11A-15. Repealed by SL 2017, ch 174, § 13.

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### **36-11A-16. Inspection--Exemption--Penalty.**

For the purpose of conducting an inspection, persons authorized by the board and showing identification may enter during normal business hours all premises in this state purporting or appearing to be used by a drug distributor. No person may deny the right of entry as provided in this section to an authorized person. Any licensee who provides documentation of the most recent satisfactory inspection that is less than two years old by either the United States Food and Drug Administration or a state agency, if it is determined to be comparable by the board, is exempt from further inspection for a period of time to be determined by the board. This exemption does not bar the board from initiating an investigation pursuant to a public or governmental complaint received by the board regarding a wholesale drug distributor.

Any person who violates this section is guilty of a Class 1 misdemeanor for the first conviction and a Class 6 felony for any subsequent conviction.

**Source:** SL 1991, ch 307, §§ 16, 20; SL 2017, ch 174, § 14.

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### **36-11A-17. Records--Availability.**

A licensee may keep records at a central location apart from the principal office of the wholesale drug distributor or the location at which the drugs were stored and from which the drugs were shipped if the records are made available for inspection within two working days after a request by the board. Records may be kept in any form permissible under rules adopted by the board pursuant to chapter [1-26](#). Records shall be kept at least six years.

**Source:** SL 1991, ch 307, § 17; SL 2017, ch 174, § 15.

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### **36-11A-18. Limitations on state board of pharmacy.**

The board may not require the employment of licensed pharmacists by wholesale distributor licensees unless otherwise required by law, nor may the board regulate prices or the terms and conditions of sale of prescription drugs unless otherwise specified in this chapter.

**Source:** SL 1991, ch 307, § 18.

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### **36-11A-19. Complaints--Procedure.**

Complaints arising from any provision of this chapter shall be handled in compliance with contested case procedure in chapter [1-26](#), and the board may suspend, revoke, or condition the license of the licensee if the facts warrant.

**Source:** SL 1991, ch 307, § 19.

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### **36-11A-20. Authorized distributor of record defined.**

For the purposes of this chapter, an authorized distributor of record is a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with both of the following:

- (1) The wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; and
- (2) The wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which is updated by the manufacturer on no less than a monthly basis.

**Source:** SL 2007, ch 215, § 2.

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**36-11A-21. Drop shipment defined.**

For the purposes of §§ [36-11A-20](#) to [36-11A-46](#), inclusive, drop shipment is the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug, or that manufacturer's co-licensed product partner, that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor, whereby the wholesale distributor or chain pharmacy warehouse takes title but not physical possession of such prescription drug and the wholesale distributor invoices the pharmacy or chain pharmacy warehouse, or other person authorized by law to dispense or administer such drug to a patient, and the pharmacy or chain pharmacy warehouse or other authorized person receives delivery of the prescription drug directly from the manufacturer, or that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor.

**Source:** SL 2007, ch 215, § 3.

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**36-11A-22. Manufacturer's exclusive distributor defined.**

For the purposes of §§ [36-11A-20](#) to [36-11A-46](#), inclusive, a manufacturer's exclusive distributor is any person who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. Such manufacturer's exclusive distributor must be licensed as a wholesale distributor under §§ [36-11A-20](#) to [36-11A-46](#), inclusive, and to be considered part of the normal distribution channel must also be an authorized distributor of record.

**Source:** SL 2007, ch 215, § 4.

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**36-11A-23. Normal distribution channel defined.**

For the purposes of §§ [36-11A-20](#) to [36-11A-46](#), inclusive, a normal distribution channel is a chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, or from that manufacturer to that manufacturer's co-licensed partner, or from that manufacturer to that manufacturer's third-party logistics provider, or from that manufacturer to that manufacturer's exclusive distributor, directly or by drop shipment, to:

- (1) A pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;
- (2) A wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;
- (3) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or
- (4) A chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient.

**Source:** SL 2007, ch 215, § 5.

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**36-11A-24. Third party logistics provider defined.**

For the purposes of §§ [36-11A-20](#) to [36-11A-46](#), inclusive, a third party logistics provider is any person who contracts with a prescription drug manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but does not take title to the prescription drug or have general responsibility to direct the prescription drug's sale or disposition. Any third party logistics provider shall be licensed under §§ [36-11A-20](#) to [36-11A-46](#), inclusive.

**Source:** SL 2007, ch 215, § 6; SL 2017, ch 174, § 16.

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**[36-11A-25. Wholesale distributor defined.](#)**

For the purposes of §§ [36-11A-20](#) to [36-11A-46](#), inclusive, a wholesale distributor is any person other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider or repackager, engaged in wholesale distribution.

**Source:** SL 2007, ch 215, § 7; SL 2017, ch 174, § 17.

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36-11A-26. Repealed by SL 2017, ch 174, § 18.

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**[36-11A-27. Wholesale distributor license required--Exemptions.](#)**

Any wholesale distributor who engages in the wholesale distribution of prescription drugs in this state must be licensed by the board, in accordance with §§ [36-11A-20](#) to [36-11A-46](#), inclusive, before engaging in wholesale distributions of wholesale prescription drugs. The board shall exempt manufacturers distributing their own FDA-approved drugs and devices from any qualifications required for licensing, to the extent not required by federal law or regulation, including the requirements in subdivisions 36-11A-28(7) and (8), and §§ [36-11A-29](#) to [36-11A-31](#), inclusive.

**Source:** SL 2007, ch 215, § 9.

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**[36-11A-28. Information to be provided by applicants.](#)**

The board shall require the following minimum information from each wholesale distributor applying to obtain a license under § [36-11A-27](#):

- (1) The name, full business address, and telephone number of the licensee;
- (2) Any trade or business name used by the licensee;
- (3) The address, telephone number, and the name of any contact person for any facilities used by the licensee for the storage, handling, and distribution of prescription drugs;
- (4) The type of ownership or operation;
- (5) The name of the owner and the operator of the licensee, including:
  - (a) If a person, the name of the person;
  - (b) If a partnership, the name of each partner, and the name of the partnership;
  - (c) If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and
  - (d) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;
- (6) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs;
- (7) The name of the applicant's designated representative for the facility, together with the personal information statement and fingerprints, required pursuant to subdivision (8) for such person;

- (8) Each person required by subdivision (7) to provide a personal information statement and fingerprints, if required, shall provide the following information to the board:
- (a) The person's places of residence for the past seven years;
  - (b) The person's date and place of birth;
  - (c) The person's occupations, positions of employment, and offices held during the past seven years;
  - (d) The principal business and address of any business, corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on;
  - (e) Whether the person has been, during the past seven years, the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;
  - (f) Whether, during the past seven years, the person has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs or had any criminal violations of such laws, together with details concerning any such event;
  - (g) A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party;
  - (h) A description of any misdemeanor or felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant shall, within fifteen days after the disposition of the appeal, submit to the board a copy of the final written order of disposition; and
  - (i) A photograph of the person taken in the previous one hundred eighty days.

The information required pursuant to this section shall be provided under oath.

**Source:** SL 2007, ch 215, § 10.

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**36-11A-29. Inspection of facility--Qualifications of designated representative.**

The board may not issue a wholesale distributor license to an applicant, unless the board or a nationally recognized accreditation program approved by the board:

- (1) Conducts a physical inspection of the facility at the address provided by the applicant as required in subdivision 36-11A-28(1); and
- (2) Determines that the designated representative meets the following qualifications:
  - (a) Is at least twenty-one years of age;
  - (b) Has been employed full time for at least three years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs;
  - (c) Is employed by the applicant full time in a managerial level position;
  - (d) Is actively involved in and aware of the actual daily operation of the wholesale distributor;
  - (e) Is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including sick leave and vacation leave;



- (f) Is serving in the capacity of a designated representative for only one applicant at a time, except where more than one licensed wholesale distributor is co-located in the same facility and such wholesale distributors are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code;
- (g) Does not have any convictions under any federal, state, or local laws relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and
- (h) Does not have any felony convictions under federal or state laws.

**Source:** SL 2007, ch 215, § 11.

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**36-11A-30. Criminal record check.**

The board may require the applicant to submit the fingerprints provided by a person with a license application for a statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the person.

**Source:** SL 2007, ch 215, § 12.

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**36-11A-31. Bond or other security required--Purpose--Exemption--License required for each facility.**

The board shall require every wholesale distributor applying for a license to submit a bond of at least one hundred thousand dollars, or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to a fund established by the board. The board shall establish a fund, separate from its other accounts, in which to deposit the wholesale distributor bonds. Any chain pharmacy warehouse that is not engaged in wholesale distribution is exempt from the bond requirement. The purpose of the bond is to secure payment of any fines or penalties imposed by the board and any fees and costs incurred by the board regarding that license, which are authorized pursuant to statute and which the licensee fails to pay thirty days after the fines, penalties, or costs become final. The board may make a claim against such bond or security until one year after the licensee's license ceases to be valid. A single bond may suffice to cover all facilities operated by the applicant in the state.

If a wholesale distributor distributes prescription drugs from more than one facility, the wholesale distributor shall obtain a license for each facility.

**Source:** SL 2007, ch 215, § 13.

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**36-11A-32. Changes or corrections to required information--Suspension or revocation of license.**

In accordance with each licensure renewal, the board shall send to each wholesale distributor licensed under § [36-11A-27](#) a form setting forth the information that the wholesale distributor provided pursuant to § [36-11A-28](#). Within thirty days of receiving such form, the wholesale distributor shall identify and state under oath to the board any changes or corrections to the information that was provided pursuant to § [36-11A-28](#). Changes in, or corrections to, any information in § [36-11A-28](#) shall be submitted to the board as required by such authority. The board may suspend or revoke the license of a wholesale distributor if such authority determines that the wholesale distributor no longer qualifies for the license issued under § [36-11A-28](#).

**Source:** SL 2007, ch 215, § 14.

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**36-11A-33. Continuing training of designated representative--Confidentiality of information.**

The designated representative identified pursuant to subdivision 36-11A-28(7) shall receive and complete continuing training in applicable federal and state laws governing wholesale distribution of prescription drugs.

The information provided under § [36-11A-28](#) may not be disclosed to any person or entity other than a state board or agency, government board, or government agency, determined to be comparable by the board, provided such licensing authority, government board, or agency needs such information for licensing or monitoring purposes.

**Source:** SL 2007, ch 215, § 15.

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### **[36-11A-34. Returns or exchanges of prescription drugs.](#)**

A wholesale distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy or chain pharmacy warehouse. Returns of expired, damaged, recalled, or otherwise nonsaleable pharmaceutical products shall be distributed by the receiving wholesale distributor only to either the original manufacturer or a third party returns processor. The returns or exchanges of prescription drugs, saleable or otherwise, including any redistribution by a receiving wholesaler, are not subject to the requirement of § [36-11A-39](#), so long as prescription drugs are exempt from tracing requirements under DSCSA. Wholesale distributors and pharmacies shall be held accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

**Source:** SL 2007, ch 215, § 16; SL 2017, ch 174, § 19.

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### **[36-11A-35. Verification that entity to which prescription drugs are to be furnished is licensed.](#)**

A manufacturer or wholesale distributor shall furnish prescription drugs only to a person or entity licensed by the appropriate board. Before furnishing prescription drugs to a person or entity not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person or entity is legally authorized to receive the prescription drugs by contacting the appropriate board.

**Source:** SL 2007, ch 215, § 17.

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### **[36-11A-36. Delivery of prescription drugs only to licensed premises--Exception.](#)**

Prescription drugs furnished by a licensee shall be delivered only to the premises listed on the license. However, the licensee may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

- (1) The identity and authorization of the recipient is properly established; and
- (2) This method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person.

**Source:** SL 2007, ch 215, § 18; SL 2017, ch 174, § 20.

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### **[36-11A-37. Receipt to be signed by authorized hospital pharmacy receiving personnel--Reporting of discrepancies.](#)**

Prescription drugs may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and

quantity of the prescription drug so received. Any discrepancy between receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesale distributor by the next business day after the delivery to the pharmacy receiving area.

**Source:** SL 2007, ch 215, § 19.

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**36-11A-38. Accounts for purchase of prescription drugs.**

A manufacturer or wholesale distributor may not accept payment for, or allow the use of, a person or entity's credit to establish an account for the purchase of prescription drugs from any person other than the owner of record, the chief executive officer, or the chief financial officer listed on the license of a person or entity legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee.

**Source:** SL 2007, ch 215, § 20.

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36-11A-39, 36-11A-40. Repealed by SL 2017, ch 174, §§ 21, 22.

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**36-11A-41. Confirmation of receipt of transaction information, transaction history, and transaction statement.**

Each trading partner who is engaged in the wholesale distribution of a prescription drug including repackagers, but excluding a third-party logistics provider and the original manufacturer of the finished form of the prescription drug, who is provided transaction information, transaction history, and a transaction statement for a prescription drug and attempts to further distribute that prescription drug, shall, before any distribution of a prescription drug occurs, confirm that it has received the transaction information, transaction history, and transaction statement.

**Source:** SL 2007, ch 215, § 23; SL 2017, ch 174, § 23.

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36-11A-42, 36-11A-43. Repealed by SL 2017, ch 174, §§ 24, 25.

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**36-11A-44. Retention of transaction files--Inspection.**

Each file shall be:

- (1) Maintained by the purchaser and the licensee for six years from the date of the transaction; and
- (2) Available for inspection or use within two business days upon a request of an authorized officer of the law.

**Source:** SL 2007, ch 215, § 26; SL 2017, ch 174, § 26.

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**36-11A-45. Cease and desist order for violation--Hearing.**

The board shall issue an order requiring the appropriate person including any distributor or retailer of the drug to immediately cease distribution of the drug within this state if the board finds that there is a reasonable probability that:

- (1) A wholesale distributor, other than a manufacturer, has:
  - (a) Violated a provision of §§ [36-11A-20](#) to [36-11A-46](#), inclusive; or
  - (b) Falsified a transaction document, or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use;
- (2) The prescription drug at issue as a result of a violation in subdivision (1) could cause serious, adverse health consequences or death; and

(3) Other procedures would result in unreasonable delay.

An order under this section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than ten days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

**Source:** SL 2007, ch 215, § 27; SL 2017, ch 174, § 27.

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**36-11A-46. Prohibited acts--Misdemeanor or felony.**

It is unlawful for a person to perform or cause the performance of or aid and abet any of the following acts in this state:

- (1) Failure to obtain a license in accordance with §§ [36-11A-20](#) to [36-11A-46](#), inclusive, or operating without a valid license when a license is required by §§ [36-11A-20](#) to [36-11A-46](#), inclusive;
- (2) If the requirements of § [36-11A-34](#) are applicable and are not met, the purchasing or otherwise receiving a prescription drug from a pharmacy;
- (3) If a state license is required pursuant to § [36-11A-35](#), the sale, distribution, or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug to receive the prescription drug;
- (4) Failure to deliver prescription drugs to specified premises, as required by § [36-11A-36](#);
- (5) Accepting payment or credit for the sale of prescription drugs in violation of § [36-11A-38](#);
- (6) Failure to maintain or provide transaction documentation as required by §§ [36-11A-20](#) to [36-11A-46](#), inclusive;
- (7) Failure to obtain, pass, or verify transaction documentation, as required by §§ [36-11A-20](#) to [36-11A-46](#), inclusive;
- (8) Providing the state or any of its representatives or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within the provisions of §§ [36-11A-20](#) to [36-11A-46](#), inclusive;
- (9) Obtaining or attempting to obtain a prescription drug by fraud, deceit, misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug;
- (10) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the United States Food and Drug Administration, the manufacture, repacking, sale, transfer, delivery, holding, or offering for sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution;
- (11) Except for the wholesale distribution by manufacturers of a prescription drug that has been delivered into commerce pursuant to an application approved under federal law by the United States Food and Drug Administration, the adulteration, misbranding, or counterfeiting of any prescription drug;
- (12) The receipt of any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such drug for pay or otherwise; and
- (13) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded.

Any person who violates this section is guilty of a Class 1 misdemeanor for the first conviction and a Class 6 felony for any subsequent conviction.

**Source:** SL 2007, ch 215, § 28; SL 2017, ch 174, § 28.

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## ARTICLE 20:67

### DRUG DISTRIBUTORS

Chapter	
20:67:01	Definitions.
20:67:02	Licensure requirements.
20:67:03	Drug storage and handling requirements.
20:67:04	Record keeping.
20:67:05	Policies and procedures.
20:67:06	Inspections.
20:67:07	Due process.
20:67:08	Wholesale drug distributor advisory committee, Repealed.

#### CHAPTER 20:67:01

##### DEFINITIONS

Section	
20:67:01:01	Definitions.

**20:67:01:01. Definitions.** Words defined in SDCL 36-11A have the same meaning when used in this article. In addition, terms used in this article mean:

(1) "Applicant," a wholesale or other drug distributor, as provided in SDCL 36-11A-3, represented by a person, including a proprietor, partner, corporate officer or director, or contact person, authorized to complete the application form and certifications;

(2) "DEA," the federal drug enforcement administration;

(3) "Controlled room temperature," a temperature maintained thermostatically between 15 and 30 degrees centigrade or 59 and 86 degrees Fahrenheit;

(4) "Wholesale and other drug distributor," an entity that distributes medications into this state or within this state and includes all trading partners defined in SDCL chapter 36-11A, except those exempted by federal DSCSA.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14.

**Law Implemented:** SDCL 36-11A-1, 36-11A-1.1.

#### CHAPTER 20:67:02

##### LICENSURE REQUIREMENTS

Section	
20:67:02:01	Application and fee.
20:67:02:02	Required application information.
20:67:02:03	Licensure required for each location.
20:67:02:04	Supplemental application information.
20:67:02:05	Controlled substance registration required.
20:67:02:06	Personnel requirements.
20:67:02:07	Denial of licensure when not in public interest.
20:67:02:08	Information on changes to be reported.
20:67:02:09	Temporary license valid for 90 days -- No refund.
20:67:02:10	Out-of-state wholesale or other drug distributor application -- Other state license required.
20:67:02:11	Reciprocal cooperation extended.
20:67:02:12	Exemption allowed.

**20:67:02:01. Application and fee.** A wholesale or other distributor must apply each year to the board, electronically or on a form supplied by the secretary of the board, for a license to engage in distribution of prescription drugs. Each application shall be accompanied by a license fee of \$200.

**Source:** 18 SDR 95, effective November 25, 1991; 24 SDR 160, effective May 26, 1998; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(1),(6).

**Law Implemented:** SDCL 36-11A-7, 36-11A-8.

**20:67:02:02. Required application information.** Applicants must complete the following information as part of the application form:

- (1) The name, full business address, and telephone number of the applicant;
- (2) All trade or business names used by the applicant;
- (3) Address, telephone numbers, and the name of contact person for the facility used by the applicant for the storage, handling, and distribution of prescription drugs;
- (4) The type of ownership or operation, that is, partnership, corporation, or sole proprietorship;
- (5) The name of the owner or operator, or both, of the applicant, including:
  - (a) If a person, the name of the person;
  - (b) If a partnership, the name of each partner and the name of the partnership;
  - (c) If a corporation, the name and title of each corporate officer and director, the corporate names, the name of the state of incorporation, and the name of any parent company;
  - (d) If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;
- (6) Statements pertaining to factors that may determine eligibility for licensure, including if, in the last seven years any of the following have occurred:
  - (a) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;



- (b) Any felony convictions of the applicant under federal, state, or local laws;
- (c) The applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
- (d) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;

(7) A statement certifying that the applicant will operate in a manner prescribed by federal and state law and rules adopted by the board;

(8) The type of distribution;

(9) The type of products distributed; and

(10) The type of entity to which the products are distributed.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(1),(3).

**Law Implemented:** SDCL 36-11A-7, 36-11A-8, 36-11A-28, 36-11A-35.

**20:67:02:03. Licensure required for each location.** Separate licensure is required where separate operations are conducted at more than one location within this state by a single wholesale distributor. Out-of-state wholesale or other drug distributors shipping drugs into this state are required to license each separate location from which drugs are shipped to this state.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(1).

**Law Implemented:** SDCL 36-11A-7, 36-11A-9.

**20:67:02:04. Supplemental application information.** In order to more fully consider qualifications of an applicant, the board may request supplemental information on records that are not a part of the application form.

**Source:** 18 SDR 95, effective November 25, 1991.

**General Authority:** SDCL 36-11A-14(1) to (3).

**Law Implemented:** SDCL 36-11A-7, 36-11A-8, 36-11A-12.

**20:67:02:05. Controlled substance registration required.** Wholesale or other drug distributors that deal in controlled substances shall register with the South Dakota department of health and with the DEA and shall comply with all applicable state, local, and DEA regulations.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(3).

**Law Implemented:** SDCL 36-11A-7, 36-11A-12.

**Cross-Reference:** Annual registration of manufacturers, distributors and dispensers required, SDCL 34-20B-29.

**20:67:02:06. Personnel requirements.** As a condition for receiving and retaining a license, wholesale or other drug distributors shall employ sufficient numbers of personnel with education, training, and experience, or any combination thereof, so that all assigned functions are performed in a manner that

assures that drug product quality, safety, and security will at all times be maintained as required by law. Lists of officers, directors, managers, and other persons in charge of drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications, shall be established and maintained.

**Source:** 18 SDR 95, effective November 25, 199; 45 SDR 86, effective December 24, 20181.

**General Authority:** SDCL 36-11A-14(3),(11).

**Law Implemented:** SDCL 36-11A-7, 36-11A-18, 36-11A-28, 36-11A-33.

**20:67:02:07. Denial of licensure when not in public interest.** The board may deny a license to an applicant if it determines that the granting of such a license would not be in the public interest based on health, safety, and welfare considerations, including:

(1) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(2) Compliance with licensing requirements under previously granted licenses;

(3) Compliance with the requirements to maintain or make available to the board or to federal, state, or local law enforcement officials those records required to be maintained by wholesale or other drug distributors.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(1),(3).

**Law Implemented:** SDCL 36-11A-12.

**Cross-Reference:** Record keeping, ch 20:67:04.

**20:67:02:08. Information on changes to be reported.** Changes in any information required in this chapter shall be submitted to the secretary of the board within 60 days with the exception of routine changes in the names and titles of corporate officers and directors, which may be reported upon license renewal.

**Source:** 18 SDR 95, effective November 25, 1991.

**General Authority:** SDCL 36-11A-14(1),(11).

**Law Implemented:** SDCL 36-11A-7, 36-11A-12.

**20:67:02:09. Temporary license valid for 90 days -- No refund.** Upon the request of the applicant and receipt of a completed application and the license fee as provided in § 20:67:02:01, the secretary of the board may issue a letter granting temporary licensure provided that information contained on the application form shows no apparent reason for denial of licensure and the board has not previously denied, suspended, or revoked a license of the applicant.

The board shall approve or deny the application for license within 90 days after receipt of the application. Upon approval or notice of denial, the temporary license becomes void unless the applicant appeals the decision of the board pursuant to SDCL chapter 1-26. If a temporary license is issued, the license fee may not be refunded if the application is subsequently denied by the board.

**Source:** 18 SDR 95, effective November 25, 1991.

**General Authority:** SDCL 36-11A-14(1),(3),(4).

**Law Implemented:** SDCL 36-11A-7, 36-11A-10.

**20:67:02:10. Out-of-state wholesale or other drug distributor application -- Other state license required.** Out-of-state wholesale or other drug distributors must meet the application and fee requirements of this chapter and must also submit a copy of their wholesale drug distributor's license or its equivalent from the state in which the distributor is located if a license is issued by that state.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(1).

**Law Implemented:** SDCL 36-11A-7, 36-11A-11, 36-11A-28.

**20:67:02:11. Reciprocal cooperation extended.** The board shall cooperate with other states that license and regulate wholesale or other drug or pharmacy distributors to verify information contained on license applications and for the purpose of investigating complaints against distributors located in this state or the sharing of inspection reports, investigative reports, or licensure status if the other state extends the same reciprocal cooperation to the board.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(5).

**Law Implemented:** SDCL 36-11A-11.

**20:67:02:12. Exemption allowed.** An exemption to licensure is allowed when an out-of-state wholesale or other drug distributor supplies a drug to another drug distributor licensed in this state in an emergency. The amount of the distribution allowed is confined to the emergency.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(1).

**Law Implemented:** SDCL 36-11A-2(5).

## CHAPTER 20:67:03

### DRUG STORAGE AND HANDLING REQUIREMENTS

#### Section

20:67:03:01	Facilities.
20:67:03:02	Storage conditions.
20:67:03:03	Examination upon receipt required.
20:67:03:04	Outgoing shipments to be inspected.
20:67:03:05	Quarantine required.
20:67:03:06	Opened containers to be identified.
20:67:03:07	Standards for returned drugs to be met.

**20:67:03:01. Facilities.** All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall meet the following conditions:

- (1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
- (2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a separate quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, recalled, misbranded, or adulterated or that are in immediate or sealed secondary containers that have been opened;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) Be secured from unauthorized entry by:

(a) A well-lighted outside perimeter of the premises;

(b) An alarm system to detect entry after hours; and

(c) A security system that provides protection against theft and diversion, including, if applicable, theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(7),(10).

**Law Implemented:** SDCL 36-11A-7.

**20:67:03:02. Storage conditions.** All prescription drugs shall be stored as required by the labeling of the drugs. If no storage requirements are established for a prescription drug, the drug may be held at controlled room temperature to help ensure that its identity, strength, quality, and purity are not adversely affected. Manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized, as applicable, to document proper storage of prescription drugs.

**Source:** 18 SDR 95, effective November 25, 1991.

**General Authority:** SDCL 36-11A-14(7).

**Law Implemented:** SDCL 36-11A-7.

**20:67:03:03. Examination upon receipt required.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

**Source:** 18 SDR 95, effective November 25, 1991.

**General Authority:** SDCL 36-11A-14(7),(13).

**Law Implemented:** SDCL 36-11A-7.

**20:67:03:04. Outgoing shipments to be inspected.** Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

**Source:** 18 SDR 95, effective November 25, 1991.

**General Authority:** SDCL 36-11A-14(7),(13).

**Law Implemented:** SDCL 36-11A-7.

**20:67:03:05. Quarantine required.** Prescription drugs that are outdated, damaged, deteriorated, recalled, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(7).  
**Law Implemented:** SDCL 36-11A-7, 36-11A-34.

**20:67:03:06. Opened containers to be identified.** Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

**Source:** 18 SDR 95, effective November 25, 1991.  
**General Authority:** SDCL 36-11A-14(7),(13).  
**Law Implemented:** SDCL 36-11A-7.

**20:67:03:07. Standards for returned drugs to be met.** If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.

**Source:** 18 SDR 95, effective November 25, 1991.  
**General Authority:** SDCL 36-11A-14(7),(13).  
**Law Implemented:** SDCL 36-11A-7.

## CHAPTER 20:67:04

### RECORD KEEPING

#### Section

20:67:04:01	Record keeping.
20:67:04:02	Retention and inspection of records.
20:67:04:03	Retrieval of records.
20:67:04:04	Financial records treated as confidential materials.

**20:67:04.01. Record keeping.** Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs, including outdated drugs. These records shall include the following information:

- (1) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;
- (2) The identity and quantity of the drugs received and distributed or disposed of;
- (3) The dates of receipt and distribution or other disposition of the drugs; and
- (4) Documentation of storage conditions as required in § 20:67:03:02.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.  
**General Authority:** SDCL 36-11A-14(8).  
**Law Implemented:** SDCL 36-11A-1.4, 36-11A-7, 36-11A-34, 36-11A-41.

**20:67:04.02. Retention and inspection of records.** Inventories and records required by this chapter may be maintained by manual or electronic means in a form that allows inspection and photocopying of requested records during inspections. All records shall be retained for six years following disposition of the drugs.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(8),(14).

**Law Implemented:** SDCL 36-11A-16, 36-11A-17, 36-11A-44.

**20:67:04.03. Retrieval of records.** Records described in this chapter that are kept at the inspection site at a central location apart from the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.

**Source:** 18 SDR 95, effective November 25, 1991.

**General Authority:** SDCL 36-11A-14(8),(14).

**Law Implemented:** SDCL 36-11A-7, 36-11A-17.

**20:67:04.04. Financial records treated as confidential materials.** Any financial records inspected or photocopied by the board shall be treated as confidential materials and not open to public inspection.

**Source:** 18 SDR 95, effective November 25, 1991.

**General Authority:** SDCL 36-11A-14(2),(13).

**Law Implemented:** SDCL 36-11A-16.

## CHAPTER 20:67:05

### POLICIES AND PROCEDURES

#### Section

20:67:05:01 Policies and procedures to be established.

**20:67:05:01. Policies and procedures to be established.** Wholesale and other drug distributors shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories. Wholesale and other drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement if the deviation is temporary;

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs due to:

(a) Any action initiated at the request of the food and drug administration or any other federal, state, or local law enforcement or governmental agency, including the board;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design;

(3) A procedure to ensure that wholesale and other drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster or other situations of local, state, or national emergency;

(4) A procedure to ensure that any outdated prescription drugs are segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs;

(5) A procedure to keep access from outside the premises to a minimum and well controlled; and

(6) A procedure to limit entry into areas where prescription drugs are held to authorized personnel only.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(7),(10),(12).

**Law Implemented:** SDCL 36-11A-7.

## CHAPTER 20:67:06

### INSPECTIONS

#### Section

20:67:06:01	Regular inspections required.
20:67:06:02	Exemption from inspection.
20:67:06:03	Out-of-state wholesale and other drug distributor exemption.

**20:67:06:01. Regular inspections required.** All drug distributors, including third party logistics providers, located within the state shall be inspected by the board every two years with follow-ups if problems are found. The following areas may be reviewed when inspections are performed:

- (1) Responsibility for operation;
- (2) Policies and procedures;
- (3) Purchases and sales;
- (4) Record keeping;
- (5) Recalls;
- (6) Facilities;
- (7) Security;
- (8) Storage conditions; and
- (9) Returned goods.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(14).

**Law Implemented:** SDCL 36-11A-7, 36-11A-16.

**20:67:06:02. Exemption from inspection.** Wholesale and other drug distributors that have received a satisfactory rating as the result of a full inspection of all operations and procedures by the food and drug administration are exempt from further inspection by the board until any subsequent inspection results in a less than satisfactory rating or until two or more years have passed since the last full inspection by the food and drug administration. Less than satisfactory ratings may include documentation of deficiencies in any drug distribution, repackaging, labeling, quality control, or environmental policies. Deficiencies include any statement which is a part of a compliance report recorded by federal inspection with or without sanctions, penalties, fines, or discipline imposed.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(14).

**Law Implemented:** SDCL 36-11A-7, 36-11A-16.

**20:67:06:03. Out-of-state wholesale and other drug distributor exemption.** The board may exempt from inspection any out-of-state wholesale drug distributor pursuant to § 20:67:06:02 on demonstration of a satisfactory rating on an equivalent inspection conducted by the licensing agency of the state where the distributor is located or other inspection agency recognized by the board.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(14).

**Law Implemented:** SDCL 36-11A-7, 36-11A-11, 36-11A-16, 36-11A-29.

## CHAPTER 20:67:07

### DUE PROCESS

#### Section

20:67:07:01      Designation of registered agent.

**20:67:07:01. Designation of registered agent.** Out-of-state drug distributors shall designate a resident agent in this state for service of process. If an agent is not designated, the secretary of state of this state shall be considered to be its true and lawful agent, upon whom may be served all legal process in any action or proceeding against the out-of-state drug distributor. A copy of any service of process shall be mailed by certified mail, return receipt requested, postage prepaid, at the address the out-of-state wholesale drug distributor has designated on its application for licensure. If any out-of-state wholesale drug distributor is not licensed in this state, service on the secretary of state is sufficient service.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**General Authority:** SDCL 36-11A-14(15).

**Law Implemented:** SDCL 36-11A-7, 36-11A-19.

## CHAPTER 20:67:08

### WHOLESALE DRUG ADVISORY COMMITTEE

(Repealed)

(45 SDR 86, effective December 24, 2018)



Section	
20:67:08:01	Repealed.
20:67:08:02	Repealed.
20:67:08:03	Repealed.
20:67:08:04	Repealed.
20:67:08:05	Repealed.
20:67:08:06	Repealed.

**20:67:08:01. Terms to begin on July 1.** Repealed.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**20:67:08:02. Applicants to be solicited for recommendations.** Repealed.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**20:67:08:03. Recommendations to remain on file.** Repealed.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**20:67:08:04. Board to review recommendations on file.** Repealed.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**20:67:08:05. Unexpired terms to be filled within three months of vacancy.** Repealed.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

**20:67:08:06. Appointees to indicate willingness to serve.** Repealed.

**Source:** 18 SDR 95, effective November 25, 1991; 45 SDR 86, effective December 24, 2018.

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## CHAPTER [34-20B](#)

### DRUGS AND SUBSTANCES CONTROL

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### **34-20B-1. Definitions.**

Terms as used in this chapter mean:

- (1) "Administer," to deliver a controlled drug or substance to the ultimate user or human research subject by injection, inhalation, or ingestion, or by any other means;
- (2) "Agent," an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser and includes a common or contract carrier, public warehouseman, or employee thereof;
- (3) "Control," to add, remove, or change the placement of a drug, substance, or immediate precursor under §§ [34-20B-27](#) and [34-20B-28](#);
- (4) "Counterfeit substance," a controlled drug or substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person or persons who manufactured, distributed, or dispensed such substance and which thereby falsely purports or is represented to be the product of, or to have been distributed by, such other manufacturer, distributor, or dispenser;
- (5) "Deliver" or "delivery," the actual, constructive, or attempted transfer of a controlled drug, substance, or marijuana whether or not there exists an agency relationship;
- (6) "Department," the Department of Health created by chapter [1-43](#);
- (7) "Dispense," to deliver a controlled drug or substance to the ultimate user or human research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for such delivery, and a dispenser is one who dispenses;
- (8) "Distribute," to deliver a controlled drug, substance, or marijuana. A distributor is a person who delivers a controlled drug, substance, or marijuana;
- (9) "Hashish," the resin extracted from any part of any plant of the genus cannabis that contains a delta-9 tetrahydrocannabinol concentration of more than three-tenths of one percent on a dry weight basis;
- (10) "Imprisonment," imprisonment in the state penitentiary unless the penalty specifically provides for imprisonment in the county jail;
- (11) "Manufacture," the production, preparation, propagation, compounding, or processing of a controlled drug or substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. A manufacturer includes any person who packages, repackages, or labels any container of any controlled drug or substance, except practitioners who dispense or compound prescription orders for delivery to the ultimate consumer;
- (12) "Marijuana," all parts of any plant of the genus cannabis, whether growing or not; the seeds thereof; and every compound, manufacture, salt, derivative, mixture, or preparation

- of such plant or its seeds. The term does not include fiber produced from the mature stalks of the plant, or oil or cake made from the seeds of the plant, or the resin when extracted from any part of the plant or cannabidiol in a drug product approved by the United States Food and Drug Administration. The term does not include the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than three-tenths of one percent on a dry weight basis;
- (13) "Narcotic drug," any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
- (a) Opium, coca leaves, and opiates;
  - (b) A compound, manufacture, salt, derivative, or preparation of opium, coca leaves, or opiates;
  - (c) A substance (and any compound, manufacture, salt, derivative, or preparation thereof) which is chemically identical with any of the substances referred to in subsections (a) and (b) of this subdivision;
- except that the term, narcotic drug, as used in this chapter does not include decocainized coca leaves or extracts of coca leaves, which extracts do not contain cocaine or ecgonine;
- (14) "Opiate" or "Opioid," any controlled drug or substance having an addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability;
- (15) "Opium poppy," the plant of the species *papaver somniferum* L., except the seeds thereof;
- (16) "Person," any corporation, association, limited liability company, partnership or one or more individuals;
- (17) "Poppy straw," all parts, except the seeds, of the opium poppy, after mowing;
- (18) "Practitioner," a doctor of medicine, osteopathy, podiatry, optometry, dentistry, or veterinary medicine licensed to practice their profession, or pharmacists licensed to practice their profession; physician assistants certified to practice their profession; certified nurse practitioners, certified nurse midwives, and certified registered nurse anesthetists to practice their profession; government employees acting within the scope of their employment; and persons permitted by certificates issued by the department to distribute, dispense, conduct research with respect to, or administer a substance controlled by this chapter;
- (19) "Prescribe," an order of a practitioner for a controlled drug or substance.
- (20) "Production," the manufacture, planting, cultivation, growing, or harvesting of a controlled drug or substance;
- (21) "State," the State of South Dakota;
- (22) "Ultimate user," a person who lawfully possesses a controlled drug or substance for personal use or for the use of a member of the person's household or for administration to an animal owned by the person or by a member of the person's household;
- (23) "Controlled substance analogue," any of the following:
- (a) A substance that differs in its chemical structure to a controlled substance listed in or added to the schedule designated in schedule I or II only by substituting one or more hydrogens with halogens or by substituting one halogen with a different halogen; or
  - (b) A substance that is an alkyl homolog of a controlled substance listed in or added to schedule I or II; or
  - (c) A substance intended for human consumption; and
    - (i) The chemical structure of which is substantially similar to the chemical structure of a controlled substance in schedule I or II;
    - (ii) Which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II; or

- (iii) With respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in schedule I or II;

However, the term, controlled substance analogue, does not include a controlled substance or any substance for which there is an approved new drug application.

**Source:** SL 1970, ch 229, § 6; SDCL Supp, § 39-17-44; SL 1972, ch 216, § 1; SL 1974, ch 266, § 1; L 1975, ch 256; SL 1976, ch 158, § [42-9](#); SL 1981, ch 260, §§ 1, 2; SL 1981, ch 375, §§ 18, 19; SL 1984, ch 239, § 1; SL 1985, ch 185, § 2; SL 1986, ch 306, § 11; SL 1989, ch 21, § 158; SL 1989, ch 293, § 1; SL 1994, ch 351, § 61; SL 1995, ch 191, § 4; SL 2004, ch 229, § 1; SL 2013, ch 156, § 1, eff. Mar. 6, 2013; SL 2017, ch 155, § 1; SL 2017, ch 171, § 50; SL 2019, ch 148, § 1, eff. Feb. 19, 2019; SL 2020, ch 176, § 23, eff. Mar. 27, 2020; SL 2020, ch 169, § 4.

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### **34-20B-2. Drug defined.**

For the purposes of this chapter, unless the context otherwise requires, "drug" means:

- (1) Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them, unless the department shall determine that any such article is inconsistent with the provisions of this chapter or are not appropriate to conditions which exist in this state, and by regulation specifically excludes any such article;
- (2) Articles intended for use, or used, in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
- (3) Articles (other than food) intended to affect, or affecting, the structure or any function of the body of man or other animals; and
- (4) Articles intended for use, or used, as a component of any articles specified in clauses (1), (2), or (3) of this section, but does not include mechanical devices or their components, parts, or accessories.

**Source:** SL 1970, ch 229, § 6 (j); SDCL Supp, § 39-17-45.

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### **34-20B-3. Controlled drug or substance defined.**

For the purposes of this chapter, unless the context otherwise requires, "controlled drug or substance" means a drug, substance, or immediate precursor in Schedules I through IV of §§ [34-20B-11](#) to [34-20B-26](#), inclusive.

**Source:** SL 1970, ch 229, § 6 (e); SDL Supp, § 39-17-46; SL 1976, ch 158, § [42-10](#).

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### **34-20B-3.1. Controlled substance analogue.**

A controlled substance analogue shall be treated as a controlled substance in schedule I.

**Source:** SL 2013, ch 156, § 2, eff. Mar. 6, 2013.

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#### **34-20B-4. Precursor defined.**

For the purposes of this chapter, unless the context otherwise requires, "precursor" or "immediate precursor" means a substance which the department has found to be and by regulation designates as being a principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used, in the manufacture of a controlled drug or substance, the control of which is necessary to prevent, curtail, or limit such manufacture.

**Source:** SL 1970, ch 229, § 6 (u); SDCL Supp, § 39-17-47.

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#### **34-20B-4.1. Anabolic steroid defined.**

An anabolic steroid is any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids, that promotes muscle growth and includes:

- (1) Androstenediol:
  - (a) 3 $\beta$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androstane;
  - (b) 3 $\alpha$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androstane;
- (2) Androstenedione (5 $\alpha$ -androst-3,17-dione);
- (3) Androstenediol:
  - (a) 1-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androst-1-ene);
  - (b) 1-androstenediol (3 $\alpha$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androst-1-ene);
  - (c) 4-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxy-androst-4-ene);
  - (d) 5-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxy-androst-5-ene);
- (4) Androstenedione:
  - (a) 1-androstenedione ([5 $\alpha$ ]-androst-1-en-3,17-dione);
  - (b) 4-androstenedione (androst-4-en-3,17-dione);
  - (c) 5-androstenedione (androst-5-en-3,17-dione);
- (5) Bolasterone (7 $\alpha$ ,17 $\alpha$ -dimethyl-17 $\beta$ -hydroxyandrost-4-en-3-one);
- (6) Boldenone (17 $\beta$ -hydroxyandrost-1,4,-diene-3-one);
- (7) Calusterone (7 $\beta$ ,17 $\alpha$ -dimethyl-17 $\beta$ -hydroxyandrost-4-en-3-one);
- (8) Clostebol (4-chloro-17 $\beta$ -hydroxyandrost-4-en-3-one);
- (9) Dehydrochloromethyltestosterone (4-chloro-17 $\beta$ -hydroxy-17 $\alpha$ -methyl-androst-1,4-dien-3-one);
- (10) ?1-dihydrotestosterone (a.k.a. "1-testosterone") (17 $\beta$ -hydroxy-5 $\alpha$ -androst-1-en-3-one);
- (11) 4-dihydrotestosterone (17 $\beta$ -hydroxy-androst-3-one);
- (12) Drostanolone (17 $\beta$ -hydroxy-2 $\alpha$ -methyl-5 $\alpha$ -androst-3-one);
- (13) Ethylestrenol (17 $\alpha$ -ethyl-17 $\beta$ -hydroxyestr-4-ene);
- (14) Fluoxymesterone (9-fluoro-17 $\alpha$ -methyl-11 $\beta$ ,17 $\beta$ -dihydroxyandrost-4-en-3-one);
- (15) Formebolone (2-formyl-17 $\alpha$ -methyl-11 $\alpha$ ,17 $\beta$ -dihydroxyandrost-1,4-dien-3-one);
- (16) Furazabol (17 $\alpha$ -methyl-17 $\beta$ -hydroxyandrostano[2,3-c]- furazan);
- (17) 13 $\beta$ -ethyl-17 $\alpha$ -hydroxygon-4-en-3-one;
- (18) 4-hydroxytestosterone (4,17 $\beta$ -dihydroxy-androst-4-en-3-one);
- (19) 4-hydroxy-19-nortestosterone (4,17 $\beta$ -dihydroxy-estr-4-en-3-one);
- (20) Mestanolone (17 $\alpha$ -methyl-17 $\beta$ -hydroxy-5 $\alpha$ -androst-3-one);
- (21) Mesterolone (1 $\alpha$ -methyl-17 $\beta$ -hydroxy-[5 $\alpha$ ]-androst-3-one);
- (22) Methandienone (17 $\alpha$ -methyl-17 $\beta$ -hydroxyandrost-1,4-dien-3-one);
- (23) Methandriol (17 $\alpha$ -methyl-3 $\beta$ ,17 $\beta$ -dihydroxyandrost-5-ene);
- (24) Methenolone (1-methyl-17 $\beta$ -hydroxy-5 $\alpha$ -androst-1-en-3-one);
- (25) 17 $\alpha$ -methyl-3 $\beta$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androstane;
- (26) 17 $\alpha$ -methyl-3 $\alpha$ ,17 $\beta$ -dihydroxy-5 $\alpha$ -androstane;
- (27) 17 $\alpha$ -methyl-3 $\beta$ ,17 $\beta$ -dihydroxyandrost-4-ene;
- (28) 17 $\alpha$ -methyl-4-hydroxynandrolone (17 $\alpha$ -methyl-4-hydroxy-17 $\beta$ -hydroxyestr-4-en-3-one);



- (29) Methyldienolone (17a-methyl-17 $\beta$ -hydroxyestra-4,9(10)-dien-3-one);
- (30) Methyltrienolone (17a-methyl-17 $\beta$ -hydroxyestra-4,9-11-trien-3-one);
- (31) Methyltestosterone (17a-methyl-17 $\beta$ -hydroxyandrost-4-en-3-one);
- (32) Mibolerone (7a,17a-dimethyl-17 $\beta$ -hydroxyestr-4-en-3-one);
- (33) 17a-methyl- $\Delta$ 1-dihydrotestosterone (17 $\beta$ -hydroxy-17a-methyl-5a-androst-1-en-3-one)  
(also known as 17-a-methyl-1-testosterone);
- (34) Nandrolone (17 $\beta$ -hydroxyestr-4-en-3-one);
- (35) Norandrostenediol:
  - (a) 19-nor-4-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxyestr-4-ene);
  - (b) 19-nor-4-androstenediol (3a,17 $\beta$ -dihydroxyestr-4-ene);
  - (c) 19-nor-5-androstenediol (3 $\beta$ ,17 $\beta$ -dihydroxyestr-5-ene);
  - (d) 19-nor-5-androstenediol (3a,17 $\beta$ -dihydroxyestr-5-ene);
- (36) Norandrostenedione:
  - (a) 19-nor-4-androstenedione (estr-4-en-3,17-dione);
  - (b) 19-nor-5-androstenedione (estr-5-en-3,17-dione);
- (37) Norbolethone (13 $\beta$ ,17a-diethyl-17 $\beta$ -hydroxygon-4-en-3-one);
- (38) Norclostebol (4-chloro-17 $\beta$ -hydroxyestr-4-en-3-one);
- (39) Norethandrolone (17a-ethyl-17 $\beta$ -hydroxyestr-4-en-3-one);
- (40) Normethandrolone (17a-methyl-17 $\beta$ -hydroxyestr-4-en-3-one);
- (41) Oxandrolone (17a-methyl-17 $\beta$ -hydroxy-2-oxa-[5a]-androstan-3-one);
- (42) Oxymesterone (17a-methyl-4,17 $\beta$ -dihydroxyandrost-4-en-3-one);
- (43) Oxymetholone (17a-methyl-2-hydroxymethylene-17 $\beta$ -hydroxy-[5a]-androstan-3-one);
- (44) Stanozolol (17a-methyl-17 $\beta$ -hydroxy-[5a]-androst-2-eno[3,2-c]-pyrazole);
- (45) Stenbolone (17 $\beta$ -hydroxy-2-methyl-[5a]-androst-1-en-3-one);
- (46) Testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);
- (47) Testosterone (17 $\beta$ -hydroxyandrost-4-en-3-one);
- (48) Tetrahydrogestrinone (13 $\beta$ ,17a-diethyl-17 $\beta$ -hydroxygon-4,9,11-trien-3-one);
- (49) Trenbolone (17 $\beta$ -hydroxyestr-4,9,11-trien-3-one);
- (50) Boldione (androsta-1,4-diene-3,17-dione);
- (51) Desoxymethyltestosterone (17a-methyl-5a-androst-2-en-17a-ol) (also known as madol);
- (52) 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione);
- (53) Prostanazol (17 $\beta$ -hydroxy-5a-androstano[3,2-c]pyrazole);
- (54) Methasterone (2a,17a-dimethyl-5a-androstan-17 $\beta$ -ol-3-one);
- (55) 5a-Androstan-3,6,17-trione;
- (56) 6-bromo-androstan-3,17-dione;
- (57) 6-bromo-androsta-1,4-diene-3,17-dione;
- (58) 4-chloro-17a-methyl-androsta-1,4-diene-3,17 $\beta$ -diol;
- (59) 4-chloro-17a-methyl-androst-4-ene-3 $\beta$ ,17 $\beta$ -diol;
- (60) 4-chloro-17a-methyl-17 $\beta$ -hydroxy-androst-4-en-3-one;
- (61) 4-chloro-17a-methyl-17 $\beta$ -hydroxy-androst-4-ene-3,11-dione;
- (62) 4-chloro-17a-methyl-androsta-1,4-diene-3,17 $\beta$ -diol;
- (63) 2a,17a-dimethyl-17 $\beta$ -hydroxy-5a-androstan-3-one;
- (64) 2a,17a-dimethyl-17 $\beta$ -hydroxy-5 $\beta$ -androstan-3-one;
- (65) 2a,3a-epithio-17a-methyl-5a-androstan-17 $\beta$ -ol;
- (66) [3,2-c]-furazan-5a-androstan-17 $\beta$ -ol;
- (67) 3 $\beta$ -hydroxy-estra-4,9,11-trien-17-one;
- (68) 17a-methyl-androst-2-ene-3,17 $\beta$ -diol;
- (69) 17a-methyl-androsta-1,4-diene-3,17 $\beta$ -diol;
- (70) Estra-4,9,11-triene-3,17-dione;
- (71) 18a-Homo-3-hydroxy-estra-2,5(10)-dien-17-one;
- (72) 6a-Methyl-androst-4-ene-3,17-dione;
- (73) 17a-Methyl-androstan-3-hydroxyimine-17 $\beta$ -ol;

- (74) 17 $\alpha$ -Methyl-5 $\alpha$ -androstan-17 $\beta$ -ol;
- (75) 17 $\beta$ -Hydroxy-androstano[2,3-d]isoxazole;
- (76) 17 $\beta$ -Hydroxy-androstano[3,2-c]isoxazole;
- (77) 4-Hydroxy-androst-4-ene-3,17-dione[3,2-c]pyrazole-5 $\alpha$ -androstan-17 $\beta$ -ol;
- (78) [3,2-c]pyrazole-androst-4-en-17 $\beta$ -ol;
- (79) [3,2-c]pyrazole-5 $\alpha$ -androstan-17 $\beta$ -ol; and
- (80) Any salt, ester, or ether of a drug or substance described or listed in this section, if that salt, ester, or ether promotes muscle growth.

The term, anabolic steroid, as defined in this section, does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species. However, if any person prescribes, dispenses, or distributes such a steroid for human use, the person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this section.

**Source:** SL 1990, ch 269, § 1; SL 1992, ch 245, § 4; SL 2006, ch 179, § 1, eff. Feb. 9, 2006; SL 2010, ch 174, § 1, eff. Feb. 24, 2010; SL 2013, ch 156, § 3, eff. Mar. 6, 2013; SL 2016, ch 175, § 1, eff. Feb. 18, 2016.

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34-20B-5 to 34-20B-9. Superseded.

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#### **34-20B-10. Scheduled substances to be controlled--Nomenclature in schedules.**

All controlled drugs and substances listed in §§ [34-20B-11](#) to [34-20B-26](#), inclusive, are hereby controlled. The schedules set forth in said sections include the controlled drugs and substances listed or to be listed, by whatever official name, common or usual name, or trade name designated.

**Source:** SL 1970, ch 229, §§ 7, 8; SDCL Supp, § 39-17-53.

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#### **34-20B-11. Criteria for inclusion of substance in Schedule I.**

To be included within Schedule I, a substance shall have:

- (1) A high potential for abuse;
- (2) No accepted medical use in the United States; and
- (3) A lack of accepted safety for use under medical supervision.

**Source:** SL 1970, ch 229, § 8 (a); SDCL Supp, § 39-17-54; SL 1976, ch 158, § [42-11](#).

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#### **34-20B-12. Specific substances included in Schedule I.**

Any of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, is included in Schedule I, unless specifically excepted, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

- (1) Acetylmethadol;
- (2) Allylprodine;
- (3) Alphacetylmethadol, except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate or LAAM;
- (4) Alphameprodine;
- (5) Alphamethadol;

- (6) Benzethidine;
- (7) Betacetylmethadol;
- (8) Betameprodine;
- (9) Betamethadol;
- (10) Betaprodine;
- (11) Clonitazene;
- (12) Dextromoramide;
- (13) Diampromide;
- (14) Diethylambutene;
- (15) Dimenoxadol;
- (16) Dimepheptanol;
- (17) Dimethylambutene;
- (18) Dioxaphetyl butyrate;
- (19) Dipipanone;
- (20) Ethylmethylthiambutene;
- (21) Etonitazene;
- (22) Etoxidine;
- (23) Furethidine;
- (24) Hydroxypethidine;
- (25) Ketobemidone;
- (26) Levomoramide;
- (27) Levophenacetylmorphan;
- (28) Mecloqualone;
- (29) Morpheridine;
- (30) Noracymethadol;
- (31) Norlevorphanol;
- (32) Normethadone;
- (33) Norpipanone;
- (34) Phenadoxone;
- (35) Phenampromide;
- (36) Phenomorphan;
- (37) Phenoperidine;
- (38) Piritramide;
- (39) Proheptazine;
- (40) Properidine;
- (41) Racemoramide;
- (42) Trimeperidine;
- (43) Methaqualone;
- (44) N-benzylpiperazine;
- (45) 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]-2-piperidinylidene]-benzenesulfonamide, W-18; N,N-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine, also known as isotonitazene;
- (46) 2-(2-(4-butoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine (butonitazene);
- (47) 2-(2-(4-ethoxybenzyl)-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine (etodesnitazene, etazene);
- (48) N,N-diethyl-2-(2-(4-fluorobenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (flunitazene);
- (49) N,N-diethyl-2-(2-(4-methoxybenzyl)-1H-benzimidazol-1-yl)ethan-1-amine (metodesnitazene);
- (50) N,N-diethyl-2-(2-(4-methoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (metonitazene);

- (51) 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole (N-pyrrolidino etonitazene, etonitazepyne); and
- (52) N,N-diethyl-2-(5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl)ethan-1-amine (protonitazene).

**Source:** SL 1970, ch 229, § 8 (a) (1); SDCL Supp, § 39-17-55; SL 1977, ch 315, § 1; SL 1985, ch 278, § 50; SL 1994, ch 278, § 1; SL 2003, ch 183, § 1; SL 2018, ch 203, § 1, eff. Feb. 8, 2018; SL 2021, ch 144, § 1, eff. Feb. 17, 2021; SL 2022, ch 109, § 1, eff. Feb. 9, 2022.

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### **34-20B-13. Opium derivatives and opiates included in Schedule I.**

Any of the following opium derivatives and opiates, their salts, isomers, esters, ethers, and salts of isomers, esters, and ethers, is included in Schedule I, unless specifically excepted, whenever the existence of such salts, isomers, esters, ethers, and salts of isomers, esters, and ethers is possible within the specific chemical designation:

- (1) Acetylcodeine;
- (2) Benzylmorphine;
- (3) Codeine methylbromide;
- (4) Codeine-N-Oxide;
- (5) Desomorphine;
- (6) Drotebanol;
- (7) Heroin;
- (8) Hydromorphanol;
- (9) Methydesorphine;
- (10) Methylhydromorphanol;
- (11) Morphine methylbromide;
- (12) Morphine methylsulfonate;
- (13) Morphine-N-Oxide;
- (14) Myrophine;
- (15) Nicocodeine;
- (16) Nicomorphine;
- (17) Normorphine;
- (18) Thebacon;
- (19) 3-Methylfentanyl;
- (20) Fentanyl analogs. Any substituted derivatives of fentanyl unless specifically excepted, listed in another schedule, or contained within a pharmaceutical product approved by the United States Food and Drug Administration, that is structurally related to fentanyl by modification in any one or more of the following ways:
  - (a) By replacement of the phenyl portion of the phenethyl group by any monocycle whether or not further substituted in or on the monocycle;
  - (b) By substitution in or on or replacement of the phenethyl group with alkyl, alkenyl, alkoxy, hydroxyl, halo, haloalkyl, amino, or nitro groups;
  - (c) By substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxyl, halo, haloalkyl, amino, phenyl, substituted phenyl, or nitro groups;
  - (d) By replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; or
  - (e) By the replacement of the N-propionyl group by another acyl group.

Some trade and other names: N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (acetyl fentanyl); N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-2-carboxamide (furan fentanyl); N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryl fentanyl, acryloylfentanyl); N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide (ortho-fluorofentanyl or 2-fluorofentanyl); N-(1-

phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (tetrahydrofuranyl fentanyl); 2-methoxy-N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide (methoxyacetyl fentanyl); N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (cyclopropyl fentanyl), N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (valeryl fentanyl); N-(1-phenethylpiperidin-4-yl)-N-phenylbutyramide (butyl fentanyl); N-[1-(2-hydroxy-2-thiophen-2-ylethyl)piperidin-4-yl]-N-phenylpropanamide (Beta-Hydroxythiofentanyl); N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (para-fluorobutyryl fentanyl); N-(4-methoxyphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (para-methoxybutyryl fentanyl); N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide (para-chloroisobutyryl fentanyl); N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide (isobutyryl fentanyl); N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide (cyclopentyl fentanyl); N-(2-fluorophenyl)-2-methoxy-N-(1-phenethylpiperidin-4-yl)acetamide (ocfentanyl); N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide (para-fluoroisobutyryl fentanyl); (E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide (Crotonyl fentanyl);

- (21) 1-Methyl-4-phenyl-4-propionoxypiperidine;
- (22) 1-(2-phenethyl)-4-phenyl-4-acetoxypiperidine;
- (23) 3,4-dichloro-N[2-(dimethylamino)cyclohexyl]-N-methylbenzamide (U-47700);
- (24) 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (MT-45);
- (25) 3,4-dichloro-N-[1-(dimethylamino)cyclohexylmethyl]benzamide (AH-7921);
- (26) 2-(2,4-dichlorophenyl)-N-2-(dimethylamino)cyclohexyl)-N-methylacetamide (U-48800);
- (27) Trans-3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methyl-benzamide (U-49900);
- (28) N-[2-(dimethylamino)cyclohexyl]-N-methyl-1,3-benzodioxole-5-carboxamide (Methylenedioxy-U-47700);
- (29) 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-isopropylbenzamide (Isopropyl-U-47700);
- (30) 1-(1,2-Diphenylethyl)piperidine (Diphenidine);
- (31) N-Ethyl-1,2-diphenylethylamine (Ephenidine); and
- (32) 1-(1-(1-(4-bromophenyl)ethyl)piperidin-4-yl)-1,3-dihydro-2H-benzo[d]imidazol-2-one (Brorphine).

**Source:** SL 1970, ch 229, § 8(a)(1); SDCL Supp, § 39-17-56; SL 1977, ch 315, § 2; SL 1981, ch 261, § 4; SL 1987, ch 255, § 1; SL 1988, ch 282, § 1; SL 2016, ch 175, § 2, eff. Feb. 18, 2016; SL 2017, ch 156, § 1, eff. Feb. 3, 2017; SL 2018, ch 203, § 2, eff. Feb. 8, 2018; SL 2019, ch 148, § 2, eff. Feb. 19, 2019; SL 2020, ch 144, § 1, eff. Mar. 9, 2020; SL 2021, ch 144, § 2, eff. Feb. 17, 2021.

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#### **34-20B-14. Hallucinogenic substances included in Schedule I.**

Any material, compound, mixture, or preparation that contains any quantity of the following hallucinogenic substances, their salts, isomers, and salts of isomers, is included in Schedule I, unless specifically excepted, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) Bufotenine;
- (2) Diethyltryptamine (DET);
- (3) Dimethyltryptamine (DMT);
- (4) 5-methoxy-N, N-Dimethyltryptamine (5-MeO-DMT);
- (5) 5-methoxy-3, 4-methylenedioxy amphetamine;
- (6) 4-bromo-2, 5-dimethoxyamphetamine;
- (7) 4-methoxyamphetamine;
- (8) 4-methoxymethamphetamine;
- (9) 4-methyl-2, 5-dimethoxyamphetamine;
- (10) Hashish and hash oil;
- (11) Ibogaine;

- (12) Lysergic acid diethylamide;
- (13) Mescaline;
- (14) N-ethyl-3-piperidyl benzilate;
- (15) N-methyl-3-piperidyl benzilate;
- (16) 1-(2-thienyl)cyclohexyl piperidine (TCP);
- (17) Peyote, except that when used as a sacramental in services of the Native American church in a natural state which is unaltered except for drying or curing and cutting or slicing, it is hereby excepted;
- (18) Psilocybin;
- (19) Psilocyn;
- (20) Tetrahydrocannabinol, other than that which occurs in industrial hemp as defined in § [38-35-1](#) or marijuana in its natural and unaltered state, including any compound, except nabilone or compounds listed under a different schedule, structurally derived from 6,6 dimethyl-benzo[c]chromene by substitution at the 3- position with either alkyl (C3 to C8), methyl cycloalkyl, or adamantyl groups, whether or not the compound is further modified in any of the following ways:
  - (a) By partial to complete saturation of the C-ring; or
  - (b) By substitution at the 1-position with a hydroxyl or methoxy group; or
  - (c) By substitution at the 9-position with a hydroxyl, methyl, or methylhydroxyl group; or
  - (d) By modification of the possible 3-alkyl group with a 1,1 dimethyl moiety, a 1,1 cyclic moiety, an internal methylene group, an internal acetylene group, or a terminal halide, cyano, azido, or dimethylcarboxamido group.

Some trade and other names: JWH-051; JWH-057; JWH-133; JWH-359; HHC; AM-087; AM-411; AM-855, AM-905; AM-906; AM-2389; HU-210; HU-211; HU-243; HU-336;

- (21) 3, 4, 5-trimethoxy amphetamine;
- (22) 3, 4-methylenedioxy amphetamine;
- (23) 3-methoxyamphetamine;
- (24) 2, 5-dimethoxyamphetamine;
- (25) 2-methoxyamphetamine;
- (26) 2-methoxymethamphetamine;
- (27) 3-methoxymethamphetamine;
- (28) Phencyclidine;
- (29) 3, 4-methylenedioxymethamphetamine (MDMA);
- (30) 3, 4-methylenedioxy-N-ethylamphetamine;
- (31) N-hydroxy-3, 4-methylenedioxyamphetamine;
- (32) 4-methylaminorex (also known as 2-Amino-4-methyl/x-5-phenyl-2-oxazoline);
- (33) 2,5 Dimethoxy-4-ethylamphetamine;
- (34) N,N-Dimethylamphetamine;
- (35) 1-(1-(2-thienyl)cyclohexyl)pyrrolidine;
- (36) Aminorex;
- (37) 4,4'-Dimethylaminorex (4,4'-DMAR; 4,5-dihydro-4-methyl-5-(4-methylphenyl)-2-oxazolamine; 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine);
- (38) Cathinone and other variations, defined as any compound, material, mixture, preparation or other product unless listed in another schedule or an approved FDA drug (e.g. bupropion, pyrovalerone), structurally derived from 2-aminopropan-1-one by substitution at the 1-position with either phenyl, naphthyl, or thiophene ring systems, whether or not the compound is further modified in any of the following ways:
  - (a) By substitution in the ring system to any extent with alkyl, alkylendioxy, alkoxy, haloalkyl, hydroxyl, or halide substituents, whether or not further substituted in the ring system by one or more other univalent substituents;
  - (b) By substitution at the 3-position with an acyclic alkyl substituent;

- (c) By substitution at the 2-amino nitrogen atom with alkyl, dialkyl, benzyl, or methoxybenzyl groups or by inclusion of the 2-amino nitrogen atom in a cyclic structure.

Some trade or other names: methcathinone, 4-methyl-N-methylcathinone (mephedrone); 3,4-methylenedioxy-N-methylcathinone (methylone); 3,4-methylenedioxypropylvalerone (MDPV); Naphthylpyrovalerone (naphyrone); 4-fluoromethcathinone (flephedrone); 4-methoxymethcathinone (methedrone; Bk-PMMA); Ethcathinone (N-Ethylcathinone); 3,4-methylenedioxyethcathinone (ethylone); Beta-keto-N-methyl-3,4-benzodioxolylbutanamine (butylone); N,N-dimethylcathinone (metamfepramone); Alpha-pyrrolidinopropiophenone (alpha-PPP); 4-methoxy-alpha-pyrrolidinopropiophenone (MOPPP); 3,4-methylenedioxyalphapyrrolidinopropiophenone (MDPPP); Alpha-pyrrolidinovalerophenone (alpha-PVP); 3-fluoromethcathinone; 4-Methyl-alpha-pyrrolidinobutiophenone (MPBP); Methyl-alpha-pyrrolidinopropiophenone (MPPP); Methyl-alpha-pyrrolidino-hexanophenone (MPHP); Buphedrone; Methyl-N-ethylcathinone; Pentedrone; Dimethylmethcathinone (DMMC); Dimethylethcathinone (DMEC); Methylenedioxyethcathinone (MDMC); Pentylone; Ethylethcathinone; Ethylmethcathinone; Fluoroethcathinone; methyl-alpha-pyrrolidinobutiophenone (MPBP); Methylethcathinone (MEC); Methylenedioxy-alpha-pyrrolidinobutiophenone (MDPBP); Methoxymethcathinone (MOMC); Methylbuphedrone (MBP); Benzedrone (4-MBC); Dibutylone (DMBDB); Dimethylone (MDDMA); Diethylcathinone; Eutylone (EBDB); N-ethyl-N-Methylcathinone; N-ethylbuphedrone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one (N-Ethylpentylone); 4'-Methyl-alpha-pyrrolidinopropiophenone (4-MEPPP, MPPP or MaPPP); alpha-Pyrrolidinobutiophenone (a;PBP); 1-(1,3-benzodioxol-5-yl)-2-(tert-butylamino)propan-1-one (Tertylone); 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)hexan-1-one (N-ethyl Hexylone); 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (Pentylone);

(39) 2,5-Dimethoxy-4-ethylamphetamine (DOET);

(40) Alpha-ethyltryptamine;

(41) 4-Bromo-2,5-dimethoxy phenethylamine;

(42) 2,5-dimethoxy-4-(n-propylthiophenethylamine (2C-T-7);

(43) 1-(3-trifluoromethylphenyl) piperazine (TFMPP);

(44) Alpha-methyltryptamine (AMT);

(45) 5-methoxy-N,N-diisopropyltryptamine (5-MeO-DIPT);

(46) 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT);

(47) Synthetic cannabinoids. Any material, compound, mixture, or preparation that is not listed as a controlled substance in another schedule, is not an FDA-approved drug, and contains any quantity of the following substances, their salts, isomers (whether optical, positional, or geometric), homologues, modifications of the indole ring by nitrogen heterocyclic analog substitution or nitrogen heterocyclic analog substitution of the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, cumyl, or propionaldehyde structure, and salts of isomers, homologues, and modifications, unless specifically excepted, whenever the existence of these salts, isomers, homologues, modifications, and salts of isomers, homologues, and modifications is possible within the specific chemical designation:

- (a) Naphthoylindoles. Any compound containing a 2-(1-naphthoyl)indole or 3-(1-naphthoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, cyanoalkyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, (tetrahydropyran-4-yl)methyl, benzyl, or halobenzyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the naphthyl ring to any extent.

Some trade or other names: JWH-015; 1-pentyl-3-(1-naphthoyl)indole (JWH-018); 1-hexyl-3-(1-naphthoyl)indole (JWH-019); 1-butyl-3-(1-naphthoyl)indole (JWH-

073); 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081); 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122); 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200); JWH-210; JWH-398; 1-pentyl-3-(1-naphthoyl)indole (AM-678); 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM-2201); WIN 55-212; JWH-004; JWH-007; JWH-009; JWH-011; JWH-016; JWH-020; JWH-022; JWH-046; JWH-047; JWH-048; JWH-049; JWH-050; JWH-070; JWH-071; JWH-072; JWH-076; JWH-079; JWH-080; JWH-082; JWH-094; JWH-096; JWH-098; JWH-116; JWH-120; JWH-148; JWH-149; JWH-164; JWH-166; JWH-180; JWH-181; JWH-182; JWH-189; JWH-193; JWH-198; JWH-211; JWH-212; JWH-213; JWH-234; JWH-235; JWH-236; JWH-239; JWH-240; JWH-241; JWH-258; JWH-262; JWH-386; JWH-387; JWH-394; JWH-395; JWH-397; JWH-399; JWH-400; JWH-412; JWH-413; JWH-414; JWH-415; JWH-424; AM-678; AM-1220; AM-1221; AM-1235; AM-2232, THJ-2201;

- (b) Naphthylmethylindoles. Any compound containing a 1H-indol-2-yl-(1-naphthyl)methane or 1H-indol-3-yl-(1-naphthyl)methane structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, cyanoalkyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, (tetrahydropyran-4-yl)methyl, benzyl, or halobenzyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the naphthyl ring to any extent.

Some trade or other names: JWH-175; JWH-184; JWH-185; JWH-192; JWH-194; JWH-195; JWH-196; JWH-197; JWH-199;

- (c) Phenylacetylindoles. Any compound containing a 2-phenylacetylindole or 3-phenylacetylindole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl, cyanoalkyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, (tetrahydropyran-4-yl)methyl, benzyl, or halobenzyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the phenyl ring to any extent.

Some trade or other names: 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18); 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (RCS-8); 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250); 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203); JWH-167; JWH-201; JWH-202; JWH-204; JWH-205; JWH-206; JWH-207; JWH-208; JWH-209; JWH-237; JWH-248; JWH-249; JWH-251; JWH-253; JWH-302; JWH-303; JWH-304; JWH-305; JWH-306; JWH-311; JWH-312; JWH-313; JWH-314; JWH-315; JWH-316; Cannabipiperidiethanone;

- (d) Benzoylindoles. Any compound containing a 2-(benzoyl)indole or 3-(benzoyl)indole structure with substitution at the nitrogen atom of the indole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, cyanoalkyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, (tetrahydropyran-4-yl)methyl, benzyl, or halobenzyl group, whether or not further substituted on the indole ring to any extent and whether or not substituted on the phenyl ring to any extent.

Some trade or other names: 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM-694); 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19); Pravadoline (WIN 48,098); 1-pentyl-3-[(4-methoxy)-benzoyl]indole (RCS-4); AM-630; AM-661; AM-2233; AM-1241;

- (e) Naphthoypyrroles. Any compound containing a 2-(1-naphthoyl)pyrrole or 3-(1-



naphthoyl)pyrrole structure with substitution at the nitrogen atom of the pyrrole ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, cyanoalkyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, (tetrahydropyran-4-yl)methyl, benzyl, or halobenzyl group, whether or not further substituted on the pyrrole ring to any extent and whether or not substituted on the naphthyl ring to any extent.

Some trade or other names: JWH-307; JWH-030; JWH-031; JWH-145; JWH-146; JWH-147; JWH-150; JWH-156; JWH-242; JWH-243; JWH-244; JWH-245; JWH-246; JWH-292; JWH-293; JWH-308; JWH-309; JWH-346; JWH-348; JWH-363; JWH-364; JWH-365; JWH-367; JWH-368; JWH-369; JWH-370; JWH-371; JWH-373; JWH-392;

- (f) Naphthylmethylindenes. Any compound containing a naphthylideneindene structure with substitution at the 3-position of the indene ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, cyanoalkyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, (tetrahydropyran-4-yl)methyl, benzyl, or halobenzyl group, whether or not further substituted on the indene ring to any extent and whether or not substituted on the naphthyl ring to any extent.

Some trade or other names: JWH-171; JWH-176; JWH-220;

- (g) Cyclohexylphenols. Any compound containing a 2-(3-hydroxycyclohexyl)phenol structure with substitution at the 5-position of the phenolic ring by an alkyl, haloalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, or 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, (tetrahydropyran-4-yl)methyl, benzyl, or halobenzyl group, whether or not substituted on the cyclohexyl ring to any extent.

Some trade or other names: 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP 47, 497 and homologues, which includes C8); cannabicyclohexanol; CP-55,490; CP-55,940; CP-56,667;

- (h) (6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl) 6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol. Some trade or other names: HU-210;

- (i) 2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-naphthalenyl.

Some trade or other names: WIN 55, 212-2;

- (j) Substituted Acetylindoles. Any compound containing a 2-acetyl indole or 3-acetyl indole structure substituted at the acetyl by replacement of the methyl group with a tetramethylcyclopropyl, adamantyl, benzyl, cumyl, or propionaldehyde substituent whether or not further substituted on the tetramethylcyclopropyl, adamantyl, benzyl, cumyl, or propionaldehyde substituent to any extent and whether or not further substituted at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, (tetrahydropyran-4-yl)methyl, benzyl, or halobenzyl group whether or not further substituted on the indole ring to any extent.

Some trade and or names: (1-Pentylindol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144); (1-(5-fluoropentyl)indol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (XLR-11); (1-(2-morpholin-4-ylethyl)-1H-indol-3-yl)-(2,2,3,3-tetramethylcyclopropyl)methanone (A-796,260); 1-[(N-methylpiperidin-2-yl)methyl]-3-(adamant-1-oyl)indole (AM-1248); 1-Pentyl-3-(1-adamantoyl)indole (AB-001 and JWH-018 adamantyl analog); AM-679;

- (k) Substituted Carboxamide Indole. Any compound containing a 2-carboxamide indole or 3-carboxamide indole structure substituted at the nitrogen of the carboxamide

with a tetramethylcyclopropyl, naphthyl, adamantyl, cumyl, phenyl, or propionaldehyde substituent, whether or not further substituted on the tetramethylcyclopropyl, adamantyl, cumyl, naphthyl, phenyl, or propionaldehyde substituent to any extent and whether or not further substituted at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, (tetrahydropyran-4-yl)methyl, benzyl, or halobenzyl group whether or not further substituted on the indole ring to any extent.

Some trade and other names: JWH-018 adamantyl carboxamide; STS-135; MN-18; 5-Fluoro-MN-18, 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide (5F-CUMYL-P7AICA); N-(Adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (5F-APINACA); methyl (2R)-2-[[1-(5-fluoropentyl)indazole-3-carbonyl]amino]-3,3-dimethylbutanoate (5F-ADB); N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (AB-CHMINACA); 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (4-CN-CUMYL-BUTINACA); N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (ADB-CHMINACA or MAB-CHMINACA); methyl (2S)-2-[[1-[4-fluorophenyl)methyl]indazole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-FUBINACA); methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate (MMB-CHMICA); methyl (2S)-2-[[1-[4-fluorophenyl)methyl]indazole-3-carbonyl]amino]-3-methylbutanoate (AMB-FUBINACA); Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (5F-AMB); methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (5F-MDMB-PICA); methyl (S)-3,3-dimethyl-2-[[1-(pent-4-enyl)indazole-3-carbonyl]amino]butanoate (MDMB-4en-PINACA); methyl 2-(1-(4-fluorobutyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (4F-MDMB-BUTINACA);

- (l) Substituted Carboxylic Acid Indole. Any compound containing a 1H-indole-2-carboxylic acid or 1H-indole-3-carboxylic acid substituted at the hydroxyl group of the carboxylic acid with a phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, quinolinyl, isquinolinyl, cumyl, or propionaldehyde substituent whether or not further substituted on the phenyl, benzyl, naphthyl, adamantyl, cyclopropyl, cumyl, quinolinyl, isquinolinyl, or propionaldehyde substituent to any extent and whether or not further substituted at the nitrogen atom of the indole ring by an alkyl, haloalkyl, cyanoalkyl, alkenyl, cycloalkylmethyl, cycloalkylethyl, 1-(N-methyl-2-piperidinyl)methyl, 2-(4-morpholinyl)ethyl, 1-(N-methyl-2-pyrrolidinyl)methyl, 1-(N-methyl-3-morpholinyl)methyl, tetrahydropyranylmethyl, benzyl, or halo benzyl group whether or not further substituted on the indole ring to any extent.

Some trade and other names: Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (NM2201);

- (48) 6,7-dihydro-5H-indeno-(5,6-d)-1,3-dioxol-6-amine (MDAI);  
 (49) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E);  
 (50) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D);  
 (51) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C);  
 (52) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I);  
 (53) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2);  
 (54) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4);  
 (55) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H);  
 (56) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N);  
 (57) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P);  
 (58) Substituted phenethylamine. Any compound, unless specifically exempt, listed as a

controlled substance in another schedule or an approved FDA drug, structurally derived from phenylethan-2-amine by substitution on the phenyl ring in any of the following ways, that is to say--by substitution with a fused methylenedioxy, fused furan, or fused tetrahydrofuran ring system; by substitution with two alkoxy groups; by substitution with one alkoxy and either one fused furan, tetrahydrofuran, or tetrahydropyran ring system; by substitution with two fused ring systems from any combination of the furan, tetrahydrofuran, or tetrahydropyran ring systems; whether or not the compound is further modified in any of the following ways:

- (a) By substitution on the phenyl ring by any halo, hydroxyl, alkyl, trifluoromethyl, alkoxy, or alkylthio groups;
- (b) By substitution on the 2-position by any alkyl groups; or
- (c) By substitution on the 2-amino nitrogen atom with acetyl, alkyl, dialkyl, benzyl, methoxybenzyl, or hydroxybenzyl groups.

Some trade and other names: 2-(2,5-dimethoxy-4-(methylthio)phenyl)ethanamine (2C-T or 4-methylthio-2,5- dimethoxyphenethylamine); 1-(2,5-dimethoxy-4-iodophenyl)propan-2-amine (DOI or 2, 5-Dimethoxy-4- iodoamphetamine); 1-(4-Bromo-2,5-dimethoxyphenyl)-2-aminopropane (DOB or 2,5-Dimethoxy-4- bromoamphetamine); 1-(4-chloro-2,5-dimethoxy-phenyl)propan-2-amine (DOC or 2,5-Dimethoxy-4- chloroamphetamine); 2-(4-bromo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (2C-B- NBOMe; 25B-NBOMe or 2,5-Dimethoxy-4-bromo-N-(2-methoxybenzyl)phenethylamine); 2-(4-iodo-2,5- dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (2C-I-NBOMe; 25I-NBOMe or 2,5- Dimethoxy-4-iodo-N-(2-methoxybenzyl)phenethylamine); N-(2-Methoxybenzyl)-2-(3,4,5-trimethoxyphenyl)ethanamine (Mescaline-NBOMe or 3,4,5-trimethoxy-(2-methoxybenzyl)phenethylamine); 2-(4-chloro-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine (2C-C-NBOMe; 25C-NBOMe or 2,5- Dimethoxy-4-chloro-N-(2-methoxybenzyl)phenethylamine); 2-(7-Bromo-5-methoxy-2,3-dihydro-1-benzofuran-4-yl)ethanamine (2CB-5-hemiFLY); 2-(8-bromo-2,3,6,7-tetrahydrofuro [2,3-f][1]benzofuran-4-yl)ethanamine (2C-B-FLY); 2-(10-Bromo-2,3,4,7,8,9-hexahydropyrano[2,3-g]chromen-5-yl)ethanamine (2C-B-butterFLY); -(2-Methoxybenzyl)-1-(8-bromo-2,3,6,7-tetrahydrobenzo[1,2-b:4,5-b ]difuran-4-yl)-2-aminoethane (2C-B-FLY-NBOMe); 1-(4-Bromofuro[2,3-f][1]benzofuran-8-yl)propan-2-amine (bromo- benzodifuranyl-isopropylamine or bromo-dragonFLY); -(2-Hydroxybenzyl)-4-iodo-2,5- dimethoxyphenethylamine (2C-I-NBOH or 25I-NBOH); 5-(2-Aminopropyl)benzofuran (5-APB); 6(2-Aminopropyl)benzofuran (6-APB); 5-(2-Aminopropyl)-2,3-dihydrobenzofuran (5-APDB); 6-(2-Aminopropyl)-2,3-dihydrobenzofuran (6-APDB);

- (59) Substituted tryptamines. Any compound, unless specifically exempt, listed as a controlled substance in another schedule or an approved FDA drug, structurally derived from 2-(1H-indol-3-yl)ethanamine (i.e, tryptamine) by mono- or di-substitution of the amine nitrogen with alkyl or alkenyl groups or by inclusion of the amino nitrogen atom in a cyclic structure whether or not the compound is further substituted at the alpha- position with an alkyl group or whether or not further substituted on the indole ring to any extent with any alkyl, alkoxy, halo, hydroxyl, or acetoxy groups.

Some trade and other names: 5-methoxy-N,N-diallyltryptamine (5-MeO-DALT); 4-acetoxy-N,N- dimethyltryptamine (4-AcO-DMT or O-Acetylpsilocin); 4-hydroxy-N-methyl-N-ethyltryptamine (4-HO- MET); 4-hydroxy-N,N-diisopropyltryptamine (4-HO-DIPT); 5-methoxy-N-methyl-N-isopropyltryptamine (5-MeO-MiPT);

- (60) Naphthalen-1-yl-(4-pentyloxynaphthalen-1-yl)methanone (CB-13);
- (61) N-Adamantyl-1-pentyl-1H-Indazole-3-carboxamide (AKB 48);
- (62) 1-(4-Fluorophenyl)piperazine (pFPP);
- (63) 1-(3-Chlorophenyl)piperazine (mCPP);
- (64) 1-(4-Methoxyphenyl)piperazine (pMeOPP);
- (65) 1,4-Dibenzylpiperazine (DBP);

- (66) Isopentadrono;
- (67) Fluoromethamphetamine;
- (68) Fluoroamphetamine;
- (69) Fluorococaine;
- (70) 1-pentyl-8-quinolinyl ester-1H-indole-3-carboxylic acid (PB-22);
- (71) 1-(5-fluoropentyl)-8-quinolinyl ester-1H-indole-3-carboxylic acid (5 Fluoro-PB-22);
- (72) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide (AB-PINACA);
- (73) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (5 Fluoro-AB- PINACA);
- (74) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (AB-FUBINACA);
- (75) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indole-3-carboxamide (ADB-PINACA (ADBICA));
- (76) N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indole-3-carboxamide (5 Fluoro-ADB-PINACA (5 Fluoro-ADBICA));
- (77) N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (ADB-FUBINACA); and
- (78) N-(1-carbamoyl-2-methyl-propyl)-2-(5-fluoropentyl)-5-(4-fluorophenyl)pyrazole-3-carboxamide (5-Fluoro- 3,5-AB-PFUPPYCA).

**Source:** SL 1970, ch 229, § 8(a)(1); SDCL Supp, § 39-17-57; SL 1973, ch 259; SL 1976, ch 158, §§ 42-12, 42-13; SL 1977, ch 315, § 3; SL 1979, ch 238, § 1; SL 1987, ch 255, § 2; SL 1988, ch 282, § 2; SL 1989, ch 293, § 2; SL 1990, ch 270, § 1; SL 1993, ch 247, § 1; SL 1994, ch 278, § 2; SL 2003, ch 183, § 2; SL 2004, ch 230, § 1; SL 2011, ch 160, § 1, eff. Feb. 24, 2011; SL 2012, ch 183, § 1, eff. Feb. 23, 2012; SL 2013, ch 156, § 4, eff. Mar. 6, 2013; SL 2014, ch 165, § 1, eff. Feb. 10, 2014; SL 2015, ch 180, § 1, eff. Feb. 18, 2015; SL 2019, ch 148, § 3, eff. Feb. 19, 2019; SL 2020, ch 176, § 24, eff. Mar. 27, 2020; SL 2021, ch 144, § 3, eff. Feb. 17, 2021; SL 2022, ch 109, § 2, eff. Feb. 9, 2022.

**34-20B-15. Criteria for inclusion of substances in Schedule II.**

To be included within Schedule II, a substance shall have:

- (1) A high potential for abuse,
- (2) Currently accepted medical use in the United States, or currently accepted medical use with severe restrictions, and
- (3) Abuse which may lead to severe psychic or physical dependence.

**Source:** SL 1970, ch 229, § 8 (b); SDCL Supp, § 39-17-58; SL 1976, ch 158, § 42-14.

**34-20B-16. Substances included in Schedule II.**

Any of the following substances, including their salts, isomers, and salts of isomers, is included in Schedule II except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

- (1) Opium (except when it meets the requirements of subdivision [34-20B-23\(7\)](#) or [34-20B-26\(5\)](#)), coca leaves, and opiate;
- (2) Any salt, compound, derivative, or preparation of opium, coca leaves (including cocaine), or opiate, excluding apomorphine, dextrophan, naloxone, naloxegol, naldemedine,

- nalbuphine, nalmeffene, naltrexone, 6β- naltrexol, and samidorphan;
- (3) Any salt, compound, derivative, or preparation thereof that is chemically equivalent or identical with any of the substances referred to in subdivisions (1) and (2), except that these substances may not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine; and may not include the isoquinoline alkaloids of opium;
  - (4) Opium poppy and poppy straw;
  - (5) Amphetamine;
  - (6) Methamphetamine;
  - (7) Amobarbital;
  - (8) Pentobarbital;
  - (9) Secobarbital;
  - (10) Methylphenidate;
  - (11) Phenmetrazine;
  - (12) Etorphine;
  - (13) Diprenorphine;
  - (14) Deleted by SL 2000, ch 170, § 1;
  - (15) Nabilone;
  - (16) Glutethimide;
  - (17) Phencyclidine immediate precursors:
    - (a) 1-phenylcyclohexylamine;
    - (b) 1-piperidinocyclohexanecarbonitrile (PCC);
  - (18) Lisdexamfetamine, its salts, isomers, and salts of its isomers;
  - (19) Tapentadol; and
  - (20) Dronabinol [(-)-delta-9-trans tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the United States Food and Drug Administration.

**Source:** SL 1970, ch 229, § 8 (b) (1); SDCL Supp, § 39-17-59; SL 1977, ch 315, § 4; SL 1978, ch 249, § 1; SL 1981, ch 13, § 9; SL 1981, ch 261, § 1; SL 1985, ch 278, § 51; SL 1986, ch 284; SL 1987, ch 255, § 3; SL 1992, ch 245, § 1; SL 1993, ch 247, § 2; SL 2000, ch 170, § 1; SL 2008, ch 170, § 1, eff. Feb. 13, 2008; SL 2010, ch 174, § 2, eff. Feb. 24, 2010; SL 2012, ch 183, § 2, eff. Feb. 23, 2012; SL 2015, ch 180, § 2, eff. Feb. 18, 2015; SL 2016, ch 175, § 3, eff. Feb. 18, 2016; SL 2018, ch 203, § 3, eff. Feb. 8, 2018; SL 2021, ch 144, § 4, eff. Feb. 17, 2021; SL 2022, ch 109, § 3, eff. Feb. 9, 2022.

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#### **34-20B-17. Opiates included in Schedule II.**

Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, is included in Schedule II, unless specifically excepted, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

- (1) Alphaprodine;
- (2) Anileridine;
- (3) Bezitramide;
- (4) Diphenoxylate;
- (5) Fentanyl;
- (6) Isomethadone;
- (7) Levomethorphan;
- (8) Levorphanol;
- (9) Metazocine;
- (10) Methadone;
- (11) Methadone-intermediate, 4-cyano-2-dimethylamine-1, 4-diphenyl butane;

- (12) Moramide-intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid;
- (13) Pethidine;
- (14) Pethidine-intermediate, A, 4-cyano-1-methyl-4-phenylpiperidine;
- (15) Pethidine-intermediate, B, ethyl-4-phenylpiperidine-4-carboxylate;
- (16) Pethidine-intermediate, C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
- (17) Phenazocine;
- (18) Piminodine;
- (19) Racemethorphan;
- (20) Racemorphan;
- (21) Sufentanil;
- (22) Alfentanil;
- (23) Carfentanil;
- (24) Levo-alpha-acetylmethadol, also known as levo-alpha-acetylmethadyl acetate or LAAM;
- (25) Remifentanil;
- (26) Oxymorphone;
- (27) Oripavine (3-O-demethylthebaine or 6,7,8,14-tetrahydro-4,5-alpha-epoxy-6-methoxy-17-methylmorphinan-3-ol);
- (28) 4-anilino-N-phenethylpiperidine (ANPP);
- (29) Morphine, except when it meets subdivision [34-20B-23\(8\)](#);
- (30) Hydrocodone (Dihydrocodeinone);
- (31) Codeine, except when it meets subdivision [34-20B-23\(1\)](#), [34-20B-23\(2\)](#), or [34-20B-26\(1\)](#);
- (32) Dihydrocodeine, except when it meets subdivision [34-20B-23\(5\)](#) or [34-20B-26\(2\)](#);
- (33) Ethylmorphine, except when it meets subdivision [34-20B-23\(6\)](#) or [34-20B-26\(3\)](#);
- (34) Oxycodone;
- (35) Hydromorphone;
- (36) Thiafentanil;
- (37) Noroxymorphone;
- (38) N-phenyl-N-(piperidin-4-yl)propionamide (norfentanyl); and
- (39) Oliceridine (N-[(3-methoxythiophen-2-yl)methyl] (2-[(9R)-9-(pyridin-2-yl)-6-oxaspiro [4.5]decan-9-yl]ethyl)amine fumarate).

**Source:** SL 1970, ch 229, § 8 (b) (1); SDCL Supp, § 39-17-60; SL 1985, ch 278, § 52; SL 1987, ch 255, § 4; SL 1989, ch 293, § 3; SL 1994, ch 278, § 3; SL 2002, ch 167, § 1; SL 2007, ch 194, § 1, eff. Feb. 1, 2007; SL 2008, ch 170, § 2, eff. Feb. 13, 2008; SL 2011, ch 160, § 2, eff. Feb. 24, 2011; SL 2015, ch 180, § 3, eff. Feb. 18, 2015; SL 2017, ch 156, § 2, eff. Feb. 3, 2017; SL 2020, ch 144, § 2, eff. Mar. 9, 2020; SL 2021, ch 144, § 5, eff. Feb. 17, 2021.

### **34-20B-18. Criteria for inclusion of substances in Schedule III.**

To be included within Schedule III, a substance shall have:

- (1) A potential for abuse less than the substances listed in Schedules I and II;
- (2) Well documented and approved medical use in the United States; and
- (3) Abuse which may lead to moderate or low physical dependence or high psychological dependence.

**Source:** SL 1970, ch 229, § 8 (c); SDCL Supp, § 39-17-61; SL 1976, ch 158, § 42-15.

### **34-20B-19. Stimulants specifically included in Schedule III.**

Any material, compound, mixture, or preparation is included in Schedule III which contains any quantity of the following substances having a potential for abuse associated with a stimulant

effect on the central nervous system:

- (1) Benzphetamine;
- (2) Chlorphentermine;
- (3) Phendimetrazine;
- (4) Ephedrine.

**Source:** SL 1970, ch 229, § 8 (c); SDCL Supp, § 39-17-62; SL 1977, ch 315, § 5; SL 1993, ch 247, § 3; SL 1995, ch 195, § 1; SL 1997, ch 202, § 1.

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#### **34-20B-19.1. Ephedrine defined.**

For the purposes of § [34-20B-19](#), the term, ephedrine includes ephedra, herbs and herbal products that contain ephedrine alkaloids, including ma huang, Chinese ephedra, ephedra sinica, ephedra herb powder, epitonin, or any extract of those substances, but the term does not include any drug that contains ephedrine and is lawfully sold, transferred, or furnished over the counter with or without a prescription pursuant to § [34-20B-21](#).

**Source:** SL 2004, ch 231, § 1.

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#### **34-20B-20. Depressants specifically included in Schedule III.**

Any material, compound, mixture, or preparation is included in Schedule III that contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

- (1) Any substance that contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid, except those substances that are specifically listed in other schedules;
- (2) Chloral betaine;
- (3) Chloral hydrate;
- (4) Chlorhexadol;
- (5) Lysergic acid;
- (6) Lysergic acid amide;
- (7) Methyprylon;
- (8) Sulfondiethylmethane;
- (9) Sulfonethylmethane;
- (10) Sulfonmethane;
- (11) Amobarbital, pentobarbital, and secobarbital in suppository dosage form;
- (12) Gamma hydroxy butyrate;
- (13) Dronabinol in sesame oil and encapsulated in a gelatin capsule in a drug product approved for marketing by the United States Food and Drug Administration;
- (14) Buprenorphine;
- (15) Embutramide;
- (16) Perampanel [2-(2-oxo-1-phenyl-5-pyridin-2-yl-1,2-dihydropyridin-3-yl) benzonitrile], including its salts, isomers, and salts of isomers.

**Source:** SL 1970, ch 229, § 8 (c) (1); SDCL Supp, § 39-17-63; SL 1973, ch 260; SL 1979, ch 238, § 2; SL 1980, ch 240, § 1; SL 1992, ch 245, § 2; SL 1993, ch 247, § 4; SL 1999, ch 174, § 1; SL 2000, ch 170, § 2; SL 2003, ch 183, § 3; SL 2007, ch 194, § 2, eff. Feb. 1, 2007; SL 2014, ch 165, § 2, eff. Feb. 10, 2014; SL 2018, ch 203, § 4, eff. Feb. 8, 2018.

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#### **34-20B-20.1. Gamma hydroxyl butyrate defined.**

For the purposes of § [34-20B-20](#), the term, gamma hydroxyl butyrate, includes gamma-butyrolactone, 1,4- butanediol or any other substances which convert to gamma hydroxyl butyrate upon ingestion. However, the term does not include any product which is lawfully used for mechanical, industrial, manufacturing, or scientific purposes.

**Source:** SL 2006, ch 180, § 1.

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#### **34-20B-21. Exception from Schedule III of stimulants and depressants used in medicinal preparations.**

The department may by rules promulgated pursuant to chapter [1-26](#) except any compound, mixture, or preparation containing any stimulant, depressant substance, or anabolic steroid listed in §§ [34-20B-19](#), [34-20B-20](#), and [34-20B-22](#) if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a stimulant, depressant, or anabolic steroid effect. Such admixtures shall be included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the substances which do have a stimulant, depressant, or anabolic steroid effect.

**Source:** SL 1970, ch 229, § 8 (c); SDCL Supp, § 39-17-64; SL 1993, ch 247, § 5; SL 1997, ch 202, § 2.

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#### **34-20B-22. Specific substances included in Schedule III.**

The following are included in Schedule III:

- (1) Nalorphine;
- (2) Preparations which contain both Tiletamine and Zolazepam;
- (3) Anabolic steroids as listed in § [34-20B-4.1](#);
- (4) Ketamine.

**Source:** SL 1970, ch 229, § 8 (c); SDCL Supp, § 39-17-65; SL 1971, ch 224, §§ 1, 2; SL 1988, ch 282, § 3; SL 1992, ch 245, § 5; SL 1993, ch 247, § 6; SL 2000, ch 170, § 3.

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#### **34-20B-23. Narcotics specifically included in Schedule III.**

Any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs or any salts thereof is included in Schedule III:

- (1) Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of isoquinoline alkaloid of opium;
- (2) Not more than 1.80 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts;
- (3) Deleted by SL 2015, ch 180, § 4;
- (4) Deleted by SL 2015, ch 180, § 4;
- (5) Not more than 1.80 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts;
- (6) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts;



- (7) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, non-narcotic ingredients in recognized therapeutic amounts; and
- (8) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams with one or more active, non-narcotic ingredients in recognized therapeutic amounts.

**Source:** SL 1970, ch 229, § 8 (c); SDCL Supp, § 39-17-66; SL 2015, ch 180, § 4, eff. Feb. 18, 2015.

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**34-20B-24. Criteria for inclusion of substances in Schedule IV.**

To be included within Schedule IV, a substance shall have:

- (1) A low potential for abuse relative to the substances listed in Schedule III;
- (2) Currently accepted medical use in the United States; and
- (3) Limited physical dependence or psychological dependence liability or potential, or both, relative to the substances listed in Schedule III.

**Source:** SL 1970, ch 229, § 8 (d); SDCL Supp, § 39-17-67; SL 1976, ch 158, § 42-16.

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**34-20B-25. Substances included in Schedule IV.**

The following are included in Schedule IV:

- (1) Chlordiazepoxide, but not including librax (chlordiazepoxide hydrochloride and clindinium bromide) or menrium (chlordiazepoxide and water soluble esterified estrogens);
- (2) Clonazepam;
- (3) Clorazepate;
- (4) Diazepam;
- (5) Flunitrazepam;
- (6) Flurazepam;
- (7) Mebutamate;
- (8) Oxazepam;
- (9) Prazepam;
- (10) Lorazepam;
- (11) Triazolam;
- (12) Any substance which contains any quantity of a benzodiazepine, or salt of benzodiazepine, except substances which are specifically listed in other schedules;
- (13) Alprazolam;
- (14) Midazolam;
- (15) Temazepam;
- (16) Cathine;
- (17) Fencamfamine;
- (18) Fenproporex;
- (19) Mefenorex;
- (20) Pyrovalerone;
- (21) Propoxyphene;
- (22) Pentazocine;
- (23) Diethylpropion;
- (24) Ethchlorvynol;
- (25) Ethinamate;
- (26) Fenfluramine;

- (27) Mazindol;
- (28) Mephobarbital;
- (29) Methohexitol;
- (30) Paraldehyde;
- (31) Pemoline;
- (32) Petrichloral;
- (33) Phentermine;
- (34) Barbital;
- (35) Phenobarbital;
- (36) Meprobamate;
- (37) Zolpidem;
- (38) Butorphanol;
- (39) Modafinil, including its salts, isomers, and salts of isomers;
- (40) Sibutramine;
- (41) Zaleplon;
- (42) Dichloralphenazone;
- (43) Zopiclone (also known as eszopiclone), including its salts, isomers, and salts of isomers;
- (44) Pregabalin;
- (45) Lacosamide;
- (46) Fospropofol, including its salts, isomers, and salts of isomers;
- (47) Clobazam;
- (48) Carisoprodol, including its salts, isomers, and salts of isomers;
- (49) Ezogabine, [2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester], including its salts, isomers, and salts of isomers;
- (50) Lorcaserin, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible;
- (51) Alfaxalone, 5[alpha]-pregnan-3[alpha]-ol-11,20-dione, including its salts, isomers, and salts of isomers;
- (52) Tramadol, 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers and salts of these isomers;
- (53) Suvorexant, including its salts, isomers, and salts of isomers;
- (54) Eluxadolone, (5-[[[(2S)-2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl]][(1S)-1-(4-phenyl-1H-imidazol-2-yl)ethyl]amino]methyl)-2-methoxybenzoic acid) including its optical isomers and its salts, isomers, and salts of isomers;
- (55) Brivaracetam;
- (56) Solriamfetol (2-amino-3-phenylpropyl carbamate; benzenepropanol, beta-amino-, carbamate (ester)), including its salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible;
- (57) Brexanolone, (3[alpha]-hydroxy-5[alpha]-pregnan-20-one), including its salts, isomers, and salts of isomers whenever the existence of the salts, isomers, and salts of isomers is possible;
- (58) Cenobamate ([[(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate; 2H-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alphaR)-; carbamic acid (R)-(+)-1-(2-chlorophenyl)-2-(2H-tetrazol-2-yl)ethyl ester);
- (59) Lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl)-benzamide];
- (60) Lemborexant, including its salts, isomers, and salts of isomers;
- (61) Remimazolam, and
- (62) Serdexmethylphenidate.

**Source:** SL 1977, ch 315, § 6; SL 1978, ch 249, §§ 2, 3; SL 1980, ch 240, § 2; SL 1981, ch 261, § 3; SL 1985, ch 278, § 53; SL 1987, ch 255; SL 1989, ch 293, § 4; SL 1990, ch 270, § 2; SL 1992, ch

245, § 3; SL 1993, ch 247, § 7; SL 1994, ch 278, § 4; SL 1995, ch 191, § 2; SL 1999, ch 174, § 2; SL 2000, ch 170, § 4; SL 2002, ch 167, § 2; SL 2003, ch 183, § 4; SL 2006, ch 179, § 2, eff. Feb. 9, 2006; SL 2010, ch 174, § 3, eff. Feb. 24, 2010; SL 2012, ch 183, § 3, eff. Feb. 23, 2012; SL 2013, ch 156, § 5, eff. Mar. 6, 2013; SL 2015, ch 180, § 5, eff. Feb. 18, 2015; SL 2016, ch 175, § 4, eff. Feb. 18, 2016; SL 2017, ch 156, § 3, eff. Feb. 3, 2017; SL 2017, ch 155, § 2; SL 2019, ch 148, § 4, eff. Feb. 19, 2019; SL 2020, ch 144, § 3, eff. Mar. 9, 2020; SL 2021, ch 144, § 6, eff. Feb. 17, 2021; SL 2022, ch 109, § 4, eff. Feb. 9, 2022.

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**34-20B-26. Narcotic compounds specifically included in Schedule IV.**

Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs is included in Schedule IV which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

- (1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams;
- (2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams;
- (3) Not more than 50 milligrams of ethylmorphine per 100 milliliters or per 100 grams;
- (4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;
- (5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams, or not more than 5 milligrams per dosage unit; and
- (6) Not more than 1 milligram of difenoxin and not less than twenty-five micrograms of atropine sulfate per dosage unit.

**Source:** SL 1970, ch 229, § 8 (d) (1); SDCL Supp, § 39-17-68; SL 1980, ch 240, § 3; SL 1981, ch 261, § 2; SL 1990, ch 270, § 3; SL 2015, ch 180, § 6, eff. Feb. 18, 2015.

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**34-20B-27. Recommendations for addition, deletion, or rescheduling of scheduled substances.**

The department shall make recommendations to the Legislature that a substance be added, deleted, or rescheduled when the department determines that such substance has a different potential for abuse.

**Source:** SL 1970, ch 229, § 7 (a); SDCL Supp, § 39-17-69; 9SL 1976, ch 158, § 42-17.

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**34-20B-28. Substances not subject to control as precursors of precursors.**

If the department designates a substance as an "immediate precursor," substances which are precursors of such designated immediate precursors shall not be subject to control solely because they are precursors of the controlled precursor.

**Source:** SL 1970, ch 229, § 7 (c); SDCL Supp, § 39-17-71.

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**34-20B-28.1. Definition of terms applicable to code imprinted drugs.**

Terms used in §§ [34-20B-28.2](#) to [34-20B-28.6](#), inclusive, unless the context plainly otherwise requires, mean:

- (1) "Code imprint," a series of letters or numbers assigned by the manufacturer or distributor to a

- specific drug, or marks or monograms unique to the manufacturer or distributor of the drug, or both;
- (2) "Distributor," a person who distributes for resale a drug in solid dosage form under his own label even though he is not the actual manufacturer of the drug;
  - (3) "Legend drug," any drug defined by section 503(b) of the Federal Food, Drug and Cosmetic Act, as amended on January 15, 1980, and under which definition its label is required to bear the statement "Caution: Federal law prohibits dispensing without prescription";
  - (4) "Solid dosage form," capsules or tablets intended for oral use.

**Source:** SL 1980, ch 241, § 1.

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**34-20B-28.2. Code imprint required.**

No legend drug in solid dosage form may be manufactured or distributed in this state unless it is clearly marked or imprinted with a code imprint identifying the drug and the manufacturer or distributor of the drug.

**Source:** SL 1980, ch 241, § 2.

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**34-20B-28.3. Manufacturers' and distributors' identifying listings.**

All manufacturers and distributors of legend drugs in solid dosage form shall provide upon request to the Board of Pharmacy a listing of all such legend drugs identifying by code imprint the manufacturer and the specific type of drug. Such listing shall at all times be kept current by all manufacturers and distributors subject to §§ [34-20B-28.1](#) to [34-20B-28.6](#), inclusive.

**Source:** SL 1980, ch 241, § 3.

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**34-20B-28.4. Exemptions--Granting on appropriate showing--Inclusion in listings.**

The Board of Pharmacy may grant exemptions from the requirements of §§ [34-20B-28.1](#) to [34-20B-28.6](#), inclusive, upon application by any drug manufacturer or distributor showing size, physical characteristics, or other unique characteristics which render the application of a code imprint to a legend drug subject to §§ [34-20B-28.1](#) to [34-20B-28.6](#), inclusive, impractical or impossible. Any such exemption granted by the board shall be included by the manufacturer or distributor in the listing required by § [34-20B-28.3](#), describing the physical characteristics and type of drug to which the exemption relates.

**Source:** SL 1980, ch 241, § 4.

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**34-20B-28.5. Contraband--Seizure and forfeiture.**

All legend drugs in solid dosage form that are possessed, distributed, sold, or offered for sale in violation of the provisions of §§ [34-20B-28.1](#) to [34-20B-28.6](#), inclusive, shall be deemed contraband and shall be seized by the Board of Pharmacy and summarily forfeited to the state.

**Source:** SL 1980, ch 241, § 5.

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**34-20B-28.6. Dispensing or sale without code imprint--Misdemeanor.**

It is a Class 2 misdemeanor for a person to dispense, sell or otherwise provide to any other person any legend drug in solid dosage form that fails to comply with §§ [34-20B-28.1](#) to [34-20B-28.5](#), inclusive.

**Source:** SL 1980, ch 241, § 6.

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**34-20B-29. Registration of prescribers, manufacturers, distributors, and dispensers of controlled drug or substance.**

Any person who prescribes, manufactures, distributes, or dispenses any controlled drug or substance within this state or who proposes to engage in the prescribing, manufacture, distribution, or dispensing of any controlled drug or substance within this state, shall obtain a registration issued by the department according to the rules promulgated under this chapter.

**Source:** SL 1970, ch 229, § 9 (a); SDCL Supp, § 39-17-72; SL 1995, ch 191, § 3; SL 2004, ch 229, § 2.

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**34-20B-30. Exemptions from annual registration requirements.**

The following persons shall not be required to register under the provisions of § [34-20B-29](#):

- (1) An agent, or an employee thereof, of any manufacturer, distributor, or dispenser of any controlled drug or substance if such agent is acting in the usual course of his business or employment;
- (2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of any controlled drug or substance is in the usual course of his business or employment;
- (3) A person in possession of any controlled drug or substance pursuant to a lawful order of a practitioner.

**Source:** SL 1970, ch 229, § 9 (b); SDCL Supp, § 39-17-73.

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34-20B-31. Repealed by SL 2004, ch 232, § 2.

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**34-20B-32. Waiver of registration requirement by regulation.**

The department may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if the department finds it consistent with the public health and safety.

**Source:** SL 1970, ch 229, § 9 (c); SDCL Supp, § 39-17-75.

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**34-20B-33. Registration of previously registered or licensed establishments.**

The department shall permit persons to register who own or operate any establishment engaged in the manufacture, distribution, or dispensing of any controlled drugs and substances prior to July 1, 1972, and who are registered or licensed by the state.

**Source:** SL 1970, ch 229, § 9 (i); SDCL Supp, § 39-17-76.

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**34-20B-34. Separate registration required for each place of business or practice.**

A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled drugs and substances.

**Source:** SL 1970, ch 229, § 9 (d); SDCL Supp, § 39-17-77.

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**34-20B-35. Criteria for registration of manufacturers and distributors.**

The department shall register an applicant to manufacture and distribute controlled drugs and substances included in Schedules I through IV of §§ [34-20B-11](#) to [34-20B-26](#), inclusive, unless it is determined that the issuance of such registration is inconsistent with the public interest. In determining the public interest, the following factors shall be considered:

- (1) Maintenance of effective controls against diversion of particular controlled drugs and substances and any Schedule I or II substance compounded therefrom into other than legitimate medical, scientific, or industrial channels;
- (2) Compliance with the applicable state and local law;
- (3) Prior conviction record of applicant under federal and state laws relating to the manufacture, distribution, or dispensing of such substances;
- (4) Past experience in the manufacture of controlled drugs and substances, and the existence in the establishment of effective controls against diversion; and
- (5) Such other factors as may be relevant to and consistent with the public health and safety.

**Source:** SL 1970, ch 229, § 9 (f); SDCL Supp, § 39-17-78.

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**34-20B-36. Authorized Schedule I and II substances to be specified in manufacturer's or distributor's registration.**

Registration granted under § [34-20B-29](#) shall not entitle a registrant to manufacture and distribute controlled drugs and substances in Schedules I and II other than those specified in the registration.

**Source:** SL 1970, ch 229, § 9 (g); SDCL Supp, § 39-17-79.

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**34-20B-37. Practitioners registered to dispense Schedule II, III, and IV substances.**

Practitioners shall be registered to dispense substances in Schedules II through IV if they are authorized to dispense under the law of this state.

**Source:** SL 1970, ch 229, § 9 (h); SDCL Supp, § 39-17-80.

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34-20B-38. Repealed by SL 1989, ch 293, § 5.

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**34-20B-39. Inventories and records of controlled substances required of registrants.**

Each registrant manufacturing, distributing, or dispensing controlled drugs and substances in Schedules I, II, III, or IV shall maintain complete and accurate records of all stocks of such drugs and substances on hand. Records and inventories shall contain such information as shall be provided by rules and regulations promulgated by the department. All records required under this section shall be kept for a period of at least two years. This section shall not apply to practitioners who lawfully prescribe or administer, but not otherwise dispense, controlled drugs and substances listed in Schedules II, III, or IV of this chapter.

**Source:** SL 1970, ch 229, § 9 (j); SDCL Supp, § 39-17-82.

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**34-20B-40. Inspection of registrant's premises authorized.**

The department is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated under § [34-20B-41](#).

**Source:** SL 1970, ch 229, § 9 (e); SDCL Supp, § 39-17-86.

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**34-20B-41. Promulgation of rules by department--Fees.**

The department may promulgate rules pursuant to chapter [1-26](#) relating to exclusions from uniform drug articles pursuant to subdivision 34-20B-2(1); the definition of precursors; exceptions from Schedule III of stimulants, depressants, and anabolic steroid-estrogen combinations in medicinal preparations; the registration of manufacturers, distributors, and dispensers; waivers of registration; the suspending, revoking, surrendering, transferring, and reinstating of registration; inventories and records of controlled substances establishing minimum standards for prescribing and dispensing practices, labeling and security requirements and the issuance of prescriptions as provided by this chapter and chapter [22-42](#); and the inspection of registered premises. The department may charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled drugs and substances within this state. No fee may exceed one hundred fifty dollars.

**Source:** SL 1970, ch 229, §§ 9, 14; SDCL Supp, § 39-17-87; SL 1980, ch 238, § 2; SL 1993, ch 247, § 8; SL 2004, ch 232, § 1; SL 2009, ch 164, § 4.

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**34-20B-42. Unauthorized manufacture or distribution by registrant prohibited--Civil fine--Knowing violation as felony.**

No person who is a registrant shall manufacture, distribute, or dispense a controlled drug or substance not authorized by his registration to another registrant or other authorized person. A violation of this section may be punished by a civil fine of not more than ten thousand dollars. In addition, if the violation was done knowingly, it is a Class 5 felony.

**Source:** SL 1970, ch 229, § 10 (d) (2); SDCL Supp, § 39-17-98; SL 1977, ch 190, § 397.

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34-20B-42.1, 34-20B-42.2. Repealed by SL 1992, ch 245, §§ 7, 8.

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**34-20B-43. Omission or removal of required symbol prohibited--Civil fine--Knowing violation as misdemeanor.**

No person shall omit, remove, alter, or obliterate a symbol required by this chapter. A violation of this section may be punished by a civil fine of not more than ten thousand dollars. In addition, if the violation was done knowingly, it is a Class 1 misdemeanor.

**Source:** SL 1970, ch 229, § 10 (d) (3); SDCL Supp, § 39-17-99; SL 1976, ch 158, § 42-18; SL 1977, ch 190, § 398.

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**34-20B-44. Failure to keep or furnish required record or report prohibited--Civil fine--Knowing violation as felony.**

No person shall refuse or fail to make, keep, or furnish any record, report, notification, order form, statement, invoice, or information required under this chapter. A violation of this section may be punished by a civil fine of not more than ten thousand dollars. In addition, if the violation was done knowingly, it is a Class 6 felony.

**Source:** SL 1970, ch 229, § 10 (d) (4); SDCL Supp, § 39-17-100; SL 1977, ch 190, § 399.

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**34-20B-45. Civil fine for violation by manufacturer or distributor--Knowing violation as felony.**

Any person who violates any of §§ [34-20B-42](#) to [34-20B-44](#), inclusive, is punishable by a civil fine of not more than ten thousand dollars. In addition, if the violation is prosecuted by an information or indictment which alleges that the violation was committed knowingly and the trier of fact specifically finds that the violation was committed knowingly such person is guilty of a Class 5 felony.

**Source:** SL 1970, ch 229, § 10 (d) (7); SDCL Supp, § 39-17-103; SL 1977, ch 189, § 119.

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**34-20B-46. Intentional distribution of Schedule I or II substance without order form as felony.**

It is a Class 5 felony for any person who is a registrant knowingly to distribute a controlled drug or substance classified in Schedules I or II, in the course of his legitimate business, except pursuant to an order form as required by this chapter.

**Source:** SL 1970, ch 229, § 10 (e) (1); SDCL Supp, § 39-17-104; SL 1977, ch 189, § 120; SL 1977, ch 190, § 403.

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**34-20B-47. Intentional use of unauthorized registration number as felony.**

It is a Class 5 felony for any person knowingly to use in the course of the manufacture or distribution of a controlled drug or substance a registration number which is fictitious, revoked, suspended, or issued to another person.

**Source:** SL 1970, ch 229, § 10 (e) (2); SDCL Supp, § 39-17-105; SL 1977, ch 189, § 121; SL 1977, ch 190, § 404.

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**34-20B-48. Intentional falsification or omission of material information as felony.**

It is a Class 5 felony for any person knowingly to furnish false or fraudulent material information in, or omit any material information from, any application, report, or other document required to be kept or filed under this chapter, or any record required to be kept by this chapter.

**Source:** SL 1970, ch 229, § 10 (e) (4); SDCL Supp, § 39-17-107; SL 1977, ch 189, § 122; SL 1977, ch 190, § 406.

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**34-20B-49. Criminal penalties in addition to civil and administrative penalties.**

Any penalty imposed for violation of §§ [34-20B-42](#) to [34-20B-48](#), inclusive, shall be in addition to, and not in lieu of, any civil or administrative penalty or sanction authorized by law.

**Source:** SL 1970, ch 229, § 10 (g); SDCL Supp, § 39-17-112; SL 1977, ch 189, § 123.

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34-20B-50. Repealed by SL 1997, ch 203, § 1.

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**34-20B-51. Survival of right of action.**

In case of the death of either party, the right of action given in chapter [34-20C](#) shall survive to or against such party's personal representative.

**Source:** SL 1977, ch 316; SL 1997, ch 203, § 15.

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**34-20B-52. Civil action for recovery from unlawful distributor--Limitation of actions.**

All suits for damages under chapter [34-20C](#) shall be by civil action in any court of this state having jurisdiction thereof, which shall be commenced within two years of the date on which the injury was incurred.

**Source:** SL 1977, ch 316; SL 1997, ch 203, § 21.

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**34-20B-53. Minor's recovery payable to parent or conservator.**

All damages recovered by a minor under chapter [34-20C](#) shall be paid to such minor or to

the minor's parent or conservator as the court directs.

**Source:** SL 1977, ch 316; SL 1993, ch 213, § 228; SL 1997, ch 203, § 20.

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**34-20B-54. Cooperation by department with federal and state agencies.**

The Department of Health shall, in addition to other powers and duties vested in it by this chapter or any other act, cooperate with federal and other state agencies in discharging its responsibilities concerning traffic in drugs and substances.

**Source:** SL 1970, ch 229, § 5 (a); SDCL Supp, § 39-17-115.

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**34-20B-55. Centralized statistical unit--Availability of information.**

The Department of Health shall cooperate with the federal drug enforcement administration by establishing a centralized unit which shall accept, catalogue, file, and collect statistics, and make such information available for federal, state, and local law enforcement purposes.

**Source:** SL 1970, ch 229, § 5 (d); SDCL Supp, § 39-17-116; SL 1977, ch 190, § 412; SL 1989, ch 293, § 6.

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**34-20B-56. State agencies to cooperate with department.**

It shall be the duty of all departments, officers, agencies, and employees of the State of South Dakota to cooperate with the Department of Health in carrying out its functions under this chapter or any other act.

**Source:** SL 1970, ch 229, § 4; SDCL Supp, § 39-17-117.

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**34-20B-57. Exchange of information between governmental officials.**

The Department of Health shall, in addition to other powers and duties vested in it by this chapter or any other act, arrange for the exchange of information between governmental officials concerning the use and abuse of drugs and substances.

**Source:** SL 1970, ch 229, § 5 (b); SDCL Supp, § 39-17-118.

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**34-20B-58. County and municipal funds authorized.**

The governing bodies of the several counties and municipalities in the state are hereby authorized to establish funds and make appropriations thereto for the purpose of enforcing the provisions of this chapter.

**Source:** SL 1970, ch 229, § 13; SDCL Supp, § 39-17-119.

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**34-20B-59. Use of county and municipal funds to make illegal purchases.**

Funds established pursuant to § [34-20B-58](#) may be expended confidentially for the purpose of making purchases and acquisitions of drugs and substances which are illegal under this chapter, when such purchases are necessary to obtaining convictions under this chapter.

**Source:** SL 1970, ch 229, § 13 (a); SDCL Supp, § 39-17-120.

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**[34-20B-60](#). Use of county and municipal funds to employ special agents.**

Funds established pursuant to § [34-20B-58](#) may further be expended confidentially to employ special agents, pay their salaries and expenses, for the purpose of providing undercover assistance to local law enforcement officials in gathering evidence of violations of this chapter, making arrests thereunder, and obtaining convictions.

**Source:** SL 1970, ch 229, § 13 (b); SDCL Supp, § 39-17-121.

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**[34-20B-61](#). Law enforcement and cooperation by Division of Criminal Investigation and state's attorneys.**

It is hereby made the duty of the Division of Criminal Investigation, its officers, agents, inspectors, and representatives, and of all state's attorneys, to enforce all provisions of this chapter, except those specifically delegated, and to cooperate with all agencies charged with the enforcement of the laws of the United States, of this state, and of all other states, relating to controlled drugs and substances.

**Source:** SL 1970, ch 229, § 11 (a); SDCL Supp, § 39-17-122.

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**[34-20B-62](#). Attorney general to enforce chapter.**

The Office of the Attorney General shall retain authority for all prosecutions and other actions at law in the enforcement of this chapter.

**Source:** SL 1974, ch 261, § 8; SDCL Supp, § 39-17-122.1.

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**[34-20B-63](#). Special powers of agents of Division of Criminal Investigation.**

Any officer or employee of the Division of Criminal Investigation designated by the attorney general may:

- (1) Carry firearms;
- (2) Execute and serve search warrants, arrest warrants, administrative inspection warrants, subpoenas, and summonses issued under the authority of this state;
- (3) Make arrests without warrant for any offense under this chapter committed in his presence, or if he has probable cause to believe that the person to be arrested has committed or is committing a felony;
- (4) Make seizures of property pursuant to the provisions of this chapter; and
- (5) Perform such other law enforcement duties as the chief agent may designate.

**Source:** SL 1970, ch 229, § 11 (b); SDCL Supp, § 39-17-123.

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**34-20B-64. Drug control fund created--Administration by attorney general--Expenditures--Excess funds.**

There is hereby created in the state treasury a special revolving fund to be known as the "drug control fund," which shall be administered by the attorney general. The attorney general may authorize expenditure of moneys in the fund for purchase of controlled drugs and substances, as defined in this chapter, by authorized agents of the attorney general from unregistered dispensers and distributors. All disbursements from the fund shall be made on warrants drawn by the state auditor on vouchers approved by the attorney general. Any moneys in the fund in excess of two hundred fifty thousand dollars shall be available for distribution by the attorney general. Upon application by any local law enforcement agency, any drug law enforcement task force or the division of highway patrol, the attorney general may authorize release of any such available moneys in the fund for the purpose of assisting local law enforcement agencies in drug control and drug offender apprehension efforts.

**Source:** SL 1976, ch 5, §§ 1 to 3; SDCL Supp, § 39-17-123.1; SL 1990, ch 271.

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34-20B-65, 34-20B-66. Repealed by SL 1978, ch 178, § 577.

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**34-20B-67. Peace officers to cooperate with Division of Criminal Investigation.**

It is hereby made the duty of all peace officers within the state to cooperate with the Division of Criminal Investigation, its officers, agents, inspectors, and representatives, and to carry out all lawful orders issued by the Division of Criminal Investigation, its officers, agents, inspectors, and representatives, relating to controlled drugs and substances.

**Source:** SL 1970, ch 229, § 11 (a) (1); SDCL Supp, § 39-17-126.

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**34-20B-68. Trial court jurisdiction to enjoin violations.**

The trial courts of the state shall have jurisdiction in proceedings in accordance with the rules of these courts to enjoin violations of this chapter.

**Source:** SL 1970, ch 229, § 11 (d) (1); SDCL Supp, § 39-17-127.

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**34-20B-69. Jury trial of violations of injunction.**

In case of an alleged violation of an injunction or restraining order issued under § [34-20B-68](#), trial shall, upon demand of the accused, be by jury in accordance with the rules of the state courts.

**Source:** SL 1970, ch 229, § 11 (d) (2); SDCL Supp, § 39-17-128.

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**34-20B-70. Property subject to forfeiture.**

The following are subject to forfeiture pursuant to chapter [23A-49](#) and no property right exists

in them:

- (1) All controlled drugs and substances and marijuana which have been manufactured, distributed, dispensed, or acquired in violation of the provisions of this chapter or chapter [22-42](#);
- (2) All raw materials, products, and equipment of any kind which are used or intended for use, in manufacturing, compounding, or processing any controlled drug or substance or marijuana in excess of one-half pound in violation of the provisions of this chapter or chapter [22-42](#);
- (3) All property which is used, or intended for use, as a container for property described in subdivisions (1) and (2);
- (4) All conveyances including aircraft, vehicles, or vessels, which are used, or intended for use, to facilitate the unlawful distribution or possession with the intent to distribute marijuana in excess of one-half pound or any quantity of any other property described in subdivision (1) or (2);
- (5) All books, records, and research, including formulas, microfilm, tapes, and data which are used, or intended for use, in violation of this chapter;
- (6) Any funds or other things of value used for the purposes of unlawfully purchasing, attempting to purchase, distributing, or attempting to distribute any controlled drug or substance in an amount intended for distribution and not for personal use, and marijuana in excess of one-half pound; or
- (7) Any assets, interest, profits, income, and proceeds acquired or derived from the unlawful purchase, attempted purchase, distribution, or attempted distribution of any controlled drug or substance in an amount intended for distribution and not for personal use, and marijuana in excess of one-half pound.

Property described in subdivision (1) shall be deemed contraband and shall be summarily forfeited to the state, property described in subdivisions (2), (3), (5), (6), and (7) is subject to forfeiture under the terms of § [23A-49-14](#), and property described in subdivision (4) is subject to forfeiture under the terms of § [23A-49-15](#).

**Source:** SL 1970, ch 229, § 11 (e) (1); SDCL Supp, § 39-17-129; SL 1976, ch 158, §§ 42-19, 42-20; SL 1977, ch 189, §§ 125, 126; SL 1977, ch 317, §§ 1 to 3; SL 1982, ch 262, § 2; SL 1983, ch 255; SL 1985, ch 279, § 1; SL 2016, ch 138, § 21; SL 2021, ch 145, § 1.

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34-20B-70.1 to 34-20B-80. Repealed by SL 2016, ch 138, §§ 23 to 33.

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**[34-20B-81](#). Unlawful substances deemed contraband--Summary forfeiture.**

All property described in subdivision 34-20B-70(1) shall be deemed contraband and shall be summarily forfeited to the state. Controlled substances or marijuana which are seized or come into possession of the state, the owners of which are unknown, shall be deemed contraband and shall be summarily forfeited to the state.

**Source:** SL 1977, ch 317, § 6.

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**[34-20B-82](#). Unauthorized Schedule I substances deemed contraband--Summary seizure and forfeiture.**

All substances listed in Schedule I that are possessed, transferred, sold, or offered for sale in violation of the provisions of this chapter shall be deemed contraband and seized and summarily forfeited to the state. Similarly, all substances listed in Schedule I, which are seized or come into the possession

of the state, the owners of which are unknown, shall be deemed contraband and summarily forfeited to the state.

**Source:** SL 1970, ch 229, § 11 (e) (5); SDCL Supp, § 39-17-138.

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**34-20B-83. Seizure and summary forfeiture of plant precursors of Schedule I and II substances--Failure to produce registration as authority.**

All species of plants from which controlled substances in Schedules I and II may be derived which have been planted or cultivated in violation of this chapter, or of which the owners or cultivators are unknown, or which are wild growths, may be seized and summarily forfeited to the state. The failure, upon demand by the chief agent or any peace officer at his direction, of the person in occupancy or in control of land or premises upon which such species of plants are growing or being stored, to produce an appropriate registration, or proof that he is the holder thereof, shall constitute authority for the seizure and forfeiture.

**Source:** SL 1970, ch 229, § 11 (e) (6); SDCL Supp, § 39-17-139.

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34-20B-84 to 34-20B-89. Repealed by SL 2016, ch 138, §§ 34 to 39.

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**34-20B-90. Burden of proof as to registration or order form.**

In the absence of proof that a person is the duly authorized holder of an appropriate registration or order form issued under this chapter, he shall be presumed not to be the holder of such registration or form, and the burden of proof shall be upon him to rebut such presumption.

**Source:** SL 1970, ch 229, § 11 (f) (2); SDCL Supp, § 39-17-141.

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**34-20B-91. Enforcement officers exempt from liability.**

No liability shall be imposed by virtue of this chapter upon any duly authorized local, state, or federal officer engaged in the enforcement of this chapter, or who shall be engaged in the enforcement of any law or municipal ordinance relating to controlled drugs and substances.

**Source:** SL 1970, ch 229, § 11 (f) (3); SDCL Supp, § 39-17-142.

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**34-20B-92. Judicial review of department's decisions--Findings of fact conclusive.**

All final determinations, findings, and conclusions of the department under this chapter shall be final and conclusive decisions of the matters involved, except that any person aggrieved by such decision may obtain review of the decision in the circuit court. Findings of fact by the department, if supported by substantial evidence, shall be conclusive.

**Source:** SL 1970, ch 229, § 11 (g); SDCL Supp, § 39-17-143.

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34-20B-93 to 34-20B-99. Repealed by SL 2016, ch 169, §§ 23 to 29.

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**34-20B-100. Contracts with government agencies or private organizations.**

The Department of Health is hereby authorized to contract with agencies of the federal, state, or local government or any private organization or foundation for the purposes of carrying out its functions under this chapter.

**Source:** SL 1974, ch 263; SDCL Supp, § 39-17-150.1.

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34-20B-101, 34-20B-102. Repealed by SL 2016, ch 169, §§ 30, 31.

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34-20B-103, 34-20B-104. Repealed by SL 1985, ch 278, § 54.

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**34-20B-105. Residential alcohol and drug abuse treatment program authorized at Human Services Center.**

The Department of Social Services may establish and operate a residential alcohol and drug abuse treatment program at the South Dakota Human Services Center at Yankton.

**Source:** SL 1975, ch 255, § 1; SDCL Supp, § 39-17-151.3; SL 1985, ch 278, § 57; SL 1989, ch 21, § 160; SL 2011, ch 1 (Ex. Ord. [11-1](#)), § 163, eff. Apr. 12, 2011.

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34-20B-106 to 34-20B-109. Repealed by SL 1985, ch 278, § 54.

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34-20B-110. Repealed by SL 2016, ch 169, § 32.

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34-20B-111, 34-20B-112. Repealed by SL 1985, ch 278, § 55.

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**34-20B-113. Severability of provisions and applications.**

If a provision of this chapter is held unconstitutional or invalid, all constitutional or valid provisions that are severable shall remain in effect. If a provision of this chapter is held unconstitutional or invalid in one or more of its applications, the provision shall remain in effect in all its valid applications that are severable.

**Source:** SL 1970, ch 229, § 15; SDCL Supp, § 39-17-154.

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**34-20B-114. Citation of chapter.**

This chapter may be cited as the State Drugs and Substances Control Act.

**Source:** SL 1970, ch 229, § 17; SDCL Supp, § 39-17-155.

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**34-20B-115. Kratom--Under age--Misdemeanor.**

The following actions are unlawful:

- (1) To knowingly sell or distribute kratom to a person under the age of twenty-one;
- (2) The purchase or attempt to purchase, the receipt or attempt to receive, the possession, or the consumption of kratom by a person under the age of twenty-one; and
- (3) To purchase kratom on behalf of, or to give kratom to, any person under the age of twenty-one, unless the purchaser is a parent or guardian of the person under the age of twenty-one.

Kratom, for the purposes of this section, is a substance that contains 7hydroxymitragynine, Mitragynine, or Mitragynine pseudoindoxyl. A violation of this section is a Class 2 misdemeanor.

**Source:** SL 2021, ch 146, § 1.

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**34-20B-116. State directed opioid trust fund established--Source of funds--Purpose.**

The opioid abatement and remediation fund is established in the state treasury. Money received from the following sources may be deposited into the fund:

- (1) Money received by the state pursuant to settlements or judgments relating to opioids;
- (2) Any gifts, bequests, or donations; and
- (3) Interest earned on money in the fund established under this section shall be credited to the fund.

All money in the opioid abatement and remediation fund may only be used for purposes relating to opioid abuse treatment, prevention, and recovery programs and must be appropriated through the normal budget process. Expenditures of the state from the fund must be assigned to the Department of Social Services.

**Source:** SL 2022, ch 110, § 1, eff. Mar. 18, 2022.

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**34-20B-117. Delta-8 Tetrahydrocannabinol, THC-O Acetate, Hexahydrocannabinol--Under Age--Misdemeanor.**

The following actions are unlawful:

- (1) To knowingly sell or distribute a product intended for human consumption containing delta-8



- tetrahydrocannabinol, THC-O acetate, or hexahydrocannabinol to a person under the age of twenty-one;
- (2) The purchase or attempt to purchase, the receipt or attempt to receive, the possession, or the consumption of, a product intended for human consumption containing delta-8 tetrahydrocannabinol, THC-O acetate, or hexahydrocannabinol to a person under the age of twenty-one; and
  - (3) To purchase a product intended for human consumption containing delta-8 tetrahydrocannabinol, THC-O acetate, or hexahydrocannabinol on behalf of, or to give a product intended for human consumption containing delta-8 tetrahydrocannabinol, THC-O acetate, or hexahydrocannabinol to, any person under the age of twenty-one, unless the purchaser is a parent or guardian of the person under the age of twenty-one.

A violation of this section is a Class 2 misdemeanor.

**Source:** SL 2022, ch 111, § 1.

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## CHAPTER 34-20D

### PRODUCTS CONTAINING PSEUDOEPHEDRINE, EPHEDRINE, OR PHENYLPROPANOLAMINE

- [34-20D-1](#) Sale of packages containing pseudoephedrine or ephedrine--Number in single transaction limited--Exception--Misdemeanor.
- [34-20D-2](#) Purchase of packages containing pseudoephedrine or ephedrine--Number in single transaction limited--Exception--Misdemeanor.
- [34-20D-3](#) Requirements for display and offer of product containing pseudoephedrine or ephedrine as active ingredient.
- [34-20D-4](#) Repealed.
- [34-20D-5](#) Posting of notice.
- [34-20D-6](#) Civil liability for sale of product.
- [34-20D-7](#) County or municipality prohibited from establishing higher requirements or penalties.
- [34-20D-8](#) Identification and record of buyer of product containing pseudoephedrine, ephedrine, or phenylpropanolamine--Reporting--Stop-sale alert.
- [34-20D-8.1](#) Waiver of electronic reporting--Disclosure of record to law enforcement.
- [34-20D-9](#) Immunity from civil liability for good faith release of information to law enforcement.
- [34-20D-10](#) Possession of product, mixture, or preparation containing ephedrine base, pseudoephedrine base, or phenylpropanolamine base restricted--Exception--Misdemeanor.
- [34-20D-11](#) Real-time electronic record-keeping system--Calculation of purchase limitations--Private vendor.
- [34-20D-12](#) Law enforcement access to electronic record-keeping system.

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#### **[34-20D-1](#). Sale of packages containing pseudoephedrine or ephedrine--Number in single transaction limited--Exception--Misdemeanor.**

No retailer may sell, in a single transaction, more than two packages containing pseudoephedrine or ephedrine as an active ingredient. For purposes of this chapter, the term, retailer, means any person who sells merchandise at retail and from whom original packages of nonprescription drugs are sold or taken to be sold at retail and who is licensed by the Board of Pharmacy to sell nonprescription drugs. This restriction does not apply to any sale made pursuant to a valid prescription drug order prescribed by a practitioner as defined in § [36-11-2](#) with appropriate authority. Any retailer or any employee of a retailer who sells packages containing pseudoephedrine or ephedrine in violation of this section is guilty of a Class 1 misdemeanor.

**Source:** SL 2005, ch 178, § 1; SL 2006, ch 181, § 1.

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#### **[34-20D-2](#). Purchase of packages containing pseudoephedrine or ephedrine--Number in single transaction limited--Exception--Misdemeanor.**

No person may purchase, in a single transaction, more than two packages containing pseudoephedrine or ephedrine as an active ingredient. This restriction does not apply to purchases made with a valid prescription drug order prescribed by a practitioner as defined in § [36-11-2](#) with appropriate authority. Any person who purchases packages containing pseudoephedrine or ephedrine in violation of this section is guilty of a Class 1 misdemeanor.

**Source:** SL 2005, ch 178, § 2; SL 2006, ch 181, § 2.

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**34-20D-3. Requirements for display and offer of product containing pseudoephedrine or ephedrine as active ingredient.**

Any retailer who offers for sale a product containing pseudoephedrine or ephedrine as an active ingredient shall display and offer the product for sale, except as otherwise provided, behind a counter where the public is not permitted or in a locked case so that a customer wanting access to the package must ask a store employee for assistance. The retailer may display or offer for sale without restriction a product containing pseudoephedrine or ephedrine as an active ingredient if the product is displayed using any type of anti-theft device system including an electronic anti-theft device system that utilizes a product tag and detection alarm which prevents the theft of the product.

**Source:** SL 2005, ch 178, § 3; SL 2006, ch 181, § 3.

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34-20D-4. Repealed by SL 2006, ch 181, § 4.

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**34-20D-5. Posting of notice.**

A retailer shall post notice at the location where a product containing pseudoephedrine or ephedrine as an active ingredient is displayed or offered for sale stating the following:

South Dakota law prohibits the sale or purchase of more than two packages containing pseudoephedrine or ephedrine as an active ingredient unless sold or purchased with a valid prescription drug order prescribed by a practitioner as defined in § [36-11-2](#) with appropriate authority.

**Source:** SL 2005, ch 178, § 5; SL 2006, ch 181, § 5.

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**34-20D-6. Civil liability for sale of product.**

No employee or retailer is civilly liable to any injured person or the person's estate for any injury suffered, including any wrongful death, or property damage suffered due to the sale of any pseudoephedrine or ephedrine product in violation of § [34-20D-1](#).

**Source:** SL 2005, ch 178, § 6.

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**34-20D-7. County or municipality prohibited from establishing higher requirements or penalties.**

No county or municipality may establish requirements or establish a penalty that is higher or more stringent than the requirements or penalties established by this chapter.

**Source:** SL 2005, ch 178, § 7.

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**34-20D-8. Identification and record of buyer of product containing pseudoephedrine, ephedrine, or phenylpropanolamine--Reporting--Stop-sale alert.**

If offering for sale a product containing pseudoephedrine, ephedrine, or phenylpropanolamine as an active ingredient, a retailer shall, before making such a sale, require and make a record of the identification of the person purchasing the product. For purposes of this section, the term, identification, means a document issued by a governmental agency that contains a description of the person or a photograph of the person, and gives the person's date of birth, such as a tribal identification card, driver license, state-issued identification card, passport, or military identification card. The retailer shall electronically submit the record of identification, including the purchaser's name, date of birth, address of purchaser, the product name, the quantity sold, the date and time of the sale, and unique identification

number relating to the electronic record into the electronic record-keeping system prior to completing the sale of a product containing pseudoephedrine, ephedrine, or phenylpropanolamine unless a waiver has been granted. If a waiver is granted, the retailer shall submit written records to the Office of the Attorney General no later than the fifth day of every month. The retailer shall maintain the record of identification required by this section for two years, after which the record shall be destroyed. No retailer may use or maintain the record for any private or commercial purpose or disclose the record to any person, except as authorized by law. If the sale generates a stop-sale alert, the seller may not complete the sale unless the seller has a reasonable fear of imminent bodily harm if he or she does not complete the sale. The electronic record-keeping system shall contain an override function to the stop-sale alert for the seller to use in a situation in which a reasonable fear of imminent bodily harm is present.

**Source:** SL 2006, ch 181, § 6; SL 2012, ch 184, § 1; SL 2014, ch 166, § 1.

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**34-20D-8.1. Waiver of electronic reporting--Disclosure of record to law enforcement.**

The attorney general may grant a retailer a waiver pursuant to § [34-20D-8](#) if the retailer demonstrates that the electronic reporting will cause the retailer an undue economic hardship or that the retailer does not have the technological ability to report electronically. If a waiver is granted, the retailer shall disclose the record, upon request, to a law enforcement agency for a law enforcement purpose.

**Source:** SL 2014, ch 166, § 3.

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**34-20D-9. Immunity from civil liability for good faith release of information to law enforcement.**

Any retailer who in good faith releases information governed by this chapter to a law enforcement agency for a law enforcement purpose is immune from civil liability for such release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

**Source:** SL 2006, ch 181, § 7.

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**34-20D-10. Possession of product, mixture, or preparation containing ephedrine base, pseudoephedrine base, or phenylpropanolamine base restricted--Exception--Misdemeanor.**

No person may possess, receive, or otherwise acquire more than nine grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in any product, mixture, or preparation within any thirty-day period. This restriction does not apply to any quantity of product, mixture, or preparation obtained pursuant to a valid prescription drug order prescribed by a practitioner as defined in § [36-11-2](#) with appropriate authority.

Possession of more than nine grams of a drug product containing more than nine grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base constitutes a rebuttable presumption of the intent to use the product as a precursor to methamphetamine or another controlled substance. This rebuttable presumption does not apply to:

- (1) A retail distributor of drug products;
- (2) A wholesale drug distributor, or its agents;
- (3) A manufacturer of drug products, or its agents;
- (4) A pharmacist licensed by the Board of Pharmacy; or
- (5) A licensed health care professional possessing the drug products in the course of carrying out the profession.

Any violation of this section is a Class 1 misdemeanor.

**Source:** SL 2006, ch 181, § 8.

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**34-20D-11. Real-time electronic record-keeping system--Calculation of purchase limitations--Private vendor.**

The Office of the Attorney General may provide retailers of chemical products containing pseudoephedrine, ephedrine, or phenylpropanolamine access to a real-time electronic record-keeping system to enter into the record system any transaction required by § [34-20D-8](#). The real-time electronic record-keeping system shall be maintained in a central repository and shall have the capability to calculate state and federal ephedrine base, pseudoephedrine base, and phenylpropanolamine base purchase limitations. The electronic record-keeping system shall include a record of all the information obtained under § [34-20D-8](#) and the unique identification number, type, and state of issue. The Office of the Attorney General may contract with a private vendor to implement this section. A contractor shall comply with the confidentiality requirements of this chapter and is subject to sanctions for violation of confidentiality requirements, including termination of the contract. No cost may be assessed to the retailer associated with the implementation, access, continuation, or maintenance of the electronic record-keeping system.

**Source:** SL 2014, ch 166, § 2.

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**34-20D-12. Law enforcement access to electronic record-keeping system.**

The attorney general may grant other South Dakota law enforcement agencies access to the electronic record-keeping system for the purpose of investigating any violation of this chapter.

**Source:** SL 2014, ch 166, § 4.

## CHAPTER 34-20E

### PRESCRIPTION DRUG MONITORING PROGRAM

- [34-20E-1](#) Definition of terms .
- [34-20E-2](#) Prescription drug monitoring program to be established.
- [34-20E-2.1](#) Prescriber and dispenser registration with program required--Exception.
- [34-20E-3](#) Submission of information to central repository.
- [34-20E-4](#) Grounds for extension of time to submit information.
- [34-20E-5](#) Confidentiality of information.
- [34-20E-6](#) Procedures for security of patent information.
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- [34-20E-19](#) Knowing disclosure of information in violation of chapter as felony .
- [34-20E-20](#) Promulgation of rules.
- [34-20E-21](#) Report on monitoring and use of prescription opioids.

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#### **34-20E-1. Definition of terms.**

Terms used in this chapter mean:

- (1) "Administer," the direct application of a controlled substance to the body of a patient. The term does not include the prescribing of a controlled substance for administration by the patient or someone other than the health care provider;
- (2) "Board," the Board of Pharmacy;
- (3) "Central repository," a place where electronic data related to the prescribing and dispensing of controlled substances is collected;
- (4) "Controlled substance," any drug, substance, or immediate precursor as provided in schedules II through IV pursuant to §§ [34-20B-11](#) to [34-20B-26](#), inclusive;
- (5) "De-identified information," health information that is not individually identifiable information because an expert has made that determination pursuant to 45 C.F.R. 164.514, or direct identifiers and specified demographic information have been removed in accordance with the requirements of that section;
- (6) "Dispense," to deliver a controlled substance to an ultimate user by or pursuant to the lawful order of a health care provider, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for delivery;
- (7) "Dispenser," any person who delivers a controlled substance to the ultimate user, but does not include:

- (a) A licensed hospital pharmacy that provides a controlled substance for the purpose of inpatient hospital care;
- (b) A licensed health care provider or other authorized individual in those instances when the practitioner administers a controlled substance to a patient; or
- (c) A licensed veterinarian;
- (8) "Individually identifiable health information," the meaning set forth in 45 C.F.R. 160.103;
- (9) "Integration," the linking of the central repository into the electronic health records to allow health systems, pharmacies, or health information exchanges to seamlessly access data;
- (10) "Patient," any individual or owner of an animal who is the ultimate user of a controlled substance for whom a prescription is issued and for whom a controlled substance is dispensed;
- (11) "Prescriber," an individual licensed, registered, or otherwise authorized by the jurisdiction in which the individual is practicing to prescribe drugs in the course of professional practice. The term does not include a veterinarian;
- (12) "Program," the prescription drug monitoring program established by this chapter.

**Source:** SL 2010, ch 175, § 1; SL 2017, ch 157, § 1.

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### **34-20E-2. Prescription drug monitoring program to be established.**

The board shall establish and maintain a prescription drug monitoring program to monitor the prescribing and dispensing of all controlled substances. The program shall utilize a central repository, to which each dispenser shall submit, by electronic means, information regarding each prescription dispensed for a controlled substance. The information submitted for each prescription shall include specifically identified data elements adopted by the board and contained in the 2011 version of the electronic reporting standard for prescription monitoring programs, version 4.2 of the American Society for Automation in Pharmacy.

**Source:** SL 2010, ch 175, § 2; SL 2017, ch 157, § 2.

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### **34-20E-2.1. Prescriber and dispenser registration with program required--Exception.**

Any person who has a controlled drug or substance registration pursuant to § [34-20B-29](#) to prescribe or dispense any controlled drug or substance within this state must register with the program. Veterinarians licensed pursuant to chapter [36-12](#) are not subject to this requirement. The program shall work with the Department of Health to assure compliance with the requirement.

**Source:** SL 2017, ch 157, § 5.

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### **34-20E-3. Submission of information to central repository.**

Each dispenser shall submit the information required by this chapter to the central repository at least every twenty-four hours unless the board waives this requirement for good cause shown by the dispenser.

**Source:** SL 2010, ch 175, § 3; SL 2017, ch 157, § 3.

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### **34-20E-4. Grounds for extension of time to submit information.**

The board may grant an extension of the time in which a dispenser must report the information required by § [34-20E-2](#) to any dispenser that is unable to submit prescription information by electronic means because of one of the following occurrences:



- (1) The dispenser suffers a mechanical or electronic failure or cannot report within the required time for other reasons beyond the dispenser's control;
- (2) The central repository is unable to receive electronic submissions; or
- (3) Good cause shown by a dispenser.

**Source:** SL 2010, ch 175, § 4.

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#### **34-20E-5. Confidentiality of information.**

Information submitted to the central repository is confidential and may not be disclosed except as provided in § [34-20E-7](#).

**Source:** SL 2010, ch 175, § 5.

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#### **34-20E-6. Procedures for security of patent information.**

The board shall establish and maintain procedures to ensure that the privacy, confidentiality, and security of patient information collected, recorded, transmitted, and maintained is not disclosed except as provided in § [34-20E-7](#).

**Source:** SL 2010, ch 175, § 6.

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#### **34-20E-7. Disclosure of data in central repository to certain persons and entities.**

Unless disclosure is prohibited by law, the board may provide data in the central repository to:

- (1) Any prescriber for the purpose of providing medical care to a patient, a dispenser for the purpose of filling a prescription or providing pharmaceutical care for a patient, a prescriber or dispenser inquiring about the prescriber's or dispenser's own prescribing activity, or a prescriber or dispenser in order to further the purposes of the program including integration with electronic medical records;
- (2) Any individual who requests the prescription information of the individual or the individual's minor child;
- (3) Any state board or regulatory agency that is responsible for the licensing of individuals authorized to prescribe or dispense controlled substances if the board or regulatory agency is seeking information from the central repository that is relevant to an investigation of an individual who holds a license issued by that board or regulatory agency;
- (4) Any local, state, and federal law enforcement or prosecutorial officials engaged in the enforcement of laws relating to controlled substances who seek information for the purpose of an investigation or prosecution of the drug-related activity or probation compliance of an individual;
- (5) The Department of Social Services for purposes regarding the utilization of controlled substances by a medicaid recipient;
- (6) Any insurer for purposes regarding the utilization of controlled substances by a claimant;
- (7) Any judicial authority under grand jury subpoena or court order or equivalent judicial process for investigation of criminal violations of controlled substances laws;
- (8) Any public or private entity for statistical, research, or educational purposes after the information is de-identified with respect to any prescriber, dispenser, or patient who received a prescription for a controlled substance; or

- (9) Any peer review committee, which means any committee of a health care organization, composed of health care providers, employees, administrators, consultants, agents, or members of the health care organization's governing body, which conducts professional peer review.

**Source:** SL 2010, ch 175, § 7; SL 2017, ch 157, § 4.

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#### **34-20E-8. Fees.**

The board may charge a fee of ten dollars to any individual who requests information from the central repository pursuant to subdivision 34-20E-7(2). The board may charge a fee of one hundred dollars to any person who requests information from the central repository pursuant to subdivision 34-20E-7(8).

**Source:** SL 2010, ch 175, § 8.

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#### **34-20E-9. Records of information requests.**

The board shall maintain a record of each request for information from the central repository. The board may use the records to document and report statistics and outcomes. The board may provide records of the requests for information to:

- (1) Any board or regulatory agency responsible for the licensing of individuals authorized to prescribe or dispense controlled substances that is engaged in an investigation of the individual who submitted the request for information from the central repository; and
- (2) Any local, state, and federal law enforcement or prosecutorial official engaged in the enforcement of laws relating to controlled substances for the purpose of an active investigation of an individual who requested information from the central repository.

**Source:** SL 2010, ch 175, § 9.

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#### **34-20E-10. Contracts to facilitate operation of prescription drug monitoring program.**

The board may contract with another agency of this state, with an agency of another state, or with a private vendor to facilitate the effective operation of the prescription drug monitoring program. Any contractor is bound to comply with the provisions regarding confidentiality of prescription drug information in this chapter and is subject to termination or sanction, or both, for unlawful acts.

**Source:** SL 2010, ch 175, § 10.

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#### **34-20E-11. Immunity from civil liability.**

Nothing in this chapter requires a prescriber or dispenser to obtain information about a patient from the central repository prior to prescribing or dispensing a controlled substance. A prescriber, dispenser, or other health care provider may not be held liable in damages to any person in any civil action on the basis that the prescriber, dispenser, or other health care provider did or did not seek to obtain information from the central repository. Unless there is shown a lack of good faith, the board, a prescriber, dispenser, or any other person in proper possession of information provided under this chapter is not subject to any civil liability by reason of:

- (1) The furnishing of information under the conditions provided in this chapter;
- (2) The receipt and use of, or reliance on, such information;
- (3) The fact that any such information was not furnished; or
- (4) The fact that such information was factually incorrect or was released by the board to the wrong person or entity.

**Source:** SL 2010, ch 175, § 11.

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**34-20E-12. Board to review data and refer patients, prescribers, or dispensers engaged in improper activities to law enforcement or regulatory authorities.**

The board shall review the information received by the central repository to determine if there is reason to believe:

- (1) A prescriber or dispenser may have engaged in an activity that may be a basis for disciplinary action by the board or regulatory agency responsible for the licensing of the prescriber or dispenser; or
- (2) A patient may have misused, abused, or diverted a controlled substance.

If the board determines that there is reason to believe that any of the acts described in this section may have occurred, the board may notify the appropriate law enforcement agency or the board or regulatory agency responsible for the licensing of the prescriber or dispenser. The advisory council established in § [34-20E-15](#) shall recommend guidelines to the board for reviewing data and making determinations with respect to the referral of patients, prescribers, or dispensers to law enforcement or appropriate regulatory authorities.

**Source:** SL 2010, ch 175, § 12.

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**34-20E-13. Correction of erroneous information.**

Any patient, dispenser, or prescriber may request that erroneous information contained in the central repository be corrected or deleted. The board shall review the request to determine if the information is erroneous with respect to the patient, prescriber, or dispenser. The board shall correct any erroneous information the board discovers due to the request for review by a patient, prescriber, or dispenser.

**Source:** SL 2010, ch 175, § 13.

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**34-20E-14. Cooperation with other states.**

The board shall adopt a procedure to allow information contained in the central repository to be shared with officials in other states acting for the purpose of controlled substance monitoring and for requesting and receiving similar controlled substance monitoring information from other states.

**Source:** SL 2010, ch 175, § 14.

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**34-20E-15. Advisory council established.**

An advisory council is established to advise and make recommendations to the board regarding how to best use the program to improve patient care and foster the goal of reducing misuse, abuse, and diversion of controlled substances; to encourage cooperation and coordination among state, local, and federal agencies and other states to reduce the misuse, abuse, and diversion of controlled substances; and to provide advice and recommendations to the board regarding any other matters as requested by the board. The advisory council shall serve without compensation. The advisory council may have access to central repository information to fulfill its duties.

**Source:** SL 2010, ch 175, § 15.

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**34-20E-16. Membership of advisory council.**

The advisory council shall consist of:

- (1) One dispenser selected by the board;
- (2) One prescriber selected by the Board of Medical and Osteopathic Examiners;
- (3) One prescriber selected by the Board of Nursing;
- (4) One prescriber selected by the Board of Dentistry;
- (5) One prescriber selected by the Board of Examiners in Optometry;
- (6) One prescriber selected by the South Dakota Academy of Physician Assistants;
- (7) One member selected by the South Dakota Association of Healthcare Organizations;
- (8) One member of the South Dakota State Medical Association;
- (9) One member of the South Dakota Nurses Association;
- (10) One member of the South Dakota Pharmacists Association;
- (11) A designee of the attorney general;
- (12) A designee of the Department of Health; and
- (13) Any other prescriber or dispenser determined by the board to be necessary to meet a mandate of, or avoid a delay in implementing, an appropriations measure. The number of additional members that the board may select is limited to the number necessary to meet the mandate or avoid the delay of an appropriation.

**Source:** SL 2010, ch 175, § 16.

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#### **34-20E-17. Recommendations of advisory council.**

The advisory council shall make recommendations to the board regarding:

- (1) Safeguards for the release of information to persons who have access to the information contained in the central repository;
- (2) The confidentiality of program information and the integrity of the patient's relationship with the patient's health care provider;
- (3) Advancing the purposes of the program, including enhancement of the quality of health care delivery in this state; and
- (4) The continued benefits of maintaining the program in relationship to the cost and other burdens to the state.

**Source:** SL 2010, ch 175, § 17.

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#### **34-20E-18. Report of knowing failure to submit information or submission of incorrect information to dispenser's licensing board.**

Any dispenser who knowingly fails to submit prescription monitoring information to the board as required by this chapter or knowingly submits incorrect prescription information may be reported by the board to the dispenser's licensing board.

**Source:** SL 2010, ch 175, § 18.

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#### **34-20E-19. Knowing disclosure of information in violation of chapter as felony.**

Any person authorized to have prescription monitoring information pursuant to this chapter who knowingly discloses such information in violation of this chapter is subject to a Class 6 felony.

**Source:** SL 2010, ch 175, § 19.

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#### **34-20E-20. Promulgation of rules.**

The board shall promulgate rules, pursuant to chapter [1-26](#), for the operation of the program. Any rule promulgated shall be designed to assure the fair, equitable, and efficient operation of the program. The rules may address the following:

- (1) Criteria, procedures, and forms for submitting data to the program;
- (2) Standards for information collection;
- (3) Guidelines for reviewing data and making determinations with respect to the referral of patients, prescribers, or dispensers to law enforcement or appropriate regulatory authorities based upon an open case;
- (4) Safeguards for the release of information to individuals who have access to the information contained in the central repository;
- (5) Guidelines for maintaining the confidentiality of program information and the integrity of the patient's relationship with the patient's health care provider; and
- (6) Policies for the compilation and release of statistics and outcomes for advancing the purposes of the program, including enhancement of the quality of health care delivery in this state.

**Source:** SL 2010, ch 175, § 20.

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**[34-20E-21](#). Report on monitoring and use of prescription opioids.**

The board shall, before the fourth Tuesday in January of each year, report to the Senate and House standing committees on health and human services on the monitoring and use of prescription opioids. This report shall include the number of opioid prescriptions from the prior three years. The report shall also include an update to any changes or advances made to the prescription drug monitoring program. (This section is repealed effective June 30, 2022 pursuant to SL 2017, ch 158, § 2.)

**Source:** SL 2017, ch 158, § 1.

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## CHAPTER [34-20H](#)

### REDISTRIBUTION OF DONATED PRESCRIPTION DRUGS AND MEDICAL SUPPLIES

- [34-20H-1](#) Definitions.
  - [34-20H-2](#) Acceptance of donated drugs and supplies Conditions--Prohibitions.
  - [34-20H-3](#) Inspection requirement.
  - [34-20H-4](#) Participating pharmacy--Requirements.
  - [34-20H-5](#) Reimbursement.
  - [34-20H-6](#) Fees authorized.
  - [34-20H-7](#) Promulgation of rules.
  - [34-20H-8](#) Criminal prosecution--Civil liability--Exemptions--Immunity.
  - [34-20H-9](#) Electronic database of drugs and supplies.
- 

#### **[34-20H-1. Definitions.](#)**

Terms used in this chapter mean:

- (1) "Medical supply," any product necessary to administer a prescription drug; and
- (2) "Participating pharmacy," a pharmacy that:
  - (a) Is licensed pursuant to chapter [36-11](#); and
  - (b) Has provided written notice to the State Board of Pharmacy regarding its intent to accept donated prescription drugs and medical supplies, in accordance with §§ [34-20H-2](#) to [34-20H-6](#), inclusive.

**Source:** SL 2022, ch 137, § 1.

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#### **[34-20H-2. Acceptance of donated drugs and supplies—Conditions--Prohibitions.](#)**

Except as otherwise provided in this section, a participating pharmacy may accept a donation of prescriptions drugs and medical supplies if:

- (1) The drugs and medical supplies are in the original, sealed, and tamper-evident packaging, unless the drugs are in single-unit-dose packaging and the single-unit-dose packaging is unopened; and
- (2) The expiration date is at least six months after the date of donation, unless the State Board of Pharmacy has determined that the drug or medical supply is in high demand and dispensable before the expiration date. A participating pharmacy may not accept the donation of any controlled substance or any drug that has physical signs of tampering, misbranding, deterioration, compromised integrity, or adulteration. A participating pharmacy may not accept the donation of or distribute any drug subject to the requirements of 21U.S.C. [355-1](#)(f)(3), as of January 1, 2022.

**Source:** SL 2022, ch 137, § 2.

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#### **[34-20H-3. Inspection requirement.](#)**

A donated drug or medical supply may not be dispensed until a pharmacist, holding a permit issued in accordance with § [36-11-32](#), has inspected the drug or medical supply and repackaged it, as necessary, for dispensing.

**Source:** SL 2022, ch 137, § 3.

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#### **34-20H-4. Participating pharmacy—Requirements.**

A participating pharmacy shall:

- (1) Comply with all applicable federal and state laws regarding the storage and dispensing of any donated drugs and medical supplies;
- (2) Accept a prescription transferred pursuant to rules promulgated in accordance with chapter [1-26](#) by the State Board of Pharmacy; and
- (3) Agree to transfer any donated prescription drug or medical supply in the pharmacy's inventory to another licensed pharmacy, for use by a person who meets the eligibility criteria in accordance with § [34-20H-7](#).

**Source:** SL 2022, ch 137, § 4.

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#### **34-20H-5. Reimbursement.**

A drug or medical supply that has been donated may not be resold or considered eligible for reimbursement under the medical assistance program, as set forth in chapter [28-6](#). Nothing in this section requires a health plan or pharmacy benefit manager to be reimbursed for donated drugs or medical supplies.

**Source:** SL 2022, ch 137, § 5.

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#### **34-20H-6. Fees authorized.**

A participating pharmacy may charge a fee, in an amount established by the State Board of Pharmacy, for accepting, distributing, or dispensing donated prescription drugs and medical supplies.

**Source:** SL 2022, ch 137, § 6.

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#### **34-20H-7. Promulgation of rules.**

The State Board of Pharmacy shall promulgate rules, in accordance with chapter [1-26](#), to:

- (1) Establish eligibility criteria for persons to receive donated drugs and medical supplies, provided the criteria:
  - (a) Prioritize persons who are indigent or without insurance coverage; and
  - (b) Permit dispensing to other persons, if the supply of a donated drug or supply exceeds demand;
- (2) Establish standards and procedures for the acceptance, storage, and dispensing of donated prescription drugs and medical supplies;
- (3) Establish standards and procedures for the inspection of donated prescription drugs and medical supplies;
- (4) Establish the fee that a participating pharmacy may charge for accepting, distributing, and dispensing donated prescription drugs and medical supplies, provided the fee does not exceed the reasonable cost incurred by the pharmacy; and
- (5) Develop and make available any forms necessary for the donation, acceptance, and dispensing of donated drugs and medical supplies.



**Source:** SL 2022, ch 137, § 7.

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**34-20H-8. Criminal prosecution--Civil liability--Exemptions--Immunity.**

A drug manufacturer, acting reasonably and in good faith, is not subject to criminal prosecution, or civil liability, for the death of or injury to a person, or for damage to or destruction of property, resulting from any donation, acceptance, or dispensing of a prescription drug under §§ [34-20H-2](#) to [34-20H-6](#), inclusive, nor for any failure to transfer or communicate product information.

Any person, other than a drug manufacturer referenced in this section, acting reasonably and in good faith, is not subject to:

- (1) Criminal prosecution or civil liability, for:
  - (a) The death of, or injury to another person who received a donated prescription drug or medical supply under §§ [34-20H-2](#) to [34-20H-6](#), inclusive;
  - (b) Damage to or destruction of property resulting from the donation of a prescription drug or medical supply under §§ [34-20H-2](#) to [34-20H-6](#), inclusive; or
- (2) Disciplinary action for any act or omission related to the donation, acceptance, distribution, or dispensing of a donated prescription or medical supply, in accordance with §§ [34-20H-2](#) to [34-20H-6](#), inclusive.

**Source:** SL 2022, ch 137, §

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**34-20H-9. Electronic database of drugs and supplies.**

The State Board of Pharmacy shall develop and maintain, for use by prescribers and pharmacists, an electronic database that provides a searchable inventory of prescription drugs and medical supplies donated under this chapter. The board shall post a current list of participating pharmacies on the board's website.

**Source:** SL 2022, ch 137, § 9.

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## ARTICLE 44:58

### DRUG CONTROL

Chapter	
44:58:01	Definitions.
44:58:02	Requirements of registration.
44:58:03	Applications for registration.
44:58:04	Action on applications.
44:58:05	Hearings.
44:58:06	Modification of registration.
44:58:07	Records, reports, and inventories.
44:58:08	Prescriptions.
44:58:09	Administrative procedures.
44:58:10	Security requirements.
44:58:11	Hypodermic control regulations, Repealed.
44:58:12	General provisions, Repealed.
44:58:13	Exempted Schedule III substances.

#### CHAPTER 44:58:01

##### DEFINITIONS

Section	
44:58:01:01	Definitions.

**44:58:01:01. Definitions.** Words defined in SDCL 34-20B-1 have the same meaning when used in this article. In addition, terms used in this article mean:

- (1) "Act," the State Drugs and Substances Control Act, SDCL chapter 34-20B;
- (2) "Controlled premises," places where records required under the act are kept or places where persons registered under the act or exempted from registration under the act may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances;
- (3) "Department," the state Department of Health;
- (4) "Division," the Division of Health Systems Development and Regulation of the Department of Health;
- (5) "Drug Enforcement Administration" or "DEA," the United States Department of Justice, Drug Enforcement Administration, or its successor agency;
- (6) "Hearing," a hearing held pursuant to this article for the granting, denial, revocation, or suspension of a registration pursuant to §§ 44:58:04:02, 44:58:04:05, and 44:58:04:07 to 44:58:04:09, inclusive;
- (7) "Individual practitioner," a physician, dentist, veterinarian, optometrist, nurse practitioner, nurse midwife, physician's assistant, or podiatrist licensed by the state of South Dakota or the United States to

practice, who is registered or exempt from registration with the division to dispense, administer, or prescribe controlled substances in the course of practice;

(8) "Institutional practitioner," a hospital or other institutional employee who is licensed, registered, or otherwise permitted by the state of South Dakota or the United States, to dispense, distribute, or administer a controlled substance in the course of practice;

(9) "Long-term care facility (LTCF)," a nursing facility, retirement care, mental care, or other facility or institution which provides extended health care to residents;

(10) "Pharmacist," a pharmacist licensed by the state of South Dakota to dispense controlled substances or a pharmacist intern, authorized by the state, who is under the immediate and personal supervision of a pharmacist;

(11) "Prescription," an order for medication which is dispensed to or for an ultimate user;

(12) "Register" and "registration," the registration required and permitted by SDCL 34-20B-29 to 34-20B-37, inclusive;

(13) "Registrant," a person who is registered pursuant to SDCL 34-20B-29 to 34-20B-37, inclusive;

(14) "Research protocol," a detailed description of each research project being initiated; and

(15) "Secretary," the secretary of health or a person appointed by the secretary to act on the secretary's behalf.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 11 SDR 36, effective September 11, 1984; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995; 25 SDR 48, effective October 1, 1998.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-10 to 34-20B-26, 34-20B-28 to 34-20B-37, 34-20B-41.

## CHAPTER 44:58:02

### REQUIREMENTS OF REGISTRATION

#### Section

44:58:02:01 to 44:58:02:19	Repealed.
44:58:02:20	Activities requiring separate registration.
44:58:02:21	Activities covered by single registration.
44:58:02:22	Waiver of registration.
44:58:02:23	Compliancy requirements.

**44:58:02:01. Persons required to register.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:02. Activities deemed to be independent.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:03. Separate registration required for each independent activity.** Repealed.

Source: 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:04. Manufacturers of basic class authorized to distribute.** Repealed.

Source: 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:05. Manufacturers of substances in Schedules II through IV authorized to analyze and research.** Repealed.

Source: 1 SDR 30, effective October 7, 1974; 6 SDR 93, repealed July 1, 1980.

**44:58:02:06. Researchers of substances in Schedule I -- Limited manufacturing and research authorized.** Repealed.

Source: 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:07. Persons making chemical analysis -- Limited activities authorized.** Repealed.

Source: 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:08. Researchers of substances in Schedules II through IV -- Other activities authorized.** Repealed.

Source: 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:09. Persons dispensing or conducting research with substances in Schedules II through IV -- Authorized to conduct instructional activities.** Repealed.

Source: 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:10. Single registration for activity with more than one substance.** Repealed.

Source: 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:11. Separate registration required for separate locations.** Repealed.

Source: 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:12. Locations exempt from registration.** Repealed.

Source: 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:13. Agents and employees exempt from registration.** Repealed.

Source: 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:14. Affiliated practitioners exempt from registration.** Repealed.

Source: 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:15. Intern, resident, or foreign physician covered by employer's registration.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:16. Law enforcement officials exempt from registration.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:17. Law enforcement agency laboratories required to register -- Employees exempt.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:18. Exemption of other federal individuals.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:19. Exemption of employees of the division.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:02:20. Activities requiring separate registration.** Each of the following groups of activities is independent of the others and shall be conducted under separate registrations:

- (1) Manufacturing and distributing controlled substances;
  - (2) Dispensing controlled substances listed in Schedule II through IV;
  - (3) Conducting research and instructional activities with controlled substances listed in Schedule II through IV;
  - (4) Conducting research and instructional activities with controlled substances listed in Schedule I;
- and
- (5) Conducting chemical analysis of controlled substances listed in any schedule.

**Source:** 6 SDR 93, effective July 1, 1980.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29, 34-20B-41.

**44:58:02:21. Activities covered by single registration.** Each of the following groups of activities may be conducted under a single registration:

- (1) A person registered to manufacture controlled substances listed in Schedules II through IV is also authorized to conduct chemical analysis and research with controlled substances listed in the schedules which the person is authorized to manufacture;
- (2) A practitioner registered to prescribe or dispense controlled substances listed in Schedules II through IV is also authorized to conduct instructional activities with those substances. The person is authorized to distribute up to five percent of those controlled substances to other persons registered to prescribe, dispense, or distribute controlled substances;
- (3) A person registered or authorized to conduct research with controlled substances listed in Schedules II through IV is also authorized to conduct chemical analysis with substances listed in the schedules with which the person is authorized to conduct research; to manufacture the substances set forth in the statement filed with the person's application for registration; to distribute the substances to other persons registered or authorized to conduct chemical analysis, research or instructional activities with the substances; and to conduct instructional activities with controlled substances;

(4) A person registered to conduct research with controlled substances listed in Schedule I is also authorized to manufacture the substances set forth in the research protocol filed with the person's application for registration. The person is also authorized to distribute the substances to other persons registered to conduct research with Schedule I substances; and

(5) A person registered to conduct chemical analysis with controlled substances is also authorized to manufacture and import such substances for analytical or instructional purposes; to distribute such substances to other persons registered to conduct chemical analysis, research or instructional activities with the substances; and to conduct instructional activities with controlled substances.

**Source:** 6 SDR 93, effective July 1, 1980.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29, 34-20B-41.

**44:58:02:22. Waiver of registration.** Registration is not required for the following persons in the circumstances described:

(1) An individual practitioner who is an agent of another practitioner registered to dispense controlled substances who, when acting in the usual course of employment, administers and dispenses but does not prescribe a controlled substance if permitted to do so by the jurisdiction in which the individual practices;

(2) An institutional practitioner who dispenses, administers, and prescribes controlled substances under the registration of the hospital or other institution by which the practitioner is employed, provided the following requirements are met:

(a) The dispensing, administering, or prescribing is done in the usual course of professional practice;

(b) The employing hospital or other institution authorizes the practitioner to dispense, administer, or prescribe under its registration and designates a specific method for identifying an individual so authorized; and

(c) A current list of the institutional practitioners is kept by the hospital or other institution and is made available to the public upon request for the purpose of verifying the authority of the prescribing institutional practitioner;

(3) An officer or employee of the United States Drug Enforcement Administration, United States Bureau of Customs, or the United States Food and Drug Administration or any other federal officer who is lawfully engaged in the enforcement of any federal law relating to controlled substances, drugs, or customs and is authorized to possess controlled substances while engaged in the course of official duties;

(4) An officer or employee of a state or a political subdivision or agency of a state, who is engaged in the enforcement of a state or local law relating to controlled substances and is authorized to possess controlled substances in the course of official duties, including the following:

(a) Possession of a controlled substance and distribution of the substance to another official who is also exempted by this section; and

(b) Procurement of a controlled substance in the course of an inspection pursuant to SDCL 34-20B-40 or in the course of a criminal investigation involving the person from whom the substance was procured;

(5) An official of the United States Army, Navy, Marine Corps, Air Force, Coast Guard, or Public Health Service who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of official duties. Such officials shall follow the procedures set forth in chapter 44:58:08 regarding prescriptions, but shall state the branch of service or agency and use the official's service identification number in lieu of the required registration number;

(6) Law enforcement agency laboratory personnel when acting in the scope of their official duties under the registration of the laboratory by which they are employed. Laboratory activities do not include field or other preliminary chemical tests by officials exempted by this section; and

(7) An individual practitioner who holds a valid locum tenens certificate, as provided under SDCL 36-4-20.1 to 36-4-20.5, inclusive, who administers, dispenses, or prescribes controlled substances, provided the practitioner holds a valid DEA certificate and has filed an application for registration with the department.

**Source:** 6 SDR 93, effective July 1, 1980; 11 SDR 36, effective September 11, 1984; 18 SDR 181, effective May 4, 1992; 21 SDR 219, effective June 27, 1995; 23 SDR 91, effective December 9, 1996.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-32.

**44:58:02:23. Compliancy requirements.** Each registrant shall comply with Title 21 Code of Federal Regulations (CFR) part 1300 to end as of April 2004.

**Source:** 31 SDR 62, effective November 7, 2004.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**Reference:** Title 21 Code of Federal Regulations (CFR) 1300 to end. Copies may be obtained from the Superintendent of Documents, Attn: New Orders, P.O. Box 371954, Pittsburg, Pennsylvania 15250-7954. Phone: 1-866-512-1800. Cost: \$22.

## CHAPTER 44:58:03

### APPLICATIONS FOR REGISTRATION

#### Section

44:58:03:01	Registration required -- Expiration date.
44:58:03:02	Application forms -- Contents.
44:58:03:02.01	Registration fee.
44:58:03:03	Procedure for reregistration.
44:58:03:03.01 to 44:58:03:08	Repealed.
44:58:03:09	Additional information -- Noncompliance with request.
44:58:03:10	Repealed.

**44:58:03:01. Registration required -- Expiration date.** A person required to register may not engage in any activity which requires registration until the registration is granted and a certificate is issued by the secretary. The expiration date of the registration coincides with the expiration date of the person's DEA registration.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995; 25 SDR 48, effective October 1, 1998.



**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29.

**44:58:03:02. Application forms -- Contents.** An application shall contain the person's name; signature; full address; professional license number; type of professional practice; a statement related to conviction of a felony under state or federal law; and a statement related to the denial, revocation, or surrender of a professional license or registration to handle controlled substances. Applications to conduct research and instructional activities with controlled substances as covered by subdivisions 44:58:02:20(3) and (4) shall include evidence of a valid DEA registration to conduct such research and a copy of the research protocol or a statement describing the instructional activities. Applications to manufacture controlled substances listed in Schedule II shall include evidence of a valid DEA registration to manufacture the substances.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 11 SDR 36, effective September 11, 1984; 25 SDR 48, effective October 1, 1998.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29, 34-20B-35 to 34-20B-37, 34-20B-41.

**44:58:03:02.01. Registration fee.** Each registrant shall pay a registration fee at the time of initial registration or at renewal of registration. Registration fees are non-refundable and may not be prorated. The registration fees are as follows:

- (1) \$150 for any dentist, medical doctor, optometrist, osteopathic doctor, pharmacy, veterinarian, or podiatrist;
- (2) \$150 for any nurse practitioner, nurse midwife, or physician assistant;
- (3) \$75 for any manufacturer, distributor, analytical lab, euthanasia, teaching institution, or researcher (including any drug detection dog trainer); and
- (4) \$75 for any locum tenens certificate.

**Source:** 31 SDR 62, effective November 7, 2004; 35 SDR 305, effective July 1, 2009.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**44:58:03:03. Procedure for reregistration.** A person registered under § 44:58:02:20 shall apply for reregistration in writing to the secretary not more than 60 days before the expiration date of the person's current registration.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 11 SDR 36, effective September 11, 1984; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29.

**44:58:03:03.01. Waiver of reregistration.** Repealed.

**Source:** 6 SDR 93, effective July 1, 1980; repealed, 21 SDR 219, effective June 27, 1995.

**44:58:03:04. Federal registration must accompany applications for Schedules I and II.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:03:05. Required information for applications.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:03:06. Signatures on applications.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:03:07. Filing of applications with director -- Joint filings.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:03:08. Acceptance of filing -- Defective applications.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:03:09. Additional information -- Noncompliance with request.** The secretary may require an applicant to submit documents relevant to the application to determine if registration should be granted. The failure of the applicant to provide such documents within 15 days after the request is considered a waiver by the applicant of the opportunity to present such documents. Upon request, the secretary may extend the time for good cause.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29.

**44:58:03:10. Amendments to and withdrawal of applications.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

## CHAPTER 44:58:04

### ACTION ON APPLICATIONS

#### Section

44:58:04:01	Review of applications.
44:58:04:02	Issuance of certificate of registration -- Denial of registration.
44:58:04:03	Information contained on certificate.
44:58:04:04	Location of the certificate.
44:58:04:05	Suspension or revocation of registration.
44:58:04:06	Repealed.
44:58:04:07	Requirements of registrant upon service of notice of automatic suspension, revocation, or suspension.
44:58:04:08	Limited revocations or suspensions.
44:58:04:09	New certificate when limitation applied.
44:58:04:10 to 44:58:04:15	Repealed.

**Cross-Reference:** Procedure and appellate procedure for revocation of licenses, SDCL 1-26-16 to 1-26-37.

**44:58:04:01. Review of applications.** The secretary shall review the application for registration and other information regarding an applicant to determine that applicable standards are met.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29, 34-20B-35 to 34-20B-37, 34-20B-40.

**44:58:04:02. Issuance of certificate of registration -- Denial of registration.** The secretary shall issue a certificate of registration after reviewing the application and finding the information in compliance with this chapter and SDCL 34-20B. The secretary shall issue an order when denying an application and, if requested by the applicant, hold a hearing on the application denial pursuant to SDCL 1-26.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29 to 34-20B-37.

**44:58:04:03. Information contained on certificate.** The certificate of registration shall contain the name, address, registration number of the registrant, any applicable federal registration numbers, the activity authorized by the registration, the schedules of controlled substances which the registrant is authorized to handle, and the expiration date of the registration.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29.

**44:58:04:04. Location of the certificate.** The registrant shall conspicuously place the certificate at the registered location and shall permit inspection of the certificate and registered premises by any official of the division or other state or local agency engaged in enforcement of laws pertaining to controlled substances.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29, 34-20B-40, 34-20B-41.

**44:58:04:05. Suspension or revocation of registration.** The department may suspend or revoke any registration issued under the act as provided under SDCL 1-26.

The reasons for suspension or revocation shall include a finding that the registrant has done one or more of the following:

- (1) Has furnished false or fraudulent information in an application filed under the act;
- (2) Has been convicted of a felony under any state or federal law relating to a controlled substance;
- (3) Has had a federal registration to manufacture, distribute, or dispense controlled substances suspended, revoked, or allowed to expire;
- (4) Has been the subject of disciplinary action taken by the registrant's respective licensing board for substance abuse, misuse of controlled substances, or violation of state law related to prescribing or dispensing controlled substances; or
- (5) Has violated the requirements of the act or this article.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 11 SDR 36, effective September 11, 1984; 18 SDR 181, effective May 4, 1992; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**44:58:04:06. Procedure prior to revoking or suspending registration.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:04:07. Requirements of registrant upon service of notice of automatic suspension, revocation, or suspension.** Upon service of the notice of automatic suspension, notice of revocation, or notice of suspension, the registrant shall immediately deliver the certificate of registration to the secretary. As instructed by the secretary, the registrant shall also deliver all controlled substances in the registrant's possession to the secretary or to authorized agents of the secretary or place all controlled substances in the registrant's possession under seal, with a complete inventory of items on hand, and store the items to preclude any further disposition of them without a court order until the time for taking an appeal has elapsed or until all appeals have been concluded.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**Cross-Reference:** Events causing automatic suspension of registration, § 44:58:06:02.

**44:58:04:08. Limited revocations or suspensions.** The secretary may limit revocation or suspension of a registration to a particular schedule of controlled substance as circumstances indicate. Action required under § 44:58:04:05 is limited to the schedule or schedules revoked.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**44:58:04:09. New certificate when limitation applied.** If revocation or suspension is limited to a particular schedule, the secretary shall issue the registrant a new certificate of registration for all substances not affected. The registrant shall deliver the old certificate of registration to the secretary.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**44:58:04:10. Suspension of registration authorized pending director's final order.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:04:11. Actions required of registrant upon immediate suspension.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:04:12. Effective time period of suspension.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:04:13. Order to show cause required to revoke or suspend registration.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:04:14. Request for hearing.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:04:15. Director's agent may serve order to show cause.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

## CHAPTER 44:58:05

### HEARINGS

#### Section

44:58:05:01 Conduct of hearings generally -- Not in lieu of criminal prosecutions.

44:58:05:02 to 44:58:05:10 Repealed.

**Cross-Reference:** Hearing procedure, SDCL 1-26-16 to 1-26-29.

**44:58:05:01. Conduct of hearings generally -- Not in lieu of criminal prosecutions.**

Administrative hearings in contested cases shall be governed by the act, this article, and SDCL chapter 1-26.

A hearing held for violation of this article is independent of, and not in lieu of, criminal prosecutions or other proceedings under the act or any other law of this state.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41, 1-26-27.

**Reference:** Administrative Procedures Act, SDCL chapter 1-26.

**44:58:05:02. Purpose of hearing -- Arguments not to be offered as evidence.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:05:03. Waiver or modification of rules governing hearing procedure.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:05:04. Time to make request for hearing.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:05:05. Filing of written statement prior to hearing -- Inclusion in record.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:05:06. Failure to request hearing -- Failure to appear.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:05:07. Cancellation of hearing.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:05:08. Time and place of hearing after waiver.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:05:09. Final order -- Findings and conclusions -- Effective date -- Service.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:05:10. Hearing officers' decisions final.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

## CHAPTER 44:58:06

### MODIFICATION OF REGISTRATION

#### Section

- 44:58:06:01 Applications for modification of registration -- Contents.
- 44:58:06:02 Events causing automatic suspension of registration.
- 44:58:06:02.01 Voluntary surrender and reinstatement of registration.
- 44:58:06:03 Secretary's consent required to transfer registration.

**44:58:06:01. Applications for modification of registration -- Contents.** A registrant may apply to modify a registration by submitting a revised application and a letter of request to the secretary. The letter shall contain all information required by § 44:58:03:02.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29, 34-20B-41.

**44:58:06:02. Events causing automatic suspension of registration.** The registration of a person is automatically suspended if the person fails to maintain the person's professional license, fails to maintain DEA registration in South Dakota, discontinues professional practice within South Dakota, or changes name or address without notifying the secretary.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29, 34-20B-41.

**44:58:06:02.01. Voluntary surrender and reinstatement of registration.** A registrant may voluntarily surrender the registration to prescribe controlled substances. If the surrender is made because the

registrant is incapacitated, retires, or moves out of South Dakota, the registrant may apply for a new registration at any time.

If the surrender is due to alleged failure to comply with the provisions of SDCL 34-20B or 22-42 or both, the following requirements apply:

- (1) The surrender shall be for a specific length of time;
- (2) The surrender statement shall specify the schedule or schedules which are involved;
- (3) The registrant may not reapply for Schedule IV prescribing privileges until at least one-half of the specified time has passed;
- (4) The registrant may not reapply for Schedule III prescribing privileges until at least five-eighths of the specified time has passed;
- (5) The registrant may not reapply for Schedule II prescribing privileges until at least three-fourths of the specified time has passed;
- (6) All applicants for reinstatement must be approved by the secretary;
- (7) The applicant for reinstatement must demonstrate, through written or oral examination, a knowledge of the pharmacology and law related to the controlled substances for which the applicant is requesting prescribing privileges. The examination shall be prepared and given by at least three and no more than five health care professionals knowledgeable in the areas to be tested; and
- (8) The final decision for reinstatement rests with the secretary.

**Source:** 6 SDR 93, effective July 1, 1980; 11 SDR 36, effective September 11, 1984; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-29, 34-20B-41.

**44:58:06:03. Secretary's consent required to transfer registration.** A registration may not be transferred without written consent of the secretary. The method of transferring any existing stock of controlled substances must be indicated in a letter accompanying the certificate.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

## CHAPTER 44:58:07

### RECORDS, REPORTS, AND INVENTORIES

#### Section

- |                             |  |
|-----------------------------|--|
| 44:58:07:01 and 44:58:07:02 | Repealed.  |
| 44:58:07:03                 | Inventory requirements.                            |
| 44:58:07:04                 | Acquisition, dispensing, and distribution records. |
| 44:58:07:05                 | Theft reports.                                     |
| 44:58:07:06 to 44:58:07:08  | Repealed.  |

**44:58:07:01. Record, report, and inventory requirements generally.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:07:02. Record, report, and inventory requirements specifically.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:07:03. Inventory requirements.** Upon registration, a registrant shall make a written, typed, or printed inventory of all stocks of controlled substances. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous inventory date. The inventory shall contain the following:

- (1) An exact count or measure of all Schedule I and II substances;
- (2) An estimated count or measure of all Schedule III or IV substances; if a container holds more than 1,000 doses, the registrant shall make an accurate count; and
- (3) The date, time of day (opening or closing of business), signature of the person taking the inventory, and signature of the registrant if not the same individual.

Substances which are added to the list of controlled substances shall be inventoried on the date when the control takes effect and thereafter with the biennial inventory.

**Source:** 6 SDR 93, effective July 1, 1980; 25 SDR 48, effective October 1, 1998.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-39, 34-20B-40.

**44:58:07:04. Acquisition, dispensing, and distribution records.** A dispenser shall maintain the records required to acquire, distribute, or dispense controlled substances in a readily retrievable manner. The following minimum standards shall be met:

- (1) Acquisition of Schedule I and II substances will be verified through official order forms of the DEA;
- (2) Acquisition of Schedule III and IV substances will be verified through invoices or other records;
- (3) Dispensing of all controlled substances will be verified through prescriptions or other chronological records as follows:
  - (a) The records shall include the name and address of the patient (or species and name and address of the owner if the patient is an animal), the date, the controlled substance and dose, the quantity dispensed, and the name, address, and DEA number of the prescriber;

(b) A separate file shall be maintained for dispensed substances listed in Schedule II;

(c) Schedule III and IV records may be maintained in a separate file or marked with a red "C" at least one inch high and filed with the prescriptions for noncontrolled drugs. If the pharmacy uses an automated data processing system or electronic record keeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's



name, controlled substance dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived; and

(4) Distribution of controlled substances to another registrant as provided under subdivision 44:58:02:21(1) shall be as follows:

(a) Distribution of Schedule I and II substances will be verified by the supplier's copy of the official DEA order form; and

(b) Distribution of Schedule III and IV substances will be verified by invoices.

**Source:** 6 SDR 93, effective July 1, 1980; 11 SDR 36, effective September 11, 1984; 25 SDR 48, effective October 1, 1998.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-39, 34-20B-40.

**44:58:07:05. Theft reports.** A registrant shall notify the division of the theft or loss of a controlled substance within 48 hours. The report shall include the names and quantities of drugs and the circumstances involved in the theft or loss.

**Source:** 11 SDR 36, effective September 11, 1984; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-39, 34-20B-40, 34-20B-44, 34-20B-48.

**44:58:07:06. Emergency supplies.** Repealed.

**Source:** 25 SDR 48, effective October 1, 1998; repealed, 27 SDR 59, effective December 17, 2000.

**44:58:07:07. Limits on Schedule II controlled substances.** Repealed.

**Source:** 25 SDR 48, effective October 1, 1998; repealed, 27 SDR 59, effective December 17, 2000.

**44:58:07:08. Limits on Schedule III and IV controlled substances.** Repealed.

**Source:** 25 SDR 48, effective October 1, 1998; repealed, 27 SDR 59, effective December 17, 2000.

**44:58:07:09. Emergency supplies of controlled substances in long term care facilities.** Emergency supplies of controlled substances may be kept in long term care facilities under the following circumstances:

(1) The pharmacist supplying the controlled substances retains ownership and responsibility for the controlled substances, including a monthly physical inventory;

(2) The controlled substances are stored in a manner that allows only those individuals authorized to administer the controlled substance access to them;

(3) The controlled substances are stored in a sealed emergency box or in a separate locked cabinet, with a complete and accurate record kept of the controlled substances in the box or cabinet and their disposition;

(4) The facility notifies the pharmacist within 36 hours after the withdrawal of a Schedule II controlled substance and within 72 hours after the withdrawal of a Schedule III or IV controlled substance and the pharmacist replaces the controlled substance within 72 hours after notification; and

(5) No more than five different controlled substances are stored in the emergency box, which may contain no more than six doses of any Schedule II controlled substance, no more than six doses of any Schedule III or IV injectable controlled substance, and no more than 12 doses of any oral Schedule III or IV controlled substance.

**Source:** 25 SDR 48, effective October 1, 1998.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

## CHAPTER 44:58:08

### PRESCRIPTIONS

#### Section

44:58:08:01 and 44:58:08:02	Repealed.
44:58:08:03	Prescription prohibited for general dispensing supply.
44:58:08:04	Prescription prohibited for continuing dependence on drug.
44:58:08:05	Manner of issuance of prescriptions.
44:58:08:06 to 44:58:08:09	Repealed.
44:58:08:09.01	Dispensing controlled substances for maintenance purposes.
44:58:08:10 and 44:58:08:11	Repealed.
44:58:08:11.01	Direct administering or dispensing of controlled substances.
44:58:08:12	Repealed.
44:58:08:13	Requirements for oral authorization of Schedule II substances in emergencies.
44:58:08:14 to 44:58:08:16	Repealed.
44:58:08:17	Refilling of Schedule III and IV prescriptions -- Computerized information system authorized.
44:58:08:17.01	Refilling of Schedule II prescriptions prohibited.
44:58:08:18	Partial filling of prescriptions for Schedule II substances.
44:58:08:18.01	Partial filling of prescriptions for Schedule II substances for nursing facility or terminally ill patients.
44:58:08:18.02	Computerized system authorized for Schedule II prescription information for nursing facility or terminally ill patients.
44:58:08:18.03	Facsimile transmission of Schedule II prescriptions.
44:58:08:19	Repealed.
44:58:08:20	Labeling of prescriptions for controlled substances.
44:58:08:21 and 44:58:08:22	Repealed.
44:58:08:23	Dispensing placebo drugs.

**44:58:08:01. Persons entitled to issue prescriptions.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:02. Purpose of issuance of prescription.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:03. Prescription prohibited for general dispensing supply.** A prescription may not be issued by an individual practitioner to obtain controlled substances for general dispensing to patients.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 25 SDR 48, effective October 1, 1998.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**44:58:08:04. Prescription prohibited for continuing dependence on drug.** A prescription may not be issued for a controlled substance nor may a controlled substance be dispensed or administered to a drug dependent person for the purpose of continuing the person's dependency.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**44:58:08:05. Manner of issuance of prescriptions.** No practitioner may issue a prescription for a controlled substance for the practitioner's use. Prescriptions for controlled substances must be dated and signed on the day when issued and must bear the full name and address of the patient; the drug name, strength, dosage form, quantity prescribed, and directions for use; and the name, address, and registration number of the practitioner. A practitioner shall sign a prescription in the same manner as the practitioner would sign a legal document. If an oral order is not permitted, prescriptions must be written with ink, indelible pencil, or typewriter and must be manually signed by the practitioner. The prescriptions may be prepared by a secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible if the prescription does not conform in all essential respects to the law and this article. A liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed in this article. Prescriptions for Schedule III and IV controlled substances may be transmitted directly from the individual practitioner to the pharmacy by facsimile equipment.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 18 SDR 181, effective May 4, 1992; 21 SDR 219, effective June 27, 1995; 25 SDR 48, effective October 1, 1998.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**44:58:08:06. When hospital code number required in lieu of registration number.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:07. When service identification number required in lieu of registration number.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:08. Persons entitled to fill prescriptions.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:09. Dispensing of narcotic drugs for narcotic rehabilitation program authorized.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:09.01. Dispensing controlled substances for maintenance purposes.** The administering or dispensing directly of a controlled substance listed in any schedule to a drug dependent person for the purpose of controlled withdrawal while in treatment in a drug treatment or rehabilitation program must be within the meaning of the term, "in the course of professional practice or research".

**Source:** 6 SDR 93, effective July 1, 1980.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**44:58:08:10. Dispensing of Schedule II substances by pharmacists.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:11. Direct administering or dispensing of Schedule II substances by practitioner.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:11.01. Direct administering or dispensing of controlled substances.** An individual practitioner, in the course of professional practice only, may directly administer or dispense a controlled substance without a prescription to other persons. An individual practitioner or institutional practitioner may not order a controlled substance for direct administration or dispense a controlled substance, including any controlled substance sample, for the practitioner's use.

**Source:** 6 SDR 93, effective July 1, 1980; 25 SDR 48, effective October 1, 1998.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-30, 34-20B-41.

**44:58:08:12. Direct administering or dispensing of Schedule II substances by institutional practitioner.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:13. Requirements for oral authorization of Schedule II substances in emergencies.** In an emergency situation, as defined in SDCL 22-42-2.2, a pharmacist may dispense a controlled substance listed in Schedule II upon receiving oral authorization of an individual practitioner, if:

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;

(2) The prescription is immediately reduced to writing by the pharmacist and contains all information required in § 44:58:08:05 except for the signature of the prescribing individual practitioner;

(3) The practitioner is not known to the pharmacist, the pharmacist must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner by returning the prescriber's call using the phone number listed in the telephone directory or through other good faith efforts to assure the practitioner's identity; and

(4) Within seven days after authorizing an emergency oral prescription the individual practitioner shall supply the pharmacy with a written prescription for the emergency quantity prescribed. In addition to conforming to the requirements of § 44:58:08:05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. If the emergency prescription is sent by mail, the carrier envelope must be postmarked within the seven days. The pharmacist shall notify the department if the prescribing practitioner fails to deliver a written prescription within seven days. Failure to notify the department voids the authority to dispense the controlled substance without a written prescription.

**Source:** 1 SDR 30, effective October 6, 1974; 6 SDR 93, effective July 1, 1980; 25 SDR 48, effective October 1, 1998.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 22-42-2.1, 22-42-2.2.

**44:58:08:14. Dispensing of Schedule III and IV substances by pharmacists.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:15. Direct administering or dispensing of Schedule III or IV substances by practitioner.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:16. Direct administering or dispensing of Schedule III and IV substances by institutional practitioner.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:17. Refilling of Schedule III and IV prescriptions -- Computerized information system authorized.** A prescription for a Schedule III or IV drug or substance may be refilled up to five times within a six-month period if the refills are authorized by the practitioner on the original prescription. Each refill dispensed shall be entered on the prescription or on a patient medication record which indicates the date, quantity dispensed, and initials or name of the dispensing pharmacist. If the pharmacist merely initials and dates the prescription, the pharmacist is assumed to have dispensed a refill for the full face amount of the prescription. Additional quantities of controlled substances listed in Schedule III or IV may only be authorized by a practitioner through issuance of a new prescription.

As an alternative to the record procedures required by this section, an automated data processing system that complies with chapter 20:51:20 may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedules III and IV.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 11 SDR 36, effective September 11, 1984; 18 SDR 181, effective May 4, 1992.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 22-42-4.1, 22-42-4.2, 34-20B-41.

**Cross-Reference:** Computer pharmacy, ch 20:51:20.

**44:58:08:17.01. Refilling of Schedule II prescriptions prohibited.** No prescription for a Schedule II drug or substance may be refilled.

**Source:** 11 SDR 36, effective September 11, 1984.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 22-42-2.1, 22-42-2.2, 34-20B-41.

**44:58:08:18. Partial filling of prescriptions for Schedule II substances.** A pharmacist may partially fill a prescription for a controlled substance listed in Schedule II, if unable to supply the full quantity called for in a written or emergency oral prescription, and a notation of the quantity supplied is made on the face of the prescription. The remaining portion of the prescription may be filled within 72 hours of the partial filling; however, if the remaining portion is not filled within the 72-hour period, the pharmacist shall notify the practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 22-42-2.1, 22-42-2.2, 34-20B-41.

**44:58:08:18.01. Partial filling of prescriptions for Schedule II substances for nursing facility or terminally ill patients.** Notwithstanding the provisions of § 44:58:08:18, a pharmacist may partially fill a prescription for a substance listed in Schedule II written for a patient in a nursing facility or for a patient with a medical diagnosis documenting a terminal illness. The pharmacist shall record on the prescription whether the patient is "terminally ill" or a "nursing facility patient." For each partial filling, the pharmacist shall record on the back of the prescription the date of the partial filling, the quantity dispensed, the remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Before any subsequent partial filling the pharmacist shall determine that the additional partial filling is necessary. The total quantity of the Schedule II controlled substance dispensed in all partial fillings may not exceed the total quantity prescribed. The prescription is valid for not more than 60 days from the date of issue unless it is terminated sooner by the discontinuance of medication.

**Source:** 18 SDR 181, effective May 4, 1992; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 22-42-2.1, 22-42-2.2, 34-20B-41.

**44:58:08:18.02. Computerized system authorized for Schedule II prescription information for nursing facility or terminally ill patients.** Information pertaining to current Schedule II prescriptions for patients in a nursing facility or for patients with a medical diagnosis documenting a terminal illness may be maintained in an automated data processing system if the system has the capability to permit the following:

(1) Output, either display or printout, of the original prescription, number, date of issue, identification of the prescribing individual practitioner, identification of the patient, address of the nursing facility or hospital or the residence of the patient, identification of medication authorized (including dosage, form, strength, and quantity), a list of the partial fillings that have been dispensed under each prescription, and the information required in § 44:58:08:18.01;

(2) Immediate updating of the prescription record each time a partial filling of the prescription is made; and

(3) Retrieval of partially filled Schedule II prescription information as required by chapter 20:51:20.

**Source:** 18 SDR 181, effective May 4, 1992; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**Cross-Reference:** Computer pharmacy, ch 20:51:20.

**44:58:08:18.03. Facsimile transmission of Schedule II prescriptions.** A written prescription for a Schedule II controlled substance may be transmitted from the individual prescribing practitioner to a pharmacy by facsimile equipment, if the original written, signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance. The original prescription must be maintained as required in § 44:58:07:04.

Schedule II controlled substance prescriptions intended for direct administration to a patient by parenteral, intravenous, subcutaneous, or intraspinal infusion may be transmitted by facsimile. The facsimile prescription serves as the original prescription and shall be maintained as required in § 44:58:07:04. Schedule II controlled substance prescriptions for residents of long-term care facilities or patients residing in a Medicare certified hospice may be transmitted directly from the prescribing practitioner to the pharmacy by facsimile equipment. The facsimile prescription serves as the original

prescription and must be maintained as required in § 44:58:07:04. The facsimile prescription must be marked on the face with the notation "long term care resident" or "hospice patient."

**Source:** 21 SDR 219, effective June 27, 1995; 25 SDR 48, effective October 1, 1998.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**44:58:08:19. Partial filling of prescriptions for Schedule III and IV substances.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:20. Labeling of prescriptions for controlled substances.** The pharmacist filling any prescription for a controlled substance listed in Schedules II, III or IV shall attach to the container a label showing the date, the pharmacy name and address, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, directions for use and cautionary statements contained in the prescription or required by law. Controlled substances dispensed by an individual practitioner must be labeled with the name of the patient, the name of the practitioner, directions for use, the date, and any required cautionary statements.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-41.

**44:58:08:21. Filing of prescriptions required.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:22. Dispensing of Schedule III and IV substances without prescription prohibited.** Repealed.

**Source:** 1 SDR 30, effective October 7, 1974; repealed, 6 SDR 93, effective July 1, 1980.

**44:58:08:23. Dispensing placebo drugs.** The dispensing or prescribing of placebo or look-alike drugs by an individual practitioner is within the meaning of the term "in the course of professional practice or research".

**Source:** 11 SDR 36, effective September 11, 1984.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 22-42-16, 34-20B-41.

## CHAPTER 44:58:09

### ADMINISTRATIVE PROCEDURES

#### Section

- 44:58:09:01 Permission to make inspections required of licensees.
- 44:58:09:02 Financial data excluded from inspection.
- 44:58:09:03 Inspection requirements.
- 44:58:09:04 Required contents of notice of inspection.

**44:58:09:01. Permission to make inspections required of licensees.** As a privilege of receiving a registration under the act, each applicant must permit the secretary to enter controlled premises during regular business hours and conduct administrative inspections for the purposes of:

- (1) Inspecting, copying, and verifying the records required to be kept under the act and this article;
- (2) Inspecting all equipment, controlled substances, containers, and labeling found at the controlled premises relating to the act;
- (3) Making a physical inventory of all controlled substances on hand at the premises;
- (4) Collecting samples of controlled substances or precursors. If any samples are collected during an inspection, the inspector shall issue a receipt for the samples;
- (5) Checking records and information on distribution of controlled substances as they relate to total distribution; and
- (6) Except as provided in § 44:58:09:02, checking all other things appropriate for verification of the record referred to above or otherwise bearing on the act and this article.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-39, 34-20B-40.

**44:58:09:02. Financial data excluded from inspection.** Unless the owner, operator, or agent in charge of the controlled premises consents in writing, an inspection authorized by § 44:58:09:01 may not extend to financial, sales, or pricing data.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-40, 34-20B-44.

**44:58:09:03. Inspection requirements.** A representative of the secretary, upon stating the purpose of the inspection and presenting credentials and written notice of inspection, may enter the premises and conduct inspections. Violation of the consent agreement is grounds for automatic revocation of any registration issued under the act.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995.

**General Authority:** SDCL 34-20B-41.

**Law Implemented:** SDCL 34-20B-40, 34-20B-44.

**44:58:09:04. Required contents of notice of inspection.** The notice of inspection shall contain:

- (1) The name and title of the owner, operator, or agent in charge of the controlled premises;
- (2) The name of the controlled premises;
- (3) The address of the controlled premises;
- (4) The date and time;
- (5) A statement that a notice of inspection is given; and
- (6) The signature of the inspector.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980.



**General Authority:** SDCL 34-20B-41.  
**Law Implemented:** SDCL 34-20B-40, 34-20B-41.

## CHAPTER 44:58:10

### SECURITY REQUIREMENTS

Section  
44:58:10:01 Security requirements of registrants.

**44:58:10:01. Security requirements of registrants.** Controlled substances shall be stored in a securely locked, substantially constructed cabinet. However, substances listed in Schedules II through IV may be dispersed through the stock of noncontrolled substances in a manner to obstruct theft or diversion.

**Source:** 1 SDR 30, effective October 7, 1974; 6 SDR 93, effective July 1, 1980.  
**General Authority:** SDCL 34-20B-41.  
**Law Implemented:** SDCL 34-20B-41.

## CHAPTER 44:58:11

### HYPODERMIC CONTROL REGULATIONS (Repealed. 6 SDR 93, effective July 1, 1980)

## CHAPTER 44:58:12

### GENERAL PROVISIONS (Repealed. 6 SDR 93, effective July 1, 1980)

## CHAPTER 44:58:13

### EXEMPTED SCHEDULE III SUBSTANCES

Section  
44:58:13:01 Exempted Schedule III substances.

**44:58:13:01. Exempted Schedule III substances.** The following combinations of medicinal ingredients and Schedule III substances are exempt from control under the act or this article:

- (1) Analgesic agents which are not controlled substances, combined with a barbiturate;
- (2) Antiangina agents, combined with a barbiturate or meprobamate;
- (3) Anticholinergic agents, combined with a barbiturate, a benzodiazepine, or meprobamate;
- (4) Antiasthmatic agents, combined with a barbiturate;
- (5) Hormone replacement agents, combined with a benzodiazepine or meprobamate;
- (6) Anabolic steroid and estrogen combinations; and
- (7) Products that contain ephedrine in quantities at or less than:

(a) 25 milligrams in combination with 400 milligrams of quiafenesin, packaged in blister packs of not more than two tablets per blister; and

(b) Five percent by weight in an anorectal preparation in combination with other active medicinal ingredients.

**Source:** 6 SDR 93, effective July 1, 1980; 11 SDR 36, effective September 11, 1984; 21 SDR 14, effective August 4, 1994; 21 SDR 219, effective June 27, 1995; 23 SDR 195, effective May 26, 1997.

**General Authority:** SDCL 34-20B-21, 34-20B-41.

**Law Implemented:** SDCL 34-20B-21, 34-20B-41.

## CHAPTER 34-12B

### NURSING FACILITY PHARMACIES

- [34-12B-1](#) Right to choose pharmacy for filling prescriptions.
- [34-12B-2](#) Exclusive agreements between pharmacies and nursing facilities as misdemeanors--  
Exceptions.
- [34-12B-3](#) Acceptance by nursing facility of rebate, free equipment or fee from pharmacy as  
misdemeanor.
- [34-12B-4](#) Pharmacy splitting fees or giving rebate or free equipment and services to nursing facility as  
misdemeanor.
- [34-12B-5](#) Nursing facility prohibited from providing exclusive services to pharmacy.
- [34-12B-6](#) Violation as ground for suspension or revocation of license.
- [34-12B-7](#) Investigation of complaints.

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#### **[34-12B-1](#). Right to choose pharmacy for filling prescriptions.**

Any person shall have the right and privilege of having his prescription filled at the pharmacy or by the pharmacist of his choice.

**Source:** SL 1975, ch 225, § 1.

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#### **[34-12B-2](#). Exclusive agreements between pharmacies and nursing facilities as misdemeanors-- Exceptions.**

It is a Class 1 misdemeanor for any pharmacy, pharmacist, nursing facility, or nursing facility administrator, to contract, agree to or arrange for the exclusive right of a pharmacy or pharmacist to furnish drugs and medicines to residents or patients of a nursing facility, except in nursing facilities which are owned or operated by a licensed hospital, nursing facilities which maintain a licensed pharmacy department and nursing facilities which provide patient medication under a "unit dose" system in accordance with rules and regulations established by the State Board of Pharmacy.

**Source:** SL 1975, ch 225, § 2; SL 1977, ch 190, § 16.

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#### **[34-12B-3](#). Acceptance by nursing facility of rebate, free equipment or fee from pharmacy as misdemeanor.**

It is a Class 1 misdemeanor for any licensed nursing facility or nursing facility administrator to accept any rebate or free equipment from, or engage in splitting fees with any pharmacy department or pharmacist that is providing drugs or medicines to such home.

**Source:** SL 1975, ch 225, § 3; SL 1977, ch 190, § 17.

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#### **[34-12B-4](#). Pharmacy splitting fees or giving rebate or free equipment and services to nursing facility as misdemeanor.**

It is a Class 1 misdemeanor for any licensed pharmacy or pharmacist to split fees with, or give a rebate of any type or furnish free equipment to any nursing facility or nursing facility administrator as an

incentive to the nursing facility or nursing facility administrator to designate such pharmacy or pharmacist as an exclusive provider of drugs and medicines.

**Source:** SL 1975, ch 225, § 4; SL 1977, ch 190, § 18.

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**34-12B-5. Nursing facility prohibited from providing exclusive services to pharmacy.**

No nursing facility or nursing facility administrator shall provide services to a pharmacy or pharmacist that is not also made available to all pharmacies or pharmacists providing drugs or medicines to said nursing facility or its residents or patients. A violation of this section is a Class 1 misdemeanor.

**Source:** SL 1975, ch 225, § 6; SL 1977, ch 190, § 19.

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**34-12B-6. Violation as ground for suspension or revocation of license.**

Any violation of this chapter is grounds for the suspension or revocation of the license of a pharmacy, pharmacist, nursing facility, or nursing facility administrator by the appropriate licensing board or commission.

**Source:** SL 1975, ch 225, § 7; SL 1977, ch 190, § 20.

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**34-12B-7. Investigation of complaints.**

The Department of Health shall have the responsibility to investigate any complaints or alleged violations of this chapter.

**Source:** SL 1975, ch 225, § 5.

## CHAPTER 44:73:08

### MEDICATION CONTROL

#### Section

44:73:08:01	Repealed.
44:73:08:01.01	Policies and procedures.
44:73:08:02	Written orders for medication required.
44:73:08:03	Medication therapy reviewed monthly.
44:73:08:04	Storage and labeling of medications and drugs.
44:73:08:05	Control and accountability of medications and drugs.
44:73:08:06	Documentation of drug disposal.
44:73:08:07	Medication administration.
44:73:08:08	Medication records.
44:73:08:09	Administration of facility pharmacy.
44:73:08:10	Stock of legend drugs prohibited -- Exception.
44:73:08:11	Controlled drugs kept for emergency use.

#### **44:73:08:01. Medication control in hospitals and nursing facilities.** Repealed.

**Source:** SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; transferred from § 44:04:08:01, repealed, 42 SDR 51, effective October 13, 2015.

**44:73:08:01.01. Policies and procedures.** Each facility shall establish and practice methods and procedures for medication control that include the following;

(1) A requirement that each resident's prescribing physician, physician assistant, or nurse practitioner provide to the facility electronic or written signed orders for any medications taken by the resident; authorization for medications or drugs kept on the person or in the room of the resident; and release of medications;

(2) Provisions for proper storage of prescribed medications so that the medications are inaccessible to residents or visitors with requirements for:

- (a) Separate storage of poisons, topical medications, and oral medications;
- (b) Each resident's medication to be stored in the container in which it was originally received and not transferred to another container; and
- (c) A medication prescribed for one resident not to be administered to any other resident;

(3) Self-administration of medications to be accomplished with the supervision of a designated employee of the facility to include:

(a) A description of the responsibility of the resident, the resident's family members and the facility staff; and

(b) The provision of written educational material explaining to the resident and the resident's family the resident's rights and responsibilities associated with self-administration; and

(4) The proper disposition of medicines that are discontinued because of the discharge or death of the resident, because the drug is outdated, or because the prescription is no longer appropriate to the care of the resident.

Methods and written policies and procedures shall be established to include the manner of issuance, proper storage, control, accountability, and administration of medications or drugs in accordance with pharmaceutical and nursing practices as well as professional standards.

The facility and pharmacist shall establish a system of records of receipt and disposition for all controlled drugs in sufficient detail to enable an accurate reconciliation. The facility and pharmacist shall ensure the drug records are in order and that an account of all controlled drugs is maintained and periodically reconciled. The facility and pharmacist shall have policies and procedure for the periodic reconciliation of all controlled substances. The policies and procedure shall minimize the time between the actual loss or diversion and the time of detection and follow-up to determine the extent of the loss.

If a loss or diversion of controlled substances is identified, the facility and pharmacist shall evaluate the residents potentially affected consistent with their comprehensive assessment and plan of care. If the systems have not been effective in preventing the loss or diversion of controlled substances, the facility and pharmacist shall review and revise related controls and procedures as necessary.

**Source:** SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; 28 SDR 83, effective December 16, 2001; 29 SDR 81, effective December 11, 2002; transferred from § 44:04:08:02, 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13.

**Law Implemented:** SDCL 34-12-13.

**44:73:08:02. Written orders for medication required.** All medications or drugs administered to residents shall be ordered electronically or in writing and signed by the prescriber. Verbal orders for medications or drugs may be taken only when there is an urgent need to initiate or change an order and accepted only by a pharmacist or licensed nurse. The prescriber shall sign or initial the orders for residents on the next visit to the facility.

**Source:** SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; 26 SDR 96, effective January 23, 2000; 30 SDR 84, effective December 4, 2003; transferred from § 44:04:08:03, 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9)

**Law Implemented:** SDCL 34-12-13(9)

**44:73:08:03. Medication therapy reviewed monthly.** The pharmacist shall review the drug regimen at least monthly. The pharmacist shall review the resident's diagnosis, the drug regimen, and any pertinent laboratory findings and dietary considerations. The pharmacist shall report potential drug therapy irregularities and make recommendations for improving the drug therapy of the residents to the attending physician, physician assistant, or nurse practitioner and the administrator. The pharmacist shall document the review by preparing a monthly report of the potential irregularities and recommendations. The administrator shall retain the report in the facility. A copy of the medication review shall be in the resident medical record.

The pharmaceutical service shall be under the supervision of a licensed pharmacist who provides consultation and oversees all aspects of the pharmaceutical services.

**Source:** 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 28 SDR 83, effective December 16, 2001; 38 SDR 115, effective January 9, 2012; transferred from § 44:04:08:03.01, 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:73:08:04. Storage and labeling of medications and drugs.** All drugs or medications shall be stored in a well illuminated, locked storage area that is well ventilated, maintained at a temperature appropriate for drug storage, and inaccessible to residents or visitors at all times. Medications suitable for storage at room temperature shall be maintained between 59 and 86 degrees Fahrenheit (15 and 30 degrees centigrade). Medications that require refrigeration shall be maintained between 36 and 46 degrees Fahrenheit (2 and 8 degrees centigrade). Poisons and medications prescribed for external use shall be stored separately from internal medications, locked and made inaccessible to residents.

The medications or drugs of each resident for whom medications are facility-administered shall be stored in the containers in which they were originally received and may not be transferred to another container. Special modification of this requirement may be made if single dose packaging is used. Each prescription drug container, including manufacturer's complimentary samples, shall be labeled with the resident's name, physician, physician assistant, or nurse practitioner's name, drug name and strength, directions for use, and prescription date.

Containers with contents that will not be used within 30 days of issue or with contents that expire in less than 30 days of issue shall bear an expiration date. If a single dose system is used, the drug name and strength, expiration date, and a control number shall be on the unit dose packet.

A nursing facility may procure and stock, including in bulk form, nonlegend medications and administer them in accordance with written policies and procedures that provide for oversight by qualified personnel.

Any container with a worn, illegible, or missing label shall be destroyed pursuant to § 44:73:08:06. Licensed pharmacists are responsible for the labeling, relabeling, or altering of labels on medication containers.

**Source:** SL 1975, ch 16, § 1; 4 SDR 14, effective September 14, 1977; 5 SDR 29, effective October 22, 1978; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 27 SDR 59, effective December 17, 2000; 28 SDR 83, effective December 16, 2001; 38 SDR 115, effective January 9, 2012; transferred from § 44:04:08:04, 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:73:08:05. Control and accountability of medications and drugs.** Medications brought from home may be used if ordered by the attending physician, physician assistant, or nurse practitioner and, if prior to administration, is identified as the prescribed drug. Medications prescribed for one resident may not be administered to another. Residents may not keep medications on their person or in their room without a physician's, physician assistant, or nurse practitioner's order allowing self-administration. Written authorization by the resident's physician, physician assistant, or nurse practitioner shall be secured for the release of any medication to a resident upon discharge, transfer, or temporary leave from the facility. The release of medication shall be documented in the resident's record, indicating quantity, drug name, and strength. The facility shall maintain records that account for all medications and drugs from their receipt through administration, destruction, or return.

**Source:** 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; 26 SDR 96, effective January 23, 2000; 28 SDR 83, effective December 16, 2001; transferred from § 44:04:08:04.01, 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:73:08:06. Documentation of drug disposal.** Legend drugs not controlled under SDCL chapter 34-20B shall be destroyed or disposed of by a nurse and another witness. Destruction or disposal of medication controlled under SDCL chapter 34-20B shall be witnessed by two persons, both of whom are a nurse or pharmacist, as designated by facility policy. Methods of destruction or disposal may include:

(1) Disposal by using a professional waste hauler to take the medications to a permitted medical waste facility or by facility disposal at a permitted municipal solid waste landfill. Prior to disposal all medications shall be removed from original containers and made unpalatable by the addition of adulterants and alteration of solid dosage forms by dissolving or combination into a solid mass;

(2) Return to the dispensing pharmacy for destruction or dispose according to federal and state regulations;

(3) Return to an authorized reverse distributor company licensed by the South Dakota Board of Pharmacy; or

(4) Release to resident upon discharge after authorization by the resident's prescribing practitioner.

Medications controlled under SDCL chapter 34-20B shall not be returned to the dispensing pharmacy or to an authorized reverse distributor company. Documentation of destruction or disposal of medications shall be included in the resident's record. The documentation shall include the method of disposition (destruction, disposal, return to pharmacy, or release to resident); the medication name, strength, prescription number (as applicable), quantity, and date of disposition; and the name of any person who witnessed the destruction or disposal.

Medications, excluding those controlled under SDCL chapter 34-20B, contained in unit dose packaging meeting the requirements of § 20:51:13:02.01 may be returned to the dispensing pharmacy for credit and redispensing.

Any medication held for disposal shall be physically separated from the medications being used in the facility, locked with access limited, in an area with a system to reconcile, audit, or monitor them to prevent diversion.

**Source:** 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; transferred from § 44:04:08:04.02, 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:73:08:07. Medication administration.** Each medication administered shall be recorded in the resident's medical record and signed by the person responsible. Medication errors and drug reactions shall be reported to the resident's physician, physician assistant, or nurse practitioner and an entry made in the resident's medical record. Orders involving abbreviations and chemical symbols may be carried out only if the facility has a standard list of abbreviations and symbols approved by the medical staff or, in the absence of an organized medical staff, by the medical director and the list is available to the nursing staff. All medications shall be administered to residents by personnel acting under delegation of a licensed nurse, or licensed to administer medications.



A person may not administer medications that have been prepared by another person, other than a pharmacist.

Medication administration shall comply with §§ 44:73:08:02 to 44:73:08:05, inclusive, and with the requirements for training in §§ 20:48:04.01:14 and 20:48:04.01:15 and for supervision in § 20:48:04.01:02. The supervising nurse shall provide an orientation to the unlicensed assistive personnel who will administer medications. The orientation shall be specific to the facility and relevant to the residents receiving administered medications.

**Source:** SL 1975, ch 16, § 1; 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; 28 SDR 83, effective December 16, 2001; 31 SDR 62, effective November 7, 2004; 38 SDR 115, effective January 9, 2012; transferred from § 44:04:08:05, 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:73:08:08. Medication records.** Medication administration records shall be used and regularly checked against the physician, physician assistant, or nurse practitioner's orders. Each medication administered shall be recorded in the resident's medical record and signed by the individual responsible.

**Source:** 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:73:08:09. Administration of facility pharmacy.** The pharmaceutical service of each facility with a licensed full or part-time pharmacy shall be directed by a licensed pharmacist accountable to the administration of the facility. Only prepackaged drugs or a single dose unit may be removed from the pharmacy when the pharmacist is not available. These drugs may be removed only by a designated registered nurse or physician, physician assistant, or nurse practitioner in amounts sufficient only for immediate therapeutic needs. A record of such withdrawals shall be made by the designated nurse or the physician, physician assistant, or nurse practitioner making the withdrawal.

**Source:** SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; transferred from § 44:04:08:06, 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:73:08:10. Stock of legend drugs prohibited -- Exception.** Legend drugs or medications may be stocked in bulk form in nursing facilities which employ a licensed pharmacist full or part time to supervise, within the facility, the procurement, storage, and dispensing of such drugs and medications. Nursing facilities without a pharmacy shall use the emergency drug box kept on the premises pursuant to § 44:73:08:11.

**Source:** SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; transferred from § 44:04:08:07, 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9)

**Law Implemented:** SDCL 34-12-13(9)

**44:73:08:11. Controlled drugs kept for emergency use.** Controlled drugs may be kept for emergency use under the following circumstances:

(1) The pharmacist supplying the controlled drugs maintains ownership and responsibility for the drugs, including a monthly physical inventory;

(2) The controlled drugs are stored in a manner that allows only those individuals authorized to administer the drugs access to them;

(3) The controlled drugs are stored in a sealed emergency box or in a separate locked cabinet, with a complete and accurate record kept of the drugs in the box or cabinet and of their disposition;

(4) The facility notifies the pharmacist within 36 hours after the withdrawal of a Schedule II drug and within 72 hours after the withdrawal of Schedule III and IV drugs and the pharmacist replaces the drugs within 72 hours after notification; and

(5) No more than 5 different controlled drugs are stored in the emergency box, which may contain no more than 6 doses of any Schedule II controlled drug, no more than 6 doses of any Schedule III or IV injectable controlled drug, and no more than 12 doses of any oral Schedule III or IV controlled drug.

**Source:** 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; transferred from § 44:04:08:07.01, 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**CHAPTER 44:75:08**  
**MEDICATION CONTROL**

Section

44:75:08:01	Policies and procedures.
44:75:08:02	Written orders for medication required.
44:75:08:03	Repealed.
44:75:08:04	Storage and labeling of medications and drugs.
44:75:08:05	Control and accountability of medications and drugs.
44:75:08:06	Documentation of drug disposal.
44:75:08:07	Medication administration.
44:75:08:08	Medication records.
44:75:08:09	Administration of facility pharmacy.

**44:75:08:01. Policies and procedures.** Each facility shall establish and practice methods and procedures for medication control that include the following:

(1) A requirement that each patient's prescribing physician, physician assistant, or nurse practitioner provide to the facility electronic or written signed orders for any medications taken by the patient; authorization for medications or drugs kept on the person or in the room of the patient; and release of medications;

(2) Provisions for proper storage of prescribed medications so that the medications are inaccessible to patients or visitors with requirements for:

- (a) Separate storage of poisons, topical medications, and oral medications;
- (b) Each patient's medication to be stored in the container in which it was originally received and not transferred to another container; and
- (c) A medication prescribed for one patient not to be administered to any other patient;

(3) Self-administration of medications to be accomplished with the supervision of a licensed nurse to include:

- (a) A description of the responsibilities of the patient, the patient's family members, and the facility staff; and
- (b) The provision of written educational material explaining to the patient and the patient's family the patient's rights and responsibilities associated with self-administration; and

(4) The proper disposition of medicines that are discontinued because of the discharge or death of the patient, because the drug is outdated, or because the prescription is no longer appropriate to the care of the patient.

Methods and written policies and procedures shall be established to include the manner of issuance, proper storage, control, accountability, and administration of medications or drugs in accordance with pharmaceutical and nursing practices as well as professional standards.

**Source:** 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:75:08:02. Written orders for medication required.** All medications or drugs administered to patients shall be ordered electronically or in writing and dated, timed, and authenticated by the prescriber. Verbal orders for medications or drugs may be taken only when there is an urgent need to initiate or change an order and accepted only by a pharmacist or licensed nurse in hospitals. The prescriber shall date, time, and authenticate the orders for hospital patients on the next visit to the facility. The practitioner shall date, time, and authenticate the orders for patients promptly. A policy on stop orders for antibiotics, anticoagulants, and controlled drugs shall be established based on recommendations of the medical staff.

**Source:** 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:75:08:03. Medication therapy review.** Repealed.

**Source:** 42 SDR 51, effective October 13, 2015; 42 SDR 173, effective June 21, 2016.

**44:75:08:04. Storage and labeling of medications and drugs.** All drugs or medications shall be stored in a well illuminated, locked storage area that is well ventilated, maintained at a temperature appropriate for drug storage, and inaccessible to patients, or visitors at all times. Medications suitable for storage at room temperature shall be maintained between 59 and 86 degrees Fahrenheit (15 and 30 degrees centigrade). Medications that require refrigeration shall be maintained between 36 and 46 degrees Fahrenheit (2 and 8 degrees centigrade). Poisons and medications prescribed for external use shall be stored separately from internal medications, locked and made inaccessible to patients.

Locked storage does not apply to drugs and medications needed for emergency use in intensive care, emergency room, neonatal intensive care, pediatric intensive care, or coronary care units. Drugs and medications utilized in these care units shall be in a storage area that is readily available to the professional staff but inaccessible to patients or visitors.

The medications or drugs of each patient for whom medications are facility-administered shall be stored in the containers in which they were originally received and may not be transferred to another container. Special modification of this requirement may be made if single dose packaging is used. Each prescription drug container, including manufacturer's complimentary samples, shall be labeled with the patient's name, physician, physician assistant, or nurse practitioner's name, drug name and strength, directions for use, and prescription date.

Containers with contents that will not be used within 30 days of issue or with contents that expire in less than 30 days of issue shall bear an expiration date. If a single dose system is used, the drug name and strength, expiration date, and a control number shall be on the unit dose packet.

A co-located hospital and assisted living center may procure and stock, including in bulk form, nonlegend medications and administer them in accordance with written policies and procedures that provide for oversight by qualified personnel.

If a stock bottle system is used in a facility with a licensed pharmacy, the container shall be labeled with the drug name and strength, expiration date, and a control number. Any container with a worn, illegible, or missing label shall be destroyed pursuant to § 44:73:08:06. Licensed pharmacists are responsible for the labeling, relabeling, or altering of labels on medication containers.

**Source:** 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:75:08:05. Control and accountability of medications and drugs.** Medications brought from home may be used if ordered by the attending physician, physician assistant, or nurse practitioner, and, if prior to administration, is identified as the prescribed drug. Medications prescribed for one patient may not be administered to another. Patients may not keep medications on their person or in their room without a physician's, physician assistant, or nurse practitioner's order allowing self-administration. Written authorization by the patient's physician, physician assistant, or nurse practitioner shall be secured for the release of any medication to a patient upon discharge, transfer, or temporary leave from the facility. The release of medication shall be documented in the patient's record, indicating quantity, drug name, and strength. The facility shall maintain records that account for all medications and drugs from their receipt through administration, destruction, or return.

**Source:** 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:75:08:06. Documentation of drug disposal.** Legend drugs not controlled under SDCL chapter 34-20B shall be destroyed or disposed of by a nurse and another witness. Destruction or disposal of medications controlled under SDCL chapter 34-20B shall be witnessed by two persons, both of whom are a nurse or pharmacist, as designated by facility policy. Methods of destruction or disposal may include:

(1) Disposal by using a professional waste hauler to take the medications to a permitted medical waste facility or by facility disposal at a permitted municipal solid waste landfill. Prior to disposal all medications shall be removed from original containers and made unpalatable by the addition of adulterants and alteration of solid dosage forms by dissolving or combination into a solid mass;

(2) Return to the dispensing pharmacy for destruction or dispose according to federal and state regulations;

(3) Return to an authorized reverse distributor company licensed by the South Dakota Board of Pharmacy; or

(4) Release to patient upon discharge after authorization by the patient's prescribing practitioner.

Documentation of destruction or disposal of medications shall be included in the patient's record. The documentation shall include the method of disposition (destruction, disposal, return to pharmacy, or release to patient); the medication name, strength, prescription number (as applicable), quantity, and date of disposition; and the name of any person who witnessed the destruction or disposal.

Medications, excluding those controlled under SDCL chapter 34-20B, contained in unit dose packaging meeting the requirements of § 20:51:13:02.01 may be returned to the dispensing pharmacy for credit and redispensing.

Any medication held for disposal shall be physically separated from the medications being used in the facility, locked with access limited, in an area with a system to reconcile, audit, or monitor them to prevent diversion.

**Source:** 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:75:08:07. Medication administration.** Each medication administered shall be recorded in the patient's medical record and signed by the person responsible. Medication errors and drug reactions shall be reported to the patient's physician, physician assistant, or nurse practitioner and an entry made in the patient's medical record. Orders involving abbreviations and chemical symbols may be carried out only if the facility has a standard list of abbreviations and symbols approved by the medical staff or, in the absence of an organized medical staff, by the medical director and the list is available to the nursing staff. All medications shall be administered to patients by personnel acting under delegation of a licensed nurse, or licensed to administer medications.

A person may not administer medications that have been prepared by another person, other than a pharmacist.

Medication administration shall comply with §§ 44:75:08:02 to 44:75:08:05, inclusive, and with the requirements for training in §§ 20:48:04.01:14 and 20:48:04.01:15 and for supervision in § 20:48:04.01:02. The supervising nurse shall provide an orientation to the unlicensed assistive personnel who will administer medications. The orientation shall be specific to the facility and relevant to the patients receiving administered medications.

**Source:** 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:75:08:08. Medication records.** Medication administration records shall be used and regularly checked against the practitioner's orders. Each medication administered shall be recorded in the patient's medical record and signed by the individual responsible.

**Source:** 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

**44:73:08:09. Administration of facility pharmacy.** The pharmaceutical service of each facility with a licensed full or part-time pharmacy shall be directed by a licensed pharmacist accountable to the administration of the facility. Only prepackaged drugs or a single dose unit may be removed from the pharmacy when the pharmacist is not available. These drugs may be removed only by a designated registered nurse or physician, physician assistant, or nurse practitioner in amounts sufficient only for immediate therapeutic needs. A record of such withdrawals shall be made by the designated nurse or the physician, physician assistant, or nurse practitioner making the withdrawal.

**Source:** 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(9).

**Law Implemented:** SDCL 34-12-13(9).

## ARTICLE 44:75:14:11

### Pharmacy or Drug Room

**44:75:14:11. Pharmacy or drug room.** The pharmacy or drug room shall be well ventilated and have a locking door. The pharmacy or drug room shall be sized for the distribution system used and shall have a work counter with sink, a separate locked and fastened compartment or room for the storage of controlled substances, refrigerated and frozen storage spaces, and other approved storage for drugs. If additive injectables are prepared, a sterile products area shall be provided. The work space shall be well illuminated. Emergency power shall be provided for essential services. Heating, ventilation, and air conditioning services shall be provided to maintain the temperature of the room between 59 degrees Fahrenheit (15 degrees centigrade) and 86 degrees Fahrenheit (30 degrees centigrade).

**Source:** SL 1975, ch 16, § 1; 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; transferred from § 44:04:14:12, 42 SDR 51, effective October 13, 2015.

**General Authority:** SDCL 34-12-13(1), (3), (4) and (9).

**Law Implemented:** SDCL 34-12-13(1), (3), (4) and (9).

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## CHAPTER [36-2A](#)

### HEALTH PROFESSIONALS ASSISTANCE PROGRAM

- [36-2A-1](#) Definitions.
- [36-2A-1.1](#) Health professional assistance program--Relation to sanctions.
- [36-2A-2](#) Health professional assistance program--Standards.
- [36-2A-3](#) Repealed
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- [36-2A-7](#) Eligibility.
- [36-2A-8](#) Denial of admission.
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- [36-2A-12](#) Confidentiality of participants' records.
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- [36-2A-14](#) Promulgation of rules.
- [36-2A-15](#) Repealed
- [36-2A-16](#) Physician wellness program defined.
- [36-2A-17](#) Physician wellness program--Confidentiality--Exemption.
- [36-2A-18](#) Physician wellness program--Statewide association.
- [36-2A-19](#) Physician wellness program--Civil liability.

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#### [36-2A-1](#). **Definitions.**

Terms used in this chapter mean:

- (1) "Board," a licensing board authorized in title 36;
- (2) "Health professionals assistance program," or "program," a confidential program designed to monitor and manage the treatment and continuing care of a health professional who may be unable to practice with reasonable skill or safety, or whose practice poses a risk to the public, if the professional's mental health or substance use related issue or disorder is not appropriately managed;
- (3) "Impaired," the inability of a licensee to practice with reasonable skill or safety, or whose practice poses a risk to the public as a result of unmanaged or undermanaged mental health or substance use related issue or disorder;
- (4) "Program personnel," persons or entities providing services for or on behalf of a licensing board's health professionals assistance program.

**Source:** SL 1996, ch 227, § 1; SL 2013, ch 171, § 1; SL 2021, ch 170, § 1.

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#### [36-2A-1.1](#). **Health professional assistance program--Relation to sanctions.**

A board may use the program as an alternative to, or in conjunction with, other sanctions that may be imposed by the board.

**Source:** SL 2021, ch 170, § 2.

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### **36-2A-2. Health professional assistance program--Standards.**

A board may conduct, or contract for services with an entity to conduct, a health professionals assistance program to protect the public from impaired persons regulated by the board. The program does not affect a board's authority to discipline violators of a board's practice act.

A health professionals assistance program shall include the following standards:

- (1) Program personnel qualified to manage mental health and substance use related issues and disorders;
- (2) Admission criteria;
- (3) Criteria for denial of admission pursuant to § [36-2A-8](#);
- (4) Program participation components;
- (5) Termination criteria; and
- (6) Successful discharge criteria.

**Source:** SL 1996, ch 227, § 2; SL 2013, ch 171, § 2; SL 2021, ch 170, § 3.

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### **36-2A-3. Repealed.**

**Source:** SL 1996, ch 227, § 3; SL 2013, ch 171, § 3; SL 2021, ch 170, § 4.

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### **36-2A-4. Repealed.**

**Source:** SL 1996, ch 227, § 4; SL 2013, ch 171, § 4; SL 2021, ch 170, § 5.

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### **36-2A-5. Repealed.**

**Source:** SL 1996, ch 227, § 5; SL 2013, ch 171, § 5; SL 2021, ch 170, § 6.

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### **36-2A-6. Application to program--Admission evaluation.**

An applicant that meets admission criteria shall be allowed access to the program by self-referral, board referral, or referral from another person or agency. Program personnel shall advise the applicant of the program requirements and the implications of noncompliance and shall secure an agreement with the applicant that includes participation components before the applicant enters the program. An applicant who refuses to cooperate with the program admission process may be reported to the applicable board.

**Source:** SL 1996, ch 227, § 6; SL 2013, ch 171, § 6; SL 2021, ch 170, § 7.

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### **36-2A-7. Eligibility.**

Admission to the program is available to any person who meets the admission criteria and:

- (1) Holds licensure as a health care professional in this state;
- (2) Is eligible for and in the process of applying for licensure as a health care professional in this state;  
or
- (3) Is enrolled as a student in a program leading to licensure as a health care professional.

**Source:** SL 1996, ch 227, § 7; SL 2013, ch 171, § 7; SL 2021, ch 170, § 8.

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### **36-2A-8. Denial of admission.**

Admission to the program may be denied if the applicant:

- (1) Is not eligible for licensure in this state;
- (2) Diverted controlled substances for other than personal use;

- (3) Creates too great a risk to the public by participating in the program as determined by program personnel; or
- (4) Has engaged in sexual misconduct that meets the criteria for denial of admission.

**Source:** SL 1996, ch 227, § 8; SL 2013, ch 171, § 8; SL 2021, ch 170, § 9.

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#### **36-2A-9. Participation components.**

The program participation components may include requirements for treatment and continuing care, work-site monitoring, practice restrictions, random drug screening, support group participation, filing of reports, compliance documentation, and other requirements as necessary to manage mental health or substance use related issues or disorders and for successful completion of the program.

**Source:** SL 1996, ch 227, § 9; SL 2013, ch 171, § 9; SL 2021, ch 170, § 10.

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#### **36-2A-10. Repealed.**

**Source:** SL 1996, ch 227, § 10; SL 2013, ch 171, § 10; SL 2021, ch 170, § 11.

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#### **36-2A-11. Repealed.**

**Source:** SL 1996, ch 227, § 11; SL 2013, ch 171, § 11; SL 2021, ch 170, § 12.

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#### **36-2A-12. Confidentiality of participants' records.**

All records of program participants are confidential and are not subject to discovery or subpoena. Only authorized program personnel may have access to participant records unless the participant voluntarily provides for written release of the information. A board may only have access to records of participants who were referred by the board, who refused to cooperate with the program, or who have been terminated by the program.

**Source:** SL 1996, ch 227, § 12; SL 2013, ch 171, § 12; SL 2021, ch 170, § 13.

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#### **36-2A-13. Immunity for reports and actions related to duties.**

Any person, agency, institution, facility, or organization making reports to the board or health professionals assistance program regarding an individual suspected of practicing while impaired or reports of a participant's progress or lack of progress in the program is immune from civil liability for submitting a report in good faith to the program. Members, agents, and staff of the board and program personnel acting in good faith are immune from civil liability for any actions related to their duties under this chapter.

**Source:** SL 1996, ch 227, § 13; SL 2013, ch 171, § 13; SL 2021, ch 170, § 14.

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#### **36-2A-14. Promulgation of rules.**

Each board conducting a health professionals assistance program may promulgate rules, pursuant to chapter [1-26](#), pertaining to:

- (1) Program structure;
- (2) Admission criteria;
- (3) Criteria for denial of admission;
- (4) Required participation components;
- (5) Termination of participation and discharge criteria;
- (6) Confidentiality and retention of program records;
- (7) Program evaluation criteria; and

(8) Participation fees.

**Source:** SL 1996, ch 227, § 14; SL 2013, ch 171, § 14; SL 2021, ch 170, § 15.

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[36-2A-15](#). Repealed.

**Source:** SL 1996, ch 227, § 15; SL 2013, ch 171, § 15; SL 2021, ch 170, § 16.

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[36-2A-16](#). **Physician wellness program defined.**

The term, physician wellness program, as used in §§ [36-2A-16](#) to 36-2A-19, inclusive, means a program of evaluation, counseling, or other modality to address an issue related to career fatigue or wellness in a person licensed to practice medicine or osteopathy under chapter [36-4](#) or a physician assistant licensed under chapter [36-4A](#). The term does not include the provision of services intended to monitor for impairment.

**Source:** SL 2021, ch 171, § 1.

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[36-2A-17](#). **Physician wellness program--Confidentiality--Exemption.**

Any record of a person's participation in a physician wellness program is confidential and not subject to discovery, subpoena, or a reporting requirement to the applicable board, unless the person voluntarily provides for written release of the information or the disclosure is required to meet the licensee's obligation to report a criminal charge or action, or unprofessional or dishonorable conduct, as defined in §§ [36-4-30](#), [36-4-30.1](#), and [36-4A-38](#).

**Source:** SL 2021, ch 171, § 2.

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[36-2A-18](#). **Physician wellness program--Statewide association.**

Any statewide association, exempt from taxation under 26 U.S.C. § 501(c)(6) and that primarily represents health care professionals licensed to practice medicine or osteopathy under chapter [36-4](#), may establish a physician wellness program.

**Source:** SL 2021, ch 171, § 3.

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[36-2A-19](#). **Physician wellness program--Civil liability.**

Any person, agency, institution, facility, or organization employed by, contracting with, or operating a physician wellness program, when acting in good faith, is immune from civil liability for any action related to their duties in connection with a physician wellness program.

**Source:** SL 2021, ch 171, § 4.

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## CHAPTER 34-20A

### TREATMENT AND PREVENTION OF ALCOHOL AND DRUG ABUSE

- [34-20A-98](#) Possession and administration of opioid antagonists by first responders.
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- [34-20A-111](#) Immunity from arrest or prosecution for reporting one's own need for emergency medical assistance for drug-related overdose.
- [34-20A-112](#) Providing first aid or other medical assistance as mitigating factor--Limitations on immunity.
- [34-20A-113](#) One-time immunity.

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#### **[34-20A-98. Possession and administration of opioid antagonists by first responders.](#)**

Any first responder trained in compliance with § [34-20A-101](#) and acting under a standing order issued by a physician licensed pursuant to chapter [36-4](#) may possess and administer opioid antagonists to a person exhibiting symptoms of an opiate overdose.

**Source:** SL 2015, ch 179, § 1.

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#### **[34-20A-99. Opioid antagonist defined.](#)**

For the purposes of §§ [34-20A-98](#) to [34-20A-103](#), inclusive, the term, opioid antagonist, means naloxone hydrochloride or any other similarly acting and equally safe drug approved by the federal Food and Drug Administration for the treatment of drug overdose.

**Source:** SL 2015, ch 179, § 2.

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#### **[34-20A-100. First responder defined.](#)**

For the purposes of §§ [34-20A-98](#) to [34-20A-103](#), inclusive, the term, first responder, includes:

- (1) A law enforcement officer as defined by subdivision 22-1-2(22);
- (2) A driver and attendant responding to an emergency call as part of an ambulance service licensed pursuant to chapter [34-11](#); and

- (3) A firefighter.

**Source:** SL 2015, ch 179, § 3.

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**34-20A-101. Training of first responders.**

Each first responder authorized to administer an opioid antagonist shall be trained in the symptoms of an opiate overdose; the protocols and procedures for administration of an opioid antagonist; the symptoms of adverse responses to an opioid antagonist, and protocols and procedures to stabilize the patient if an adverse response occurs; and the procedures for storage, transport, and security of the opioid antagonist. The training shall comply with the criteria established pursuant to § [34-20A-102](#), and may be provided by the employer of first responders at the employer's discretion.

**Source:** SL 2015, ch 179, § 4.

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**34-20A-102. Promulgation of rules for training, possession, and administration of opioid antagonists.**

The Board of Medical and Osteopathic Examiners shall promulgate rules, pursuant to chapter [1-26](#), establishing:

- (1) The criteria for training a first responder to comply with the provisions of § [34-20A-101](#); and
- (2) The requirements for a physician's issuance of a standing order to a first responder authorizing a prescription for the first responder's possession of an opioid antagonist and the protocols and procedures to be followed in administering an opioid antagonist.

**Source:** SL 2015, ch 179, § 5.

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**34-20A-103. Immunity from civil liability for injuries or death associated with administration of opioid antagonists.**

A physician who issues a standing order under the rules established pursuant to § [34-20A-102](#), a first responder acting under a standing order who administers an opioid antagonist in good faith compliance with the protocols for administering an opioid antagonist, and the first responder's employer, are not civilly liable for injuries, and may not be held to pay damages to any person, or the person's parents, siblings, children, estate, heirs, or devisees, for injuries or death associated with the administration of an opioid antagonist.

**Source:** SL 2015, ch 179, § 6.

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**34-20A-104. Possession and administration of opioid antagonists by person close to person at risk of overdose.**

A person who is a family member, friend, or other close third party to a person at risk for an opioid-related drug overdose may be prescribed, possess, distribute, or administer an opioid antagonist that is prescribed, dispensed, or distributed by a licensed health care professional directly or by standing order pursuant to §§ [34-20A-104](#) to [34-20A-108](#), inclusive.

**Source:** SL 2016, ch 174, § 1.

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**34-20A-105. Prescription for opioid antagonist.**

A licensed health care professional may, directly or by standing order, prescribe an opioid antagonist to a person at risk of experiencing an opioid-related overdose, or prescribe to a family member, friend, or other close third party person the health care practitioner reasonably believes to be in a position to assist a person at risk of experiencing an opioid-related overdose.

**Source:** SL 2016, ch 174, § 2.

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**34-20A-106. Health care professional immunity from liability.**

A health care professional who is authorized to prescribe or dispense an opioid antagonist is not subject to any disciplinary action or civil or criminal liability for the prescribing or dispensing of an opioid antagonist to a person whom the health care professional reasonably believes may be in a position to assist or administer the opioid antagonist to a person at risk for an opioid-related drug overdose.

**Source:** SL 2016, ch 174, § 3.

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**34-20A-107. Prescription deemed issued for legitimate medical purpose.**

For the purpose of §§ [34-20A-104](#) to [34-20A-108](#), inclusive, any prescription issued pursuant to §§ [34-20A-104](#) to [34-20A-108](#), inclusive, is deemed to be issued for a legitimate medical purpose in the usual course of professional practice.

**Source:** SL 2016, ch 174, § 4.

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**34-20A-108. Duty or standard of care regarding opioid antagonists unaffected.**

The provisions of §§ [34-20A-104](#) to [34-20A-108](#), inclusive, do not establish a duty or standard of care with respect to the decision of whether to prescribe, dispense, or administer an opioid antagonist.

**Source:** SL 2016, ch 174, § 5.

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**34-20A-109. Definitions related to reporting person in need of emergency assistance for drug-related overdose.**

Terms used in §§ [34-20A-110](#) to [34-20A-113](#), inclusive, mean:

- (1) "Drug-related overdose," an acute condition, including mania, hysteria, extreme physical illness, coma, or death resulting from the consumption or use of a controlled substance, or another substance with which a controlled substance was combined, and that a person would reasonably believe to be a drug overdose that requires medical assistance.

**Source:** SL 2017, ch 154, § 1.

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**34-20A-110. Immunity from arrest or prosecution for reporting person in need of emergency medical assistance for drug-related overdose.**



No person may be arrested or prosecuted for any misdemeanor or felony offense of possession, inhalation, ingestion, or otherwise taking into the body any controlled drug or substance if that person contacts any law enforcement or emergency medical services and reports that a person is in need of emergency medical assistance as the result of a drug-related overdose. A person qualifies for the immunities provided in §§ [34-20A-109](#) to [34-20A-113](#), inclusive, only if:

- (1) The evidence for the charge or prosecution was obtained as a result of the person seeking medical assistance for another person;
- (2) The person seeks medical assistance for another person who is in need of medical assistance for an immediate health or safety concern; and
- (3) The person seeking medical assistance for another person remains on the scene and cooperates with medical assistance and law enforcement personnel.

**Source:** SL 2017, ch 154, § 2.

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**[34-20A-111](#). Immunity from arrest or prosecution for reporting one's own need for emergency medical assistance for drug-related overdose.**

A person who experiences a drug-related overdose and is in need of medical assistance may not be arrested, charged, or prosecuted for any misdemeanor or felony offense of possession, inhalation, ingestion, or otherwise taking into the body any controlled drug or substance if that person contacts law enforcement or emergency medical services and reports that he or she is in need of medical assistance as the result of a drug-related overdose. A person qualifies for the immunities provided in this section only if the evidence for the charge or prosecution was obtained as a result of the drug-related overdose and the need for medical assistance.

**Source:** SL 2017, ch 154, § 3.

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**[34-20A-112](#). Providing first aid or other medical assistance as mitigating factor--Limitations on immunity.**

Providing first aid or other medical assistance to someone who is experiencing a drug-related overdose may be used as a mitigating factor in a criminal prosecution for which immunity is not provided under §§ [34-20A-109](#) to [34-20A-113](#), inclusive. Nothing in §§ [34-20A-109](#) to [34-20A-113](#), inclusive, may be construed to:

- (1) Bar the admissibility of any evidence obtained in connection with the investigation and prosecution of other crimes or violations committed by a person who otherwise qualifies for limited immunity pursuant to §§ [34-20A-109](#) to [34-20A-113](#), inclusive; or
- (2) Limit, modify, or remove any immunity from liability currently available to public entities, public employees by law, or prosecutors.

**Source:** SL 2017, ch 154, § 4.

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**[34-20A-113](#). One-time immunity.**

Any person seeking medical assistance or who reports a person is in need of medical assistance shall only qualify once for immunity under §§ [34-20A-109](#) to [34-20A-112](#), inclusive.

**Source:** SL 2017, ch 154, § 5.