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DEPARTMENT OF HEALTH

ARTICLE 20:67
DRUG DISTRIBUTORS

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ARTICLE 20:67

DRUG DISTRIBUTORS

CHAPTER 20:67:01

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. 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.

Except during COVID-19 emergency when a license to ship products into state may be waived by board for good cause.

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. 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

20:67:04:04 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. 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. 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.