2017 LAW BOOK UPDATE INSTRUCTIONS

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

July 26, 2017

South Dakota Board of Pharmacy
4001 W. Valhalla Blvd, STE 106
Sioux Falls, SD 57106
605-362-2737
www.pharmacy.sd.gov

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CHAPTER 36-11A

WHOLESALE AND OTHER DRUG DISTRIBUTORS

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(1) Repealed by SL 2017, ch 174, § 1;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.

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.

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;

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(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.

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.

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.

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.

36-11A-3. Repealed by SL 2007, ch 215, § 29.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

36-11A-15. Repealed by SL 2017, ch 174, § 13.

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.

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.

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.

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.

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.

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.

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.

36-11A-23. Normal distribution channel defined. For the purposes of §§ 36-11A-20 to 35-11A-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.

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.

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.

36-11A-26. Repealed by SL 2017, ch 174, § 18.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

36-11A-39, 36-11A-40. Repealed by SL 2017, ch 174, §§ 21, 22.

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.

36-11A-42, 36-11A-43. Repealed by SL 2017, ch 174, §§ 24, 25.

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.

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.

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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CHAPTER 34-20E

PRESCRIPTION DRUG MONITORING PROGRAM

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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.
