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)

(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.

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. 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.

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 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 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.

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 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 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.

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 That § 36-11A-15 be repealed.

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 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.

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

36-11A-17. 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.

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. Any third party logistics provider shall be licensed under §§ 36-11A-20 to 36-11A-46, inclusive.

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 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.

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 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.

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

36-11A-36. 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.

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 That § 36-11A-39 be repealed.

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 That § 36-11A-40 be repealed.

Section 23. That § 36-11A-41 be amended to read:

36-11A-41. 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.

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 That § 36-11A-42 be repealed.

Section 25. That § 36-11A-43 be repealed.

Section 26. That § 36-11A-44 be amended to read:

36-11A-44. 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.

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 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 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.

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.

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I certify that the attached Act originated in the

HOUSE as Bill No. 1044

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Chief Clerk

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_____
Speaker of the House

Attest:

_____
Chief Clerk

_____
President of the Senate

Attest:

_____
Secretary of the Senate

House Bill No. 1044
File No. ____
Chapter No. _____

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Received at this Executive Office this _____ day of _____ ,

20____ at _____ M.

By _____
for the Governor

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The attached Act is hereby approved this _____ day of _____ , A.D., 20___

_____
Governor

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STATE OF SOUTH DAKOTA,
ss.
Office of the Secretary of State

Filed _____ , 20___
at _____ o'clock __ M.

_____
Secretary of State

By _____
Asst. Secretary of State