State of South Dakota

EIGHTY-SECOND SESSION
LEGISLATIVE ASSEMBLY, 2007

553N0410

HOUSE BILL NO. 1155

Introduced by: Representatives Van Etten, Boomgarden, Heineman, Jerke, Kirkeby, Lucas, Miles, Rave, Steele, and Weems and Senators Hansen (Tom), Dempster, Gant, Maher, and Olson (Ed)

FOR AN ACT ENTITLED, An Act to revise certain provisions concerning wholesale drug distributors.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF SOUTH DAKOTA:

Section 1. That § 36-11A-1 be amended to read as follows:

36-11A-1. Terms used in this chapter mean:

(1) "Authentication," to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred;

(2) "Board," the State 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 product," a prescription drug in which two or more parties have the right to engage in the manufacturing or marketing, or both, of such drug;

~~(2)~~(5) "Drug," "prescription drug," any ~~human~~ drug, including any biological product, except for blood and blood components intended for transfusion or biological

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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 ~~active ingredients~~ bulk drug substances subject to § 503(b) of the Federal Food, Drug and Cosmetic Act ~~as amended through January 1, 1991~~;

~~(3)~~(6) "Drug coupon," a form which may be redeemed at no cost or at reduced cost for a prescription drug;

(7) "Drug Enforcement Agency," the Drug Enforcement Agency of the United States Department of Justice;

~~(4)~~(8) "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;

(9) "Facility," a facility of a wholesale distributor where prescription drugs are stored, handled, repackaged, or offered for sale;

~~(5)~~(10) "Manufacturer," ~~anyone who is engaged in manufacturing, preparing, propagating, compounding, processing, packaging, repackaging or labeling of a prescription drug~~ a person licensed or approved by the federal Food and Drug Administration to engage in the manufacture of drugs or devices;

~~(6)~~(11) "Out-of-state wholesale drug distributor," a wholesale drug distributor with no physical facilities located in this state;

~~(7)~~(12) "Pharmacy," a place registered by the board under chapter 36-11 in which prescription drugs are sold at retail;

(13) "Pedigree," a document or electronic file containing information that records each distribution of any given prescription drug;

(14) "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;

(15) "Repackager," a person who repackages.

Section 2. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

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 any one 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.

Section 3. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

For the purposes of this Act, 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.

Section 4. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

For the purposes of this Act, 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 this Act, and to be considered part of the normal distribution channel must also be an authorized distributor of record.

Section 5. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

For the purposes of this Act, 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 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.

Section 6. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

For the purposes of this Act, 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. Such third party logistics provider must be licensed as a wholesale distributor under this Act, and to be considered part of the normal distribution channel must also be an authorized distributor of record.

Section 7. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

For the purposes of this Act, a wholesale distributor is any person engaged in the wholesale distribution of prescription drugs, including manufacturers; repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturer's exclusive distributors; authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; third party logistics providers; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution. To be considered part of the normal distribution channel such wholesale distributor must also be an authorized distributor of record.

Section 8. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

For the purposes of this Act, wholesale distribution is distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(1) Intracompany sales of prescription drugs, meaning any transaction or transfer between any division, subsidiary, parent or affiliated or related company under common ownership and control of a corporate entity, or any transaction or transfer between co-licensees of a co-licensed product;

(2) The sale, purchase, distribution, trade, or transfer of a prescription drug or offer to sell, purchase, distribute, trade, or transfer a prescription drug for emergency medical reasons;

(3) The distribution of prescription drug samples by manufacturers' representatives;

(4) Drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 C.F.R. § 203.23;

(5) The sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use;

(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 sale, transfer, merger, or consolidation of all or part of the business of a pharmacy or pharmacies from or with another pharmacy or pharmacies, whether accomplished as a purchase and sale of stock or business assets;

(8) The sale, purchase, distribution, trade, or transfer of a prescription drug from one authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor

of record that the manufacturer is unable to supply such prescription drug and the supplying authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(9) The delivery of, or offer to deliver, a prescription drug by a common carrier solely in the common carrier's usual course of business of transporting prescription drugs, and such common carrier does not store, warehouse, or take legal ownership of the prescription drug;

(10) The sale or transfer from a retail pharmacy or chain pharmacy warehouse of expired, damaged, returned, or recalled prescription drugs to the original manufacturer or to a third party returns processor.

Section 9. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

Any wholesale distributor who engages in the wholesale distribution of prescription drugs in this state must be licensed by the board, in accordance with this Act, before engaging in wholesale distributions of wholesale prescription drugs. The board shall exempt manufacturers distributing their own FDA-approved drugs and devices from any licensing, to the extent not required by federal law or regulation.

Section 10. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

The board shall require the following minimum information from each wholesale distributor applying to obtain a license under section 9 of this Act:

(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 thirty days.

The information required pursuant to this section shall be provided under oath.

Section 11. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

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 (1) of section 10 of this Act; 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.

Section 12. That chapter 36-11A be amended by adding thereto a NEW SECTION to read

as follows:

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.

Section 13. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

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 engaged only in intracompany transfers 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.

Section 14. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

In accordance with each licensure renewal, the board shall send to each wholesale distributor licensed under section 9 of this Act a form setting forth the information that the wholesale

distributor provided pursuant to section 10 of this Act. 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 section 10 of this Act. Changes in, or corrections to, any information in section 10 of this Act 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 section 10 of this Act.

Section 15. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

The designated representative identified pursuant to subdivision (7) of section 10 of this Act shall receive and complete continuing training in applicable federal and state laws governing wholesale distribution of prescription drugs.

The information provided under section 10 of this Act 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.

Section 16. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

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, including the returns of expired, damaged, and recalled pharmaceutical product to either the original manufacturer or a third party returns processor. The returns or exchanges are not subject to the pedigree requirement of section 21 of this Act, so long as they are exempt from pedigree under

the Federal Food and Drug Administration's currently applicable Prescription Drug Marketing Act guidance. 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.

Section 17. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

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.

Section 18. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises listed on the license. However, the manufacturer or wholesale distributor 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.

Section 19. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

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.

Section 20. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

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.

Section 21. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

Each person who is engaged in wholesale distribution of prescription drugs, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug that leave, or have ever left, the normal distribution channel shall, before each wholesale distribution of such drug, provide a pedigree to the person who receives such drug.

A retail pharmacy or chain pharmacy warehouse shall comply with the requirements of this section only if the pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs, as defined in section 8 of this Act.

Section 22. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

The board shall determine by July 1, 2009, a targeted implementation date for electronic track and trace pedigree technology. Such a determination shall be based on consultation with

manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products in this state. After consultation with interested stakeholders and prior to implementation of the electronic pedigree, the board shall determine that the technology is universally available across the entire prescription pharmaceutical supply chain. The implementation date for the mandated electronic track and trace pedigree technology shall be no sooner than July 1, 2010, and may be extended by the board in one year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.

Section 23. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

Each person who is engaged in the wholesale distribution of a prescription drug including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, who is provided a pedigree for a prescription drug and attempts to further distribute that prescription drug, shall affirmatively verify before any distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

Section 24. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

The pedigree shall include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer, or the manufacturer's third party logistics provider, co-licensed product partner, manufacturer's exclusive distributor, through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the drug. At minimum, the necessary chain of distribution information shall include:

(1) Name, address, telephone number, and if available, the e-mail address, of each owner

of the prescription drug, and each wholesale distributor of the prescription drug;

(2) Name and address of each location from which the product was shipped, if different from the owner's;

(3) Transaction dates; and

(4) Certification that each recipient has authenticated the pedigree.

Section 25. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

In addition to the requirements of section 24 of this Act, the pedigree shall also include the following minimum requirements:

(1) Name of the prescription drug;

(2) Dosage form and strength of the prescription drug;

(3) Size of the container;

(4) Number of containers;

(5) Lot number of the prescription drug; and

(6) Name of the manufacturer of the finished dosage form.

Section 26. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

Each pedigree or electronic file shall be:

(1) Maintained by the purchaser and the wholesale distributor for three years from the date of sale or transfer; and

(2) Available for inspection or use within two business days upon a request of an authorized officer of the law.

Section 27. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

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 this Act; or

(b) Falsified a pedigree, 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.

Section 28. That chapter 36-11A be amended by adding thereto a NEW SECTION to read as follows:

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 this Act, or operating without a valid license when a license is required by this Act;

(2) If the requirements of section 16 of this Act 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 section 17 of this Act, 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 section 18 of this Act;

(5) Accepting payment or credit for the sale of prescription drugs in violation of section 20 of this Act;

(6) Failure to maintain or provide pedigrees as required by this Act;

(7) Failure to obtain, pass, or authenticate a pedigree, as required by this Act;

(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 this Act;

(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 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 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.