ARTICLE 20:51

PHARMACISTS

Chapter

CHAPTER 20:51:32

PRESCRIPTION DRUG MONITORING PROGRAM

Section

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.

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.

General Authority: SDCL 34-20E-20.

Law Implemented: SDCL 34-20E-2, 34-20E-20(1), 34-20E-3.

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

(20) Prescriber phone number.

Source: 37 SDR 214, effective May 30, 2011.

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. Healthcare practitioners authorized to prescribe may designate one or more persons who are licensed or registered with their 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 by SDCL 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.

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 ~~must~~ 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 to the 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.

General Authority: SDCL 34-20E-20(4).

Law Implemented: SDCL ~~34-20E-12, 34-20E-20(4)~~ 34-20E-5, 34-20E-7(1).

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 ~~include the signature of~~ 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.

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 ~~purpose of the request, the~~ individual's name and date of birth, the date range requested, and the specific reasons for the request, which 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.

General Authority: SDCL 34-20E-20(4).

Law Implemented: SDCL 34-20E-7(4), 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 ~~purpose of the request, 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.

General Authority: SDCL 34-20E-20(4).

Law Implemented: SDCL 34-20E-7(5)(6)(8) and (9).

CHAPTER 20:51:33

COMPLAINT PROCEDURES

Section

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:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(13).

Law Implemented: SDCL 36-11-1, 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:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(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 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 registration 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:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(13).

Law Implemented: SDCL 36-11-1, 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, which 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;

(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:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(13).

Law Implemented: SDCL 36-11-1, 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:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(13).

Law Implemented: SDCL 36-11-1, 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 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:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(13).

Law Implemented SDCL 36-11-1, 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. The following procedure applies to contested case proceedings for license, registration, or certificate applications and to disciplinary proceedings before the Board of Pharmacy.

Source:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(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:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(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:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(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:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(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 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 disqualify himself from all deliberations and decisions.

Source:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(13).

Law Implemented: SDCL 36-11-28, 36-11A-45.

20:51:34:06. Final board decision. If the board hears the proceeding itself, it 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 it to present oral argument 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:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(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:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(13).

Law Implemented: SDCL 36-11-28, 36-11A-45.

20:51:34:08. Assessment of costs of disciplinary hearings. The board may assess its 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 it submits proposed findings of fact and conclusions of law.

Source:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(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 who:

(1) Is personally related to a party involved in a contested case proceeding or disciplinary action by two degrees of consanguinity;

(2) Has a direct financial interest in a party involved in a 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 a contested case proceeding or disciplinary action;

(4) Or has a spouse who has a direct financial interest or directly contracts with a party involved in a contested case proceeding or disciplinary action; may not participate in the proceeding or action concerning that party. 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:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(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, that a reasonable person would believe might result in bias or prejudgment. 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 should maintenance of a quorum be an issue, the board may recuse a member with a potential conflict of interest if it determines that the potential conflict of interest raises an unacceptable risk of bias or prejudgment in the contested case proceeding or disciplinary action.

Source:

General Authority: SDCL 36-11-11(1)(2)(3)(10)(13).

Law Implemented: SDCL 36-11-28, 36-11A-14, 36-11A-45.

ARTICLE 20:67

~~WHOLESALE~~ DRUG DISTRIBUTORS

Chapter

CHAPTER 20:67:01

DEFINITIONS

Section

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; ~~and~~

(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 36-11A, except those exempted by federal DSCSA.

Source: 18 SDR 95, effective November 25, 1991.

General Authority: SDCL 36-11A-14.

Law Implemented: SDCL ~~36-11A-7~~ 36-11A-1, 36-11A-1.1.

CHAPTER 20:67:02

LICENSURE REQUIREMENTS

Section

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 drug 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.

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 whether 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; ~~and~~

(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) Type of distribution;

(9) Type of product distributed; and

(10) Type of entity distributed to.

Source: 18 SDR 95, effective November 25, 1991.

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 ~~— Out-of-state exemption~~. ~~-~~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 ~~who do not maintain or operate a physical facility within the state~~ are ~~not~~ required to license each separate location from which drugs are shipped to this state~~, but may instead obtain licensure for the primary location of the parent entity with divisions, subsidiaries, or affiliate companies~~.

Source: 18 SDR 95, effective November 25, 1991.

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

Law Implemented: SDCL 36-11A-7, 36-11A-9.

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.

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 ~~wholesale~~ 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, 1991.

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.

General Authority: SDCL 36-11A-14(1),(3).

Law Implemented: SDCL 36-11A-12.

Cross-Reference: Record keeping, ch 20:67:04.

20:67:02:10. 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.

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.

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.

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.

General Authority: SDCL 36-11A-14(7),(10).

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.

General Authority: SDCL 36-11A-14(7).

Law Implemented: SDCL 36-11A-7, 36-11A-34.

CHAPTER 20:67:04

RECORD KEEPING

Section

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.

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 ~~two~~ six years following disposition of the drugs.

Source: 18 SDR 95, effective November 25, 1991.

General Authority: SDCL 36-11A-14(8),(14).

Law Implemented: SDCL 36-11A-16, 36-11A-17, 36-11A-44.

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.

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. ~~Wholesale~~ 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.

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.

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.

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. Out-of-state drug ~~wholesaler~~ 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 ~~wholesale~~ 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.

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)

~~Section~~

~~20:67:08:01 Terms to begin on July 1.~~

~~20:67:08:02 Applicants to be solicited for recommendations.~~

~~20:67:08:03 Recommendations to remain on file.~~

~~20:67:08:04 Board to review recommendations on file.~~

~~20:67:08:05 Unexpired terms to be filled within three months of vacancy.~~

~~20:67:08:06 Appointees to indicate willingness to serve.~~

~~**20:67:08:01. Terms to begin on July 1.** Terms of new wholesale drug advisory committee members shall begin on July 1 unless the appointment is to fill an unexpired term.~~

~~**Source:** 18 SDR 95, effective November 25, 1991.~~

~~**General Authority:** SDCL 36-11A-14(16).~~

~~**Law Implemented:** SDCL 36-11A-7, 36-11A-15.~~

~~**20:67:08:02. Applicants to be solicited for recommendations.** Each year, along with the application for wholesale drug distributor and pharmacy license renewal, the secretary of the board shall send a solicitation of recommendation for persons to serve on the wholesale drug advisory committee. The solicitation shall include the following:~~

~~(1) A list of committee members and the group represented by each member;~~

~~(2) The term expiration for each member;~~

~~(3) A request for recommendations to fill terms expiring during the licensing year; and~~

~~(4) A reprint of SDCL 36-11A-15 and this article.~~

~~**Source:** 18 SDR 95, effective November 25, 1991.~~

~~**General Authority:** SDCL 36-11A-14(16).~~

~~**Law Implemented:** SDCL 36-11A-7, 36-11A-15.~~

~~**20:67:08:03. Recommendations to remain on file.** The board shall maintain a file of recommendations for wholesale drug advisory committee membership and shall hold each recommendation until December 31 of the year following its receipt.~~

Source: 18 SDR 95, effective November 25, 1991.

General Authority: SDCL 36-11A-14(16).

Law Implemented: SDCL 36-11A-15.

20:67:08:04. Board to review recommendations on file. The board may consider recommendations received to fill all expired or unexpired terms. Appointments to fill expiring terms shall be made prior to expiration of the terms.

Source: 18 SDR 95, effective November 25, 1991.

General Authority: SDCL 36-11A-14(16).

Law Implemented: SDCL 36-11A-15.

20:67:08:05. Unexpired terms to be filled within three months of vacancy. If an unexpired term is created by death, incapacity, or written notice, the board shall appoint a person to complete the expired term within three months after receipt of notice.

Source: 18 SDR 95, effective November 25, 1991.

General Authority: SDCL 36-11A-14(16).

Law Implemented: SDCL 36-11A-15.

20:67:08:06. Appointees to indicate willingness to serve. Any person appointed to the wholesale drug advisory committee shall, prior to appointment, indicate in writing to the board a willingness to serve as a committee member.

Source: 18 SDR 95, effective November 25, 1991.

General Authority: SDCL 36-11A-14(16).

~~**Law Implemented:** SDCL 36-11A-15.~~