State of South Dakota

NINETY-SECOND SESSION
LEGISLATIVE ASSEMBLY, 2017

400Y0243

HOUSE HEALTH AND HUMAN SERVICES

ENGROSSED NO. HB 1044 - 1/19/2017

Introduced by: The Committee on Health and Human Services at the request of the Board of Pharmacy

FOR AN ACT ENTITLED, An Act to revise certain provisions regarding wholesale drug distributors, to provide for licensure and regulation of outsourcing facilities for certain drugs, and to establish a fee for licensure of outsourcing facilities.

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

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

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 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;

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(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 ~~federal~~ 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;

~~(7)~~(8) "Drug coupon," a form which may be redeemed at no cost or at reduced cost for a prescription drug;

~~(8)~~(9) "Drug Enforcement Administration," the Drug Enforcement Administration of the United States Department of Justice;

~~(9)~~(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;

~~(10)~~(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;

~~(11)~~(13) "Manufacturer," as defined by the ~~federal Food and Drug Administration's regulations implementing the Prescription Drug Marketing Act (21 C.F.R. Parts 203 and 205)~~ DSCSA;

~~(12)~~(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;

~~(13)~~(16) "Pharmacy," a place ~~registered~~ licensed by the board under chapter 36-11 in which prescription drugs are sold ~~at retail~~;

~~(14) "Pedigree," a document or electronic file containing information that records each wholesale distribution of any given prescription drug;~~

~~(15)~~(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;

~~(16)~~(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.

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

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.

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

As used in this chapter, the term, transaction, means the transfer of product between trading partners in which a change of ownership occurs. The term does not include:

(1) Intracompany distribution of any product between members of an affiliate or within a manufacturer;

(2) The distribution of a product among hospitals or other health systems that are under common control;

(3) The distribution of a product for emergency medical reasons, including a public health emergency declaration pursuant to state or federal law;

(4) The dispensing of a product pursuant to a prescription;

(5) The distribution of product samples by a manufacturer or a licensed wholesale distributor in accordance with state and federal law;

(6) The distribution of blood or blood components intended for transfusion;

(7) The distribution of minimal quantities of product by a licensed retail pharmacy to a licensed practitioner for office use;

(8) The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization to a nonprofit affiliate of the organization to the extent otherwise permitted by state and federal law;

(9) The distribution of a product pursuant to the sale or merger of a pharmacy or pharmacies or a wholesale distributor or wholesale distributors, except that any records required to be maintained for the product shall be transferred to the new owner of the pharmacy or pharmacies or wholesale distributor or wholesale distributors;

(10) A combination product that is:

(a) A product composed of a device and one or more other regulated components, such as a drug or device, biologic or device, or drug, device or biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;

(b) Two or more separate products packaged together in a single package or as a unit and composed of a drug and device or a device and biological product; or

(c) Two or more finished medical devices plus one or more drug or biological products that are packaged together in what is referred to as a medical convenience kit as described in subdivision (11);

(11) The distribution of a collection of finished medical devices, which may include a product or biological product, assembled in kit form strictly for the convenience of the purchaser or user if:

(a) The medical convenience kit is assembled in an establishment that is registered with the United States Food and Drug Administration as a device manufacturer;

(b) The medical convenience kit does not contain a federally scheduled controlled substance;

(c) In the case of a medical convenience kit that includes a product, the person who manufactured the kit purchased the product directly from the pharmaceutical manufacturer or from a wholesale distributor that purchased the product directly from the pharmaceutical manufacturer, and does not alter the primary container or label of the product as purchased from the manufacturer or wholesale distributor; and

(d) In the case of a medical convenience kit that includes a product, the product is an intravenous solution intended for the replenishment of fluids and electrolytes; a product intended to maintain the equilibrium of water and minerals in the body; a product intended for irrigation or reconstitution; an anesthetic; an anticoagulant; a vasopressor; or a sympathomimetic;

(12) The distribution of an intravenous product that, by its formulation, is intended for the replenishment of fluids and electrolytes (such as sodium, chloride, and potassium) or calories (such as dextrose and amino acids);

(13) The distribution of an intravenous product used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions;

(14) The distribution of a product that is intended for irrigation, or sterile water, whether intended for such purposes or for injection;

(15) The distribution of a medical gas; or

(16) The distribution or sale of any licensed biologic product that meets the definition of device under federal law.

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

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.

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

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.

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

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.

Section 7. That § 36-11A-2 be amended to read:

36-11A-2. ~~Wholesale drug distribution is the distribution of prescription drugs to persons~~

~~other than a consumer or patient~~ 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 ~~January 1, 1991~~ 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 ~~retail~~ pharmacy to another ~~retail~~ 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; ~~or~~

(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.

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

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.

Section 9. That § 36-11A-5 be amended to read:

36-11A-5. No person, other than a consumer or patient, may knowingly purchase or receive a prescription drug from any source other than a ~~wholesale~~ 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.

Section 10. That § 36-11A-7 be amended to read:

36-11A-7. 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 ~~wholesale~~ 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 ~~wholesale~~ 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.

Section 11. That § 36-11A-13 be amended to read:

36-11A-13. Each wholesale drug distributor license expires on December thirty-first following the date of issue. The board shall ~~mail~~ 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.

Section 12. That § 36-11A-14 be amended to read:

36-11A-14. The board shall ~~adopt necessary and reasonable~~ promulgate rules, pursuant to chapter 1-26, ~~to carry out the purposes and enforce the provisions of this chapter within ten months after July 1, 1991. The rules promulgated pursuant to this section shall conform to the guidelines for state licensing of wholesale prescription drug distributors adopted by the United States Food and Drug Administration pursuant to the Federal Prescription Drug Marketing Act of 1987, as amended through January 1, 1991. Rules may be adopted in the following areas~~ 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~~; and~~

~~(16) Advisory committee appointments~~.

Section 13. That § 36-11A-15 be repealed.

~~36-11A-15. The board shall appoint a wholesale drug distributor advisory committee composed of five members who shall serve without compensation. Committee members shall be selected as follows:~~

~~(1) At least one member shall be a pharmacist or pharmacy distributor who shall neither be a member nor an employee of the board;~~

~~(2) At least two members shall be representatives of wholesale drug distributors as defined in § 36-11A-3; and~~

~~(3) At least one member shall be a representative of manufacturers as defined in subdivision 36-11A-1(5).~~

~~In making advisory committee appointments, the board shall consider recommendations received from pharmacists, wholesale drug distributors and manufacturers. Committee members shall serve terms of three years, except initial appointees, whose terms shall be staggered so that no more than two members' terms expire in any one year. If a vacancy occurs, the board shall appoint a person to fill the unexpired term.~~

~~The advisory committee shall review and make recommendations to the board on the merit of all rules dealing with wholesale drug distributors which are proposed by the board. No rule affecting wholesale drug distributors promulgated by the board may be approved without first~~

~~being submitted to the committee for review and comment. Failure of the committee to comment on proposed rules does not prevent the board from adopting the rules in compliance with chapter 1-26.~~

Section 14. That § 36-11A-16 be amended to read:

36-11A-16. 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 ~~wholesale~~ drug distributor. No person may deny the right of entry as provided in this section to an authorized person. Any ~~wholesale drug distributor~~ 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.

Section 15. That § 36-11A-17 be amended to read:

36-11A-17. ~~Wholesale drug distributors~~ 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 ~~they~~ 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 ~~two~~ six years.

Section 16. That § 36-11A-24 be amended to read:

36-11A-24. 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. ~~Such~~ Any third party logistics provider ~~must~~ shall 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~~.

Section 17. That § 36-11A-25 be amended to read:

36-11A-25. For the purposes of §§ 36-11A-20 to 36-11A-46, inclusive, 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; hospital pharmacies; reverse distributors; 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~~ other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider or repackager, engaged in wholesale distribution.

Section 18. That § 36-11A-26 be repealed.

~~36-11A-26. For the purposes of §§ 36-11A-20 to 36-11A-46, inclusive, 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 19. That § 36-11A-34 be amended to read:

36-11A-34. 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 ~~pedigree~~ requirement of § 36-11A-39, so long as ~~they~~ prescription drugs are exempt from ~~pedigree~~ tracing requirements under ~~the Federal Food and Drug Administration's currently applicable Prescription Drug Marketing Act guidance~~ 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.

Section 20. That § 36-11A-36 be amended to read:

36-11A-36. Prescription drugs furnished by a ~~manufacturer or wholesale distributor~~ licensee shall be delivered only to the premises listed on the license. However, the ~~manufacturer or wholesale distributor~~ 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.

Section 21. That § 36-11A-39 be repealed.

~~36-11A-39. 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 § 36-11A-26.~~

Section 22. That § 36-11A-40 be repealed.

~~36-11A-40. 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 § 36-11A-41 be amended to read:

36-11A-41. Each ~~person~~ 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 ~~a pedigree~~ transaction information, transaction history, and a transaction statement for a prescription drug and attempts to further distribute that prescription drug, shall ~~affirmatively verify,~~ before any distribution of a prescription drug occurs, confirm that ~~each transaction listed on~~ it has received the ~~pedigree has occurred~~ transaction information, transaction history, and transaction statement.

Section 24. That § 36-11A-42 be repealed.

~~36-11A-42. 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 § 36-11A-43 be repealed.

~~36-11A-43. In addition to the requirements of § 36-11A-42, the pedigree shall also include the following minimum requirements:~~

~~(1) Name and national drug code number 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 § 36-11A-44 be amended to read:

36-11A-44. Each ~~pedigree or electronic~~ file shall be:

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

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

Section 27. That § 36-11A-45 be amended to read:

36-11A-45. 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 ~~pedigree~~ 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.

Section 28. That § 36-11A-46 be amended to read:

36-11A-46. 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 ~~pedigrees~~ transaction documentation as required by §§ 36-11A-20 to 36-11A-46, inclusive;

(7) Failure to obtain, pass, or ~~authenticate a pedigree~~ 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~~ 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.