HOUSE BILL NO. 536

INTRODUCED BY BECKER, LEWIS, COCCHIARELLA, GILLAN, STOKER

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; AND AMENDING SECTIONS 37-7-601, 37-7-602, 37-7-603, 37-7-604, AND 37-7-610, MCA."

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

(Refer to Introduced Bill)

Strike everything after the enacting clause and insert:

Section 1. Section 37-7-601, MCA, is amended to read:

"37-7-601. Scope and purpose. This part applies to a person or entity engaged in the wholesale distribution of prescription drugs in this state. The purpose of this part is to:

(1) implement the federal Prescription Drug Marketing Act of 1987 by providing minimum standards, terms, and conditions for licensing by the department of persons or entities engaged in wholesale distributions of prescription drugs; and

(2) ensure the integrity of the state's prescription drug supply by requiring background checks of wholesale drug distributors, inspections of wholesale drug facilities, and the creation of a system for tracking wholesale prescription drugs that have left the normal distribution channel."

Section 2. Section 37-7-602, MCA, is amended to read:

"37-7-602. Definitions. As used in this part, 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 drug 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 drug distributor and a manufacturer when the wholesale drug distributor, including the wholesale drug 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 drug distributor has a written agreement currently in effect with the manufacturer evidencing the ongoing relationship; ~~or~~ AND

(b) the wholesale drug 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.

~~(1)~~(3) "Blood" means whole blood collected from a single donor and processed either for transfusion or for further manufacturing.

~~(2)~~(4) "Blood component" means that part of blood separated by physical or mechanical means.

(5) "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.

(6) "Colicensed" means an instance in which two or more parties have the right to engage in the manufacturing or marketing of the prescription drug, consistent with the U.S. food and drug administration definition of manufacturer under the agency's regulations and guidances implementing the Prescription Drug Marketing Act of 1987.

(7) "Device" or "legend device" means a device as defined in 37-2-101 that is required under federal law to be dispensed by a health care provider or pursuant to a prescription.

(8) "Drop shipment" means the sale of a prescription drug by a manufacturer of the prescription drug, the manufacturer's colicensed partner, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor to a wholesale drug distributor under which the wholesale drug distributor takes title to but not possession of the prescription drug and the wholesale drug 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 colicensed partner, the manufacturer's third-party logistics provider, or the manufacturer's exclusive distributor.

~~(3)~~(9) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

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

~~(4)~~(11) "Manufacturer" means a person or entity engaged in the manufacturing, preparing, propagating, compounding, processing, packaging, repackaging, or labeling of a prescription drug or device.

(12) "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 drug distributor under this part and in order to be considered part of the normal distribution channel must also be an authorized distributor of record.

(13) "Normal distribution channel" means a chain of custody for a prescription drug that goes directly or by drop shipment from a manufacturer of the prescription drug, the manufacturer's colicensed 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~~;

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

~~(b)~~(C) a wholesale drug distributor for distribution to:

(I) a pharmacy and then to a patient ~~or to~~;

(II) any other designated persons authorized by law to dispense or administer the drug to a patient; OR

~~(c)~~(III) a wholesale drug 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.

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

~~(5)~~(15) "Prescription drug" has the same meaning as provided in 37-7-101.

(16) (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.

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

(18) "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 drug distributor under this part and, in order to be considered part of the normal distribution channel, must also be an authorized distributor of record.

~~(6)~~(19) (a) "Wholesale drug distribution" means distribution of prescription drugs, legend devices, or medical gases to persons 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 colicensees of a colicensed product;

(ii) 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 group purchasing organizations;

(iii) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code, 26 U.S.C. 501(c)(3), as amended, to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(iv) 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. For purposes of this subsection ~~(6)(b)(iv)~~ (19)(b)(iv), "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise.

(v) the sale, purchase, distribution, transfer, or trade of a drug or an offer to sell, purchase, distribute, transfer or trade a drug for emergency medical reasons. For the purposes of this subsection ~~(6)(b)(v)~~ (19)(b)(v), "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

(vi) the sale, purchase, or trade of a prescription drug pursuant to a prescription, ~~or~~ 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 distribution of drug samples by manufacturers' representatives or distributors' representatives;

~~or~~

(viii) the sale, purchase, or trade of blood and blood components intended for transfusion;

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

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

(xi) 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;

(xii) 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;

(xiii) 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; OR

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

~~(xv)~~(XIV) 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.

~~(7)~~(20) (a) "Wholesale drug distributor" means a person or entity engaged in wholesale distribution of prescription drugs, legend devices, or medical gases, including but not limited to manufacturers, ~~repackers~~ repackagers, own-label wholesale distributors, private-label wholesale distributors, jobbers, brokers, warehouses (including manufacturers' and wholesale drug distributors' warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, manufacturer's exclusive distributors and authorized distributors of record, drug wholesalers or distributors, third-party logistics providers, and retail and hospital pharmacies that conduct wholesale distributions.

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

Section 3. Section 37-7-603, MCA, is amended to read:

"37-7-603. Prohibited purchase or receipt of drugs -- restrictions on wholesale drug distributors -- ~~penalty~~ penalties. (1) Except as otherwise provided, it is unlawful for a person to knowingly purchase or receive a prescription drug from a source other than a person or entity licensed under this part.

(2) Licensed wholesale drug distributors other than pharmacies or medical gas suppliers may not dispense or distribute prescription drugs directly to patients.

(3) 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 this part or operating without a valid license when a license is required by this part;

(b) receiving prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse, unless the requirements in [section 6(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 6(2)];

(d) failing to deliver prescription drugs to specified premises as required in [section 6(3)];

(e) accepting payment or credit for the sale of prescription drugs in violation of [section 6(5)];

(f) failing to maintain or provide pedigrees as required by this part;

(g) failing to obtain, transfer, or authenticate a pedigree as required by this part;

(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 this part;

(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.

(4) The acts prohibited in subsection (3) 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.

~~(3)~~(5) (a) A person who violates the provisions of this section is guilty of a ~~misdemeanor~~ felony.

~~(b) A person who negligently engages in the wholesale distribution of prescription drugs in violation of this part 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.~~

~~(c)~~(B) A person who knowingly engages in wholesale distribution of prescription drugs in violation of this part is guilty of a felony and, upon conviction, shall be punished by imprisonment for not more than 25 years, by a fine not to exceed $500,000, or both."

Section 4. Section 37-7-604, MCA, is amended to read:

"37-7-604. Wholesale drug distributor licensing requirements -- fee -- federal compliance. (1) A person or distribution outlet may not act as a wholesale drug distributor without first obtaining a license from the board and paying the license fee. Manufacturers engaged in wholesale drug distribution are subject to licensing. However, information and qualification requirements for licensure, beyond those required by federal law or regulation, do not apply to manufacturers distributing their own U.S. food and drug administration-approved drugs, unless specific requirements are considered necessary and the board adopts appropriate rules.

(2) A license may not be issued or renewed for a wholesale drug distributor to operate in this state unless the applicant:

(a) agrees to abide by federal and state law and to comply with the rules adopted by the board; and

(b) pays the license fee set by the board.

(3) ~~The board in its discretion may require that a separate license be obtained for:~~

~~(a) each facility directly or indirectly owned or operated by the same business entity within the state; or~~

~~(b) a parent entity with divisions, subsidiaries, or affiliates within the state if operations are conducted~~

~~at more than one location and joint ownership and control exists among all entities.~~ If a wholesale drug distributor distributes prescription drugs from more than one facility in the state, the wholesale drug distributor shall obtain a license for each facility.

(4) In order to obtain and maintain a wholesale drug distributorship in this state, an applicant shall provide written documentation to the board attesting that the applicant has maintained and will continue to maintain:

(a) adequate storage conditions and facilities;

(b) minimum liability and other insurance that may be required by applicable federal or state law;

(c) a functioning security system that includes:

(i) an after hours central alarm or comparable entry detection system;

(ii) restricted access to the premises;

(iii) comprehensive employee applicant screening; and

(iv) safeguards against employee theft;

(d) a system of records setting forth all activities of wholesale drug distribution ~~as defined in 37-7-602~~ for at least a period of the 2 previous years. The system of records must be accessible, as defined by board regulations, for inspections authorized by the board.

(e) principals, including officers, directors, primary shareholders, and management executives, who shall at all times demonstrate and maintain their responsibility for conducting the business in conformity with sound financial practices as well as state and federal law;

(f) complete, updated information, to be provided to the board as a condition for obtaining and retaining a license, pertaining to each wholesale drug distributor to be licensed, including but not limited to:

(i) all pertinent corporate license information, if applicable; and

(ii) other information regarding ownership, principals, key personnel, and facilities;

(g) a written protocol of procedures and policies that ~~assures~~ ensures preparation by the wholesale drug distributor for the handling of security or operational problems, including but not limited to those caused by:

(i) natural disaster or government emergency;

(ii) inventory inaccuracies or product shipping and receiving;

(iii) insufficient inspections for all incoming and outgoing product shipments;

(iv) lack of control of outdated or other unauthorized products;

(v) inappropriate disposition of returned goods; and

(vi) failure to promptly comply with product recalls; and

(h) operations in compliance with all federal requirements applicable to wholesale drug distribution.

(5) An agent or employee of a licensed wholesale drug distributor need not be licensed as a wholesale drug distributor.

(6) In addition to any other requirements as provided by law or regulation, the board shall require from each wholesale drug distributor applying for a license pursuant to this part the name and fingerprints of the applicant's designated representative for the facility and ~~the following~~ OTHER information relating to the designated representative~~:~~, INCLUDING BUT NOT LIMITED TO DETAILED EMPLOYMENT HISTORY AND CRIMINAL BACKGROUND INFORMATION, AS SPECIFIED IN BOARD RULES.

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

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

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

~~(d) 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;~~

~~(e) 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;~~

~~(f) 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;~~

~~(g) 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;~~

~~(h) a description of any felony criminal offense of which the person, as an adult, was found guilty, regardless of whether the person pleaded 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.~~

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

(7) 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 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 drug 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 drug 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 drug distributor is colocated in the same facility and the wholesale drug distributors are members of an affiliated group, as defined in section 1504 of the Internal Revenue Code, 26 U.S.C. 1504; and

(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, SUBJECT TO THE PROVISIONS OF 37-1-203 AND 37-1-205.

(8) The board shall require each wholesale drug 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~~ NOT ENGAGED IN WHOLESALE DISTRIBUTION 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.

(9) The board shall submit the fingerprints provided by an applicant pursuant to subsection (6) 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.

(10) 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.

~~(6)~~(11) For purposes of this section, all rules and regulations promulgated by the board must conform to the wholesale drug distributor licensing guidelines formally adopted by the United States food and drug administration. If ~~a conflict~~ an inconsistency or contradiction arises between a UNITED STATES food and drug administration guideline and a rule or regulation of the board, the former controls~~, unless the Montana provisions are more stringent~~. THE UNITED STATES FOOD AND DRUG ADMINISTRATION GUIDELINES ARE MINIMUM REQUIREMENTS ONLY, AND THE STATE MAY ADOPT, IMPLEMENT, AND ENFORCE STRICTER GUIDELINES."

Section 5. Section 37-7-610, MCA, is amended to read:

"37-7-610. Rulemaking authority. The board shall adopt rules and regulations necessary to carry out the purpose and enforce the provisions of this part. If an inconsistency or contradiction arises between the rules and regulations ~~conflict with~~ and the wholesale drug distribution guidelines promulgated by the United States food and drug administration, the latter control~~, unless the Montana provisions are more stringent~~. THE UNITED STATES FOOD AND DRUG ADMINISTRATION GUIDELINES ARE MINIMUM REQUIREMENTS ONLY, AND THE STATE MAY ADOPT, IMPLEMENT, AND ENFORCE STRICTER GUIDELINES."

NEW SECTION. **Section 6. Restrictions on transactions.** (1) A wholesale drug 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 drug distributor and the pharmacy or chain pharmacy warehouse. The returns or exchanges that include the returns of expired, damaged, recalled, or other unsalable pharmaceutical products may be distributed by the receiving wholesale drug distributor only to either the original manufacturer or to a third-party returns processor. Returns or exchanges of salable or other prescription drugs, including any redistribution by a receiving wholesaler, are not subject to the pedigree requirements of [section 7] as long as the transactions are exempt from pedigree under the U.S. food and drug administration's currently applicable ~~prescription drug marketing guidelines~~ PRESCRIPTION DRUG MARKETING ACT GUIDANCES. Wholesale drug distributors and pharmacies must be held accountable for ~~policing~~ ADMINISTERING 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 drug 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 drug distributor, the manufacturer or wholesale drug 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 drug distributor may be delivered only to the premises listed on the license. However, the manufacturer or wholesale drug distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale drug 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 drug distributor by the next business day after delivery.

(5) A manufacturer or wholesale drug 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 7. Pedigree requirements.** (1) Except for the original manufacturer of the finished form of the prescription drug, each person, including a repackager, 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 drug 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 feasible implementation date for electronic pedigrees.

(4) Except for the original manufacturer of the finished form of the prescription drug, each person, including a repackager, 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 drug 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 drug 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 THE NATIONAL DRUG CODE NUMBER; 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 drug distributor for 3 years from the date of sale or transfer; and

(b) available for inspection or use within 2 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.

NEW SECTION. **Section 8. Enforcement -- cease distribution order.** (1) The board shall issue an

order requiring the appropriate person, including the manufacturers, wholesale drug 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 drug distributor, other than a manufacturer, has:

(i) violated a provision of this part; 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.~~

(2) NOTICE AND AN OPPORTUNITY FOR HEARING MUST BE AFFORDED TO INDIVIDUALS PURSUANT TO THE MONTANA ADMINISTRATIVE PROCEDURE ACT AND THIS TITLE.

NEW SECTION. **Section 9. Severability.** If a part of [this act] is invalid, all valid parts that are severable from the invalid part remain in effect. If a part of [this act] is invalid in one or more of its applications, the part remains in effect in all valid applications that are severable from the invalid applications.

NEW SECTION. **Section 10. Codification instruction.** [Sections 6 through 8] are intended to be codified as an integral part of Title 37, chapter 7, part 6, and the provisions of Title 37, chapter 7, apply to [sections 6 through 8].

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