HOUSE BILL NO. 536

INTRODUCED BY BECKER

A BILL FOR AN ACT ENTITLED: "AN ACT ADOPTING THE "WHOLESALE LICENSURE AND PRESCRIPTION MEDICATION INTEGRITY ACT"; PROVIDING DEFINITIONS; PROVIDING LICENSE REQUIREMENTS AND PROCEDURES FOR WHOLESALE DISTRIBUTORS OF PRESCRIPTION DRUGS; PROVIDING RESTRICTIONS ON TRANSACTIONS INVOLVING PRESCRIPTION DRUGS; PROVIDING FOR PEDIGREES FOR PRESCRIPTION DRUGS; PROVIDING ENFORCEMENT PROVISIONS; PROHIBITING CERTAIN ACTS; AND PROVIDING PENALTIES."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MONTANA:

NEW SECTION. **Section 1. Short title.** [Sections 1 through 8] may be known and may be cited as the "Wholesale Licensure and Prescription Medication Integrity Act".

NEW SECTION. **Section 2. Definitions.** As used in [sections 1 through 8], unless the context requires otherwise, the following definitions apply:

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

(2) "Authorized distributor of record" means a wholesale distributor with whom a manufacturer has established an ongoing relationship to distribute the manufacturer's prescription drug. An ongoing relationship is considered to exist between a wholesale distributor and a manufacturer when the wholesale distributor, including the wholesale distributor's affiliated group, as defined in section 1504 of the Internal Revenue Code of 1986, 26 U.S.C. 1504, complies with either of the following:

(a) the wholesale distributor has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; or

(b) the wholesale distributor is listed on the manufacturer's current list of authorized distributors of record, which list is updated by the manufacturer on no less than a monthly basis.

(3) "Board" means the board of pharmacy provided for in 2-15-1733.

(4) "Chain pharmacy warehouse" means a physical location for prescription drugs, devices, or both, that acts as a central warehouse and performs intracompany sales or transfers of the prescription drugs to a group

of chain pharmacies that have the same common ownership and control.

(5) "Co-licensed product" means a prescription drug in which two or more parties have the right to engage in the manufacturing and marketing of the prescription drug.

(6) "Drop shipment" means the sale of a prescription drug by a manufacturer of the prescription drug, the manufacturer's co-licensed product partner, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor to a wholesale distributor under which the wholesale distributor takes title to but not possession of the prescription drug and the wholesale distributor invoices the pharmacy, chain pharmacy warehouse, or other person authorized by law to dispense and administer the drug to a patient and the pharmacy, chain pharmacy warehouse, or other authorized person receives delivery of the prescription drug directly from the manufacturer, the manufacturer's co-licensed product partner, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor.

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

(8) "Manufacturer" means a person licensed or approved by the federal food and drug administration to engage in the manufacture of drugs or devices.

(9) "Manufacturer's exclusive distributor" means 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 the manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug. The manufacturer's exclusive distributor must be licensed as a wholesale distributor under [sections 1 through 8] and in order to be considered part of the normal distribution channel must also be an authorized distributor of record.

(10) "Normal distribution channel" means a chain of custody for a prescription drug that goes from a manufacturer of the prescription drug, the manufacturer's co-licensed partner, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor to:

(a) a pharmacy for distribution to a patient or to any other designated persons authorized by law to dispense or administer the drug to a patient;

(b) a wholesale distributor for distribution to a pharmacy and then to a patient or to any other designated persons authorized by law to dispense or administer the drug to a patient;

(c) a wholesale distributor for distribution to a chain pharmacy warehouse, then to that chain pharmacy warehouse's intracompany pharmacies, then to a patient or to any other designated persons authorized by law to dispense or administer the drug to a patient; or

(d) a chain pharmacy warehouse for distribution to the chain pharmacy warehouse's intracompany pharmacies and then to a patient or to any other designated persons authorized by law to dispense or administer the drug to a patient.

(11) "Pedigree" means a document or electronic file containing information that records each distribution of a prescription drug.

(12) "Prescription drug" means 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 regulation to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 353(b).

(13) (a) "Repackage" means repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug.

(b) The term does not include the dispensing of prescription drugs to the patient by a pharmacist.

(14) "Repackager" means a person who repackages.

(15) "Third-party logistics provider" means anyone who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer, but who does not take title to a prescription drug or have general responsibility to direct the prescription drug's sale or disposition. A third-party logistics provider must be licensed as a wholesale distributor under [sections 1 through 8] and, in order to be considered part of the normal distribution channel, must also be an authorized distributor of record.

(16) (a) "Wholesale distribution" means distribution of prescription drugs to persons or entities other than a consumer or patient.

(b) The term does not include:

(i) intracompany sales or transfers of prescription drugs, including a transaction or transfer between a division, subsidiary, parent, or affiliated or related company under common ownership or control of a corporate entity or any transaction or transfer between co-licensees of a co-licensed product;

(ii) 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;

(iii) the distribution of prescription drug samples by a manufacturer's representative;

(iv) drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 CFR 203.23;

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

(vi) the sale, purchase, or trade of a prescription drug pursuant to a prescription, an offer to sell, purchase, or trade a prescription drug pursuant to a prescription, or the dispensing of a prescription drug pursuant to a prescription;

(vii) 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;

(viii) the direct sale, purchase, distribution, trade, or transfer of a prescription drug from an 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 the 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;

(ix) 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 when the common carrier does not store, warehouse, or take legal ownership of the prescription drug;

(x) drop shipments of a prescription drug from a manufacturer or that manufacturer's exclusive distributor to a pharmacy or chain pharmacy warehouse; or

(xi) 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.

(17) (a) "Wholesale distributor" means any person engaged in wholesale distribution of drugs, including but not limited to:

(i) manufacturers;

(ii) repackagers;

(iii) own-label wholesale distributors and private-label wholesale distributors;

(iv) jobbers and brokers;

(v) warehouses, including manufacturers' and wholesale distributors' warehouses and wholesale drug warehouses;

(vi) manufacturer's exclusive distributors and authorized distributors of record;

(vii) drug wholesalers or distributors;

(viii) independent wholesale drug traders;

(ix) third-party logistics providers;

(x) retail and hospital pharmacies and chain pharmacy warehouses that conduct wholesale distributions.

(b) To be considered part of the normal distribution channel, the wholesale distributor must also be an authorized distributor of record.

NEW SECTION. **Section 3. Licensure.** (1) A wholesale distributor who engages in wholesale distribution of prescription drugs in this state must be licensed by the board pursuant to [sections 1 through 8].

(2) In addition to any other requirements as provided by law or regulation, the board shall require the following minimum information from each wholesale distributor applying for a license pursuant to [sections 1 through 8]:

(a) the name, full business address, and telephone number of the applicant;

(b) all trade or business names used by the applicant;

(c) addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling, and distribution of prescription drugs;

(d) the type of ownership or operation of the applicant, including but not limited to corporation, partnership, or sole proprietorship;

(e) the name or names of the owner, operator, or both, of the applicant, including:

(i) if an individual, the name of the individual;

(ii) if a partnership, the name of each partner and the name of the partnership;

(iii) 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

(iv) if a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

(f) a list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase, distribute, or possess prescription drugs; and

(g) the name and fingerprints of the applicant's designated representative for the facility and the following information relating to the designated representative:

(i) the person's places of residence for the past 7 years;

(ii) the person's date and place of birth;

(iii) the person's occupations, positions of employment, and offices held during the past 7 years;

(iv) the principal business and address of any business, corporation, or other organization in which the person held office or in which each occupation or position of employment was carried on;

(v) whether, during the past 7 years, the person has been the subject of any proceeding for the revocation of any license and, if so, the nature of the proceeding and the disposition of the proceeding;

(vi) whether, during the past 7 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, together with details concerning the event;

(vii) a description of any involvement during the past 7 years by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, that manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which any one of the businesses was named as a party;

(viii) a description of any felony criminal offense of which the person, as an adult, was found guilty, regardless of 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 15 days after the disposition of the appeal, submit to the board a copy of the final written order of disposition.

(ix) a photograph of the person taken in the previous 30 days.

(3) The information required pursuant to subsection (2) must be provided under oath.

(4) The board may not issue a license to an applicant unless the board:

(a) conducts a physical inspection of the facility at the address provided by the applicant pursuant to subsection (2)(a) if the facility is in this state; and

(b) determines that the designated representative meets the following qualifications:

(i) is at least 18 years of age;

(ii) has been employed full time for at least 3 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;

(iii) is employed by the applicant full time in a managerial level position;

(iv) is actively involved in and aware of the actual daily operation of the wholesale distributor;

(v) is physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including but not limited to sick leave and vacation leave;

(vi) 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 the wholesale distributors are members of an affiliated group, as defined in section 1504 of the Internal Revenue Code, 26 U.S.C. 1504;

(vii) 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

(viii) does not have any felony convictions under federal, state, or local laws.

(5) The board shall submit the fingerprints provided by an applicant pursuant to subsection (2)(g) to the

department of justice for a statewide criminal records check and for forwarding to the federal bureau of investigation for a national criminal records check of the applicant.

(6) The board shall require each wholesale distributor applying for a license to submit a bond of at least $100,000 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 the state. Chain pharmacy warehouses that are engaged only in intracompany transfers are 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 the license that are authorized under state law and that the licensee fails to pay 30 days after the fines, penalties, or costs become due. The board may make a claim against the bond or security until 1 year after a license ceases to be valid. The bond must cover all facilities operated by the applicant in this state.

(7) The board shall establish an account, separate from its other accounts, in which to deposit the wholesale distributor bonds.

(8) If a wholesale distributor distributes prescription drugs from more than one facility in this state, the wholesale distributor shall obtain a license for each facility.

(9) Each calendar year, the board shall send to each wholesale distributor licensed under [sections 1 through 8] a form setting forth the information that the wholesale distributor provided pursuant to subsection (2). Within 30 days after receiving the form, the wholesale distributor shall identify and state under oath to the board all changes or corrections to the information. Changes in or corrections to any information must be submitted to the board in a manner designated by the board. The board may suspend or revoke the license of a wholesale distributor if the board determines that the wholesale distributor no longer qualifies for the license issued pursuant to [sections 1 through 8].

(10) The designated representative identified pursuant to subsection (2)(g) shall complete continuing education programs as required by the board regarding federal and state laws governing wholesale distribution of prescription drugs.

(11) Except as otherwise required by law, information provided pursuant to this section may not be disclosed to any person or entity other than the board unless the information is needed for licensure or monitoring purposes by another state entity.

NEW SECTION. **Section 4. Restrictions on transactions.** (1) 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. The returns or exchanges include the returns of expired, damaged, and recalled pharmaceutical products to either the original manufacturer or to a third-party returns processor, and the returns or exchanges are not subject to the pedigree requirements of [section 5] as long as the transactions are exempt from pedigree under the federal food and drug administration's currently applicable prescription drug marketing guidelines. Wholesale distributors and pharmacies must be held accountable for policing their returns process and ensuring that their operations are secure and do not permit the entry of adulterated or counterfeit prescription drugs.

(2) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the board. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall contact the board to affirmatively verify that the person is legally authorized to receive the prescription drugs.

(3) Prescription drugs furnished by a manufacturer or wholesale distributor may 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:

(a) the identity and authorization of the recipient is properly established; and

(b) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person.

(4) Prescription drugs may be furnished to a hospital pharmacy receiving area if a pharmacist or authorized receiving employee signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the receipt and the type and quantity of the prescription drug actually received must be reported to the delivering manufacturer or wholesale distributor by the next business day after delivery.

(5) A manufacturer or wholesale distributor may not accept payment for or allow the use of a person's or entity's credit to establish an account for the purchase of prescription drugs from any person other than the owner or owners 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.

NEW SECTION. **Section 5. Pedigree requirements.** (1) Except for the original manufacturer of the finished form of the prescription drug, each person, including repackagers, who is engaged in wholesale distribution of prescription drugs that leave or have ever left the normal distribution channel shall provide a pedigree to the person that receives the prescription drugs.

(2) A retail pharmacy or chain pharmacy warehouse is required to comply with the requirements of this section only if the retail pharmacy or chain pharmacy warehouse engages in wholesale distribution of prescription drugs.

(3) The board shall conduct a study to be completed no later than July 1, 2009, that includes consultation with manufacturers, wholesale distributors, and pharmacies responsible for the sale and distribution of prescription drug products in this state. Based on the results of the study, the board shall establish a mandated implementation date for electronic pedigrees that is no sooner than July 1, 2010.

(4) Except for the original manufacturer of the finished form of the prescription drug, each person, including repackagers, who is provided a pedigree for a prescription drug and who 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.

(5) The pedigree must include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer through acquisition and sale by any wholesale distributor or repackager until final sale to a pharmacy or other person dispensing or administering the prescription drug. At a minimum, the pedigree must include:

(a) the name, address, telephone number, and, if available, e-mail address of each owner of the prescription drug and each wholesale distributor of the prescription drug;

(b) the name and address of each location from which the prescription drug was shipped, if different from the owner's;

(c) transaction dates;

(d) certification that each recipient has authenticated the pedigree;

(e) the name of the prescription drug;

(f) the dosage form and strength of the prescription drug;

(g) the size of the container;

(h) the number of containers;

(i) the lot number of the prescription drug; and

(j) the name of the manufacturer of the finished dosage form.

(6) Each pedigree must be:

(a) maintained by the dispensing pharmacy or individual and the wholesale distributor for 3 years from the date of sale or transfer; and

(b) available for inspection or use within 5 business days upon a request by the board or an authorized

officer of the law.

(7) The board shall adopt rules, including a standard form, relating to the requirements of this section no later than 90 days after [the effective date of this section].

NEW SECTION. **Section 6. Enforcement -- cease distribution order.** (1) The board shall issue an order requiring the appropriate person, including the manufacturers, wholesale distributors, or retailers of the prescription drug, to immediately cease distribution of the prescription drug in or to this state if the board finds that there is a reasonable probability that:

(a) a wholesale distributor, other than a manufacturer, has:

(i) violated a provision of [sections 1 through 8]; or

(ii) falsified a pedigree or sold, distributed, transferred, manufactured, repackaged, handled, or held a counterfeit prescription drug intended for human use;

(b) the prescription drug at issue in subsection (1)(a)(ii) could cause serious, adverse health consequences or death; and

(c) other procedures would result in unreasonable delay.

(2) An order under subsection (1) must provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order. If, after a hearing, the board determines that inadequate grounds exist to support the actions required by the order, the board shall vacate the order.

NEW SECTION. **Section 7. Prohibited activities.** (1) 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:

(a) failure to obtain a license in accordance with [sections 1 through 8] or operating without a valid license when a license is required by [sections 1 through 8];

(b) receiving prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse, unless the requirements in [section 4(1)] are met;

(c) selling, distributing, or transferring a prescription drug to a person who is not authorized to receive the prescription drug under the law of the jurisdiction in which the person receives the prescription drug in violation of [section 4(2)];

(d) failing to deliver prescription drugs to specified premises as required in [section 4(3)];

(e) accepting payment or credit for the sale of prescription drugs in violation of [section 4(5)];

(f) failing to maintain or provide pedigrees as required by [sections 1 through 8];

(g) failing to obtain, transfer, or authenticate a pedigree as required by [sections 1 through 8];

(h) providing the board 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 [sections 1 through 8];

(i) obtaining or attempting to obtain a prescription drug by fraud, deceit, or misrepresentation or engaging in misrepresentation or fraud in the distribution of a prescription drug;

(j) 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:

(i) the manufacturing, repackaging, selling, transferring, delivering, holding, or offering for sale of any prescription drug that is adulterated, misbranded, counterfeit, or suspected of being counterfeit or that has otherwise been rendered unfit for distribution; or

(ii) the adulteration, misbranding, or counterfeiting of any prescription drug;

(k) receiving any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, or counterfeit or that is suspected of being counterfeit and delivering or proffering delivery of the prescription drug for pay or otherwise; or

(l) 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.

(2) The acts prohibited in subsection (1) do not include a prescription drug manufacturer or an agent of the manufacturer obtaining a prescription drug for the sole purpose of testing the prescription drug for authenticity.

NEW SECTION. **Section 8. Criminal penalties.** (1) A person who negligently engages in the wholesale distribution of prescription drugs in violation of [sections 1 through 8] is guilty of a felony and, upon conviction, shall be punished by imprisonment for not more than 15 years, by a fine not to exceed $50,000, or both.

(2) A person who knowingly engages in wholesale distribution of prescription drugs in violation of [sections 1 through 8] is guilty of a felony and, upon conviction, shall be punished by imprisonment for not more than 25 years, by fine not to exceed $500,000, or both.

NEW SECTION. **Section 9. Codification instruction.** [Sections 1 through 8] are intended to be codified as an integral part of Title 50, and the provisions of Title 50 apply to [sections 1 through 8].

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