Wholesale Drug Distribution

This legislation limits the opportunity to introduce counterfeit drugs into the U.S. market via the wholesale transfer process. The legislation accomplishes this by tightening the rules around the licensing of prescription drug wholesalers and establishes pedigree requirements to ensure the authenticity of prescription drugs within the distribution system. The legislation also establishes penalties for violators.

Submitted as:
Idaho
Session Law Chapter 319 of 2007
Status: Enacted into law in 2007.

Suggested State Legislation

(Title, enacting clause, etc.)

Section 1. [*Short Title*.] This Act shall be cited as "The Wholesale Drug Distribution Act."

Section 2. [*Definitions*.] As used in this Act:

(1) "authentication" 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 deemed to exist between such wholesale distributor and a manufacturer when the wholesale distributor, including any affiliated group of the wholesale distributor, as defined in Section 1504 of the Internal Revenue Code, complies with the following:

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

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

(3) "board" means the board as defined under [insert citation];

(4) "chain pharmacy warehouse" means a physical location for prescription drugs that acts as a central warehouse and performs intra-company sales or transfers of such drugs to a group of chain pharmacies that have the same common ownership and control;

(5) "co-licensed partner or product" means an instance where [two (2)] or more parties have the right to engage in the manufacturing and/or marketing of a prescription drug, consistent with the federal Food and Drug Administration's implementation of the Prescription Drug Marketing Act;

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

manufacturer, or that manufacturer's third-party logistics provider, or that manufacturer's exclusive distributor;

(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, consistent with the federal Food and Drug Administration definition of "manufacturer" under its regulations and guidance implementing the Prescription Drug Marketing Act;

(9) "manufacturer's exclusive distributor" means anyone who contracts with a manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the manufacturer's prescription drug.

(a) such manufacturer's exclusive distributor must be licensed as a wholesale distributor under [insert citation], and 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, from that manufacturer to that manufacturer's co-licensed partner, from that manufacturer to that manufacturer's third-party logistics provider or from that manufacturer to that manufacturer's exclusive distributor, either directly or by drop shipment, to:

(a) a pharmacy to a patient;

(b) other designated people authorized by law to dispense or administer such drug to a patient;

(c) a wholesale distributor to a pharmacy to a patient or other designated people authorized by law to dispense or administer such drug to a patient;

(d) a wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intra-company pharmacy to a patient or other designated people authorized by law to dispense or administer such drug to a patient; or

(e) a chain pharmacy warehouse to the chain pharmacy warehouse's intra-company pharmacy to a patient or other designated people authorized by law to dispense or administer such drug to a patient.

(11) "pedigree" means a document or electronic file containing information that records each wholesale distribution of any given 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 federal 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.

(13) "repackage" means 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 product to the patient.

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

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

(16) “wholesale distributor” means anyone engaged in the wholesale distribution of prescription drugs including, but not limited to:

(a) manufacturers;

(b) repackagers;

(c) own-label distributors;

(d) private-label distributors;

(e) jobbers;

(f) brokers;

(g) warehouses, including manufacturers’ and distributors’ warehouses;

(h) manufacturer’s exclusive distributors;

(i) authorized distributors of record;

(j) drug wholesalers or distributors;

(k) independent wholesale drug traders;

(l) specialty wholesale distributors;

(m) third-party logistics providers;

(n) retail pharmacies that conduct wholesale distribution;

(o) chain pharmacy warehouses that conduct wholesale distribution, and

(p) to be considered part of the normal distribution channel, such wholesale distributor, except for a chain pharmacy warehouse not engaged in wholesale distribution, must also be an authorized distributor of record.

(17) “wholesale distribution” means distribution of prescription drugs to people other than a consumer or patient, but does not include:

(a) intra-company 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.

(b) 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.

(c) the distribution of prescription drug samples by manufacturers’ representatives.

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

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

(f) 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.

(g) 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.

(h) the sale, purchase, distribution, trade or transfer of a prescription drug from [one (1) authorized distributor of record to one (1) 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.

(i) 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.

(j) 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 third-party returns processor, including a reverse distributor.

Section 3. [*Wholesale Drug Distributor Licensing Requirement – Minimum Requirements for Licensure.*]

(A) Every wholesale distributor who engages in the wholesale distribution of prescription drugs must be licensed by the [board], and every nonresident wholesale distributor must be licensed by the [board] if it ships prescription drugs into this state in accordance with this Act before engaging in wholesale distributions of wholesale prescription drugs. The [board] shall exempt manufacturers distributing their own federal Food and Drug Administration approved drugs and devices from any licensing and other requirements to the extent not required by federal law or regulation, unless particular requirements are deemed necessary and appropriate following rulemaking.

(B) The [board] shall require the following minimum information from each wholesale distributor applying for a license under subsection (A) of this section:

(1) the name, full business address and telephone number of the licensee;

(2) all trade or business names used by the licensee;

(3) addresses, telephone numbers, and the names of contact people for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;

(4) the type of ownership or operation, i.e., partnership, corporation, or sole proprietorship;

(5) the name of each person who is an owner or an operator of the licensee;

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

(7) the name of the applicant's designated representative for the facility, together with the personal information statement and fingerprints, required pursuant to paragraph (8) of this section (3) for such individual;

(8) each individual required by paragraph (7) of this section (3) to provide a personal information statement and fingerprints shall provide the following information to the [board]:

(a) the individual's places of residence for the past [seven (7)] years;

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

(c) the individual's occupations, positions of employment and offices held during the past [seven (7)] years;

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

(e) whether the individual has been, during the past [seven (7)] years, the subject of any proceeding for the revocation of any license or any criminal violation and, if so, the nature of the proceeding and the disposition of the proceeding;

(f) whether, during the past [seven (7)] years, the individual has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control or distribution of prescription drugs or criminal violations, together with details concerning any such event;

(g) a description of any involvement by the individual with any business, including any investments, other than the ownership of stock in a publicly traded company or

mutual fund, during the past [seven (7) years], which manufactured, administered, prescribed, distributed or stored pharmaceutical products, and any lawsuits in which such businesses were named as a party;

(h) a description of any felony criminal offense of which the individual, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the individual pled guilty or nolo contendere;

(I) if the individual indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within [fifteen (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 individual taken in the previous year.

(C) The information required pursuant to subsection (B) of this section shall be provided under oath.

(D) The [board] shall not issue a wholesale distributor license to an applicant, unless the [board]:

(1) conducts a physical inspection of the facility at the address provided by the applicant as required in subsection (B)(1) of this section; and

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

(a) is at least [twenty-one (21)] years of age;

(b) has been employed full time for at least [three (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;

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

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

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

(f) is serving in the capacity of a designated representative for only [one (1)] applicant at a time, except where more than [one (1)] licensed wholesale distributor is co-located in the same facility and such wholesale distributors are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code;

(g) does not have any convictions under any federal, state or local law relating to wholesale or retail prescription drug distribution or distribution of controlled substances; and

(h) does not have any felony convictions under federal, state or local law.

(E) The [board] shall submit the fingerprints provided by a person with a license application for a statewide criminal records check and for forwarding to the Federal Bureau of Investigation for a national criminal records check of the individual.

(F) The [board] shall require every wholesale distributor applying for a license to submit a bond of at least [one hundred thousand dollars ($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 a fund established by the [board] pursuant to subsection (G) of this section. Chain pharmacy warehouses that are 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 that license, which are authorized under the law of this state and which the licensee fails to pay [thirty (30)] days after the fines, penalties or costs become final. The [board] may make a claim against such bond or

security until [one (1)] year after the licensee's license ceases to be valid. A single bond may suffice to cover all facilities operated by the applicant in this state.

(G) The [board] shall establish a fund, separate from its other accounts, in which to deposit the wholesale distributor bonds.

(H) If a wholesale distributor distributes prescription drugs from more than [one (1)] facility, the wholesale distributor shall obtain a license for each facility.

(I) In accordance with each licensure renewal, the [board] shall send to each wholesale distributor licensed under this section a form setting forth the information that the wholesale distributor provided pursuant to subsection (B) of this section. Within [thirty (30)] days of receiving such form, the wholesale distributor must identify and state under oath to the board all changes or corrections to the information that was provided pursuant to subsection (B) of this section. Changes in, or corrections to, any information in subsection (B) of this section shall be submitted to the [board] as required by the [board]. The [board] may suspend or revoke the license of a wholesale distributor if such authority determines that the wholesale distributor no longer qualifies for the license issued under this section.

(J) The designated representative identified pursuant to subsection (B)(7) of this section must receive and complete continuing training in applicable federal law and the law of this state governing wholesale distribution of prescription drugs.

(K) The [board] may adopt rules to approve an accreditation body to evaluate a wholesaler's operations to determine compliance with professional standards and any other applicable laws, and to perform inspections of each facility and location where wholesale distribution operations are conducted by the wholesaler.

(L) Information provided under this section shall not be disclosed to any person other than a state licensing authority, government board or government agency, provided such licensing authority, government board or agency needs such information for licensing or monitoring purposes.

Section 4. [*Restrictions on Transactions*.]

(A) 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 non-saleable pharmaceutical product shall be distributed by the receiving wholesale distributor only to either the original manufacturer or third party returns processor, including a reverse distributor. The returns or exchanges of prescription drugs, saleable or otherwise, including any redistribution by a receiving wholesaler, shall not be subject to the pedigree requirement of [insert citation], so long as they are exempt from pedigree under the federal Food and Drug Administration's currently applicable Prescription Drug Marketing Act Guidance. Wholesale distributors and pharmacies shall be held accountable for administering their returns process and ensuring that the aspects of this operation are secure and do not permit the entry of adulterated and counterfeit product.

(B) A manufacturer or wholesale distributor shall furnish prescription drugs only to a person licensed by the [board] or other appropriate state licensing authorities. Before furnishing prescription drugs to a person not known to the manufacturer or wholesale distributor, the manufacturer or wholesale distributor shall affirmatively verify that the person is legally authorized to receive the prescription drugs by contacting the appropriate state licensing authorities.

(C) Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises listed on the license; provided that the manufacturer or wholesale

distributor may furnish prescription drugs to an authorized person or agent of that person at the premises of the manufacturer or wholesale distributor if:

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

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

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

(E) A manufacturer or wholesale distributor shall not accept payment for, or allow the use of, a person's credit to establish an account for the purchase of prescription drugs from any person other than the owner(s) of record, the chief executive officer or the chief financial officer listed on the license of a person legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs must bear the name of the licensee.

Section 5. [*Pedigree*.]

(A) Each person who is engaged in wholesale distribution of prescription drugs, including re-packagers, but excluding the original manufacturer of the finished form of the prescription drug, that leaves, or has ever left, the normal distribution channel shall, before each wholesale distribution of such drug, provide a pedigree to the person who receives such drug.

(B) 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.

(C) 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 deem 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 will be no sooner than [July 1, 2010], and may be extended by the [board] in [one (1)] year increments if it appears the technology is not universally available across the entire prescription pharmaceutical supply chain.

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

(E) The pedigree shall include:

(1) 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, or manufacturer's exclusive distributor, through acquisition and sale by any wholesale distributor or re-packager, until final sale to a pharmacy or other person dispensing or administering the drug;

(2) the 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;

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

(4) transaction dates;

(5) certification that each recipient has authenticated the pedigree.

(6) name of the prescription drug;

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

(8) size of the container;

(9) number of containers;

(10) lot number and national drug code number of the prescription drug; and

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

(F) Each pedigree or electronic file shall be:

(1) Notwithstanding the provisions in [insert citation], maintained by the purchaser and the wholesale distributor for not less than [three (3)] years from the date of sale or transfer; and

(2) Available for inspection or use within [five (5)] business days upon a request of an authorized officer of the law.

(G) The [board] shall adopt rules and a form relating to the requirements of this section no later than [ninety (90)] days after the effective date of this Act.

Section 6. [*Enforcement - Order to Cease Distribution of a Drug*.]

(A) If the [board] finds that there is a reasonable probability that:

(1) a wholesale distributor, other than a manufacturer, has violated a provision in this Act or falsified a pedigree, or sold, distributed, transferred, manufactured, repackaged, handled or held a counterfeit prescription drug intended for human use; and

(2) the prescription drug at issue as a result of a violation in paragraph (1) of this subsection could cause serious, adverse health consequences or death; and

(3) other procedures would result in unreasonable delay;

the [board] shall issue an order requiring the appropriate person, including the distributors or retailers of the drug, to immediately cease distribution of the drug within the state.

(B) An order under subsection (A) of this section shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than [ten (10)] 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 7. [*Discipline -- Grounds -- Penalties*.]

(A) Upon a finding that a wholesale distributor is in violation of any provision of this Act, or such rules or standards of conduct and practice as may be adopted by the [board], and in accordance with the provisions of [insert citation], the [board] may impose any [one (1)] or more of the penalties provided for in [insert citation].

(B) Imposition of a penalty by the [board] or other action against a wholesale distributor by the [board] as set forth in this Act shall not be construed as barring other civil, administrative or criminal proceedings or prosecutions or entry of any available penalty or sanction as authorized by law.

Section 8. [*Prohibited Acts*.]

(A) It shall be unlawful for a person to knowingly perform, or cause the performance of, or aid and abet any of the following acts in this state:

(1) failure to obtain a license when a license is required by this Act;

(2) operate as a wholesale distributor without a valid license when a license is required by this act;

(3) purchase from or otherwise receive, return or exchange a prescription drug from a pharmacy or chain pharmacy warehouse, other than in compliance with section 4(A) of this Act;

(4) when a state license is required pursuant to section 4(B) of this Act, to sell, distribute, transfer or otherwise furnish a prescription drug to a person who is not authorized under the law of the jurisdiction in which the person received the prescription drug to receive the prescription drug;

(5) failure to deliver prescription drugs to specified premises, as required by section 4(C) of this Act;

(6) acceptance of payment or credit for the purchase of prescription drugs, other than in compliance with section 4(E) of this Act;

(7) failure to maintain or provide pedigrees as required by this Act;

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

(9) provide the [board] or any of its representatives or any federal official with false or fraudulent records or make false or fraudulent statements regarding any matter within the provisions of this Act;

(10) obtain, or attempt to obtain, a prescription drug by fraud, deceit or misrepresentation or engage in misrepresentation or fraud in the distribution of a prescription drug;

(11) manufacture, repackage, sell, transfer, deliver, hold or offer for sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit or otherwise has been rendered unfit for distribution;

(12) adulterate, misbrand or counterfeit any prescription drug;

(13) receive any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit or suspected of being counterfeit;

(14) deliver or proffer delivery of, for pay or otherwise, any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit or suspected of being counterfeit;

(15) alter, mutilate, destroy, obliterate or remove the whole or any part of the labeling of a prescription drug or commit any other act with respect to a prescription drug that results in the prescription drug being misbranded; or

(16) sell, deliver, transfer or offer to sell to a person not authorized under law to receive the return or exchange of a prescription drug, a prescription drug that has expired, been damaged or recalled by either the original manufacturer, a third party returns processor or a reverse distributor.

(B) The Acts prohibited in subsection (A) of this section do not include a prescription drug manufacturer, or agent of a prescription drug manufacturer, who obtains or attempts to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

Section 9. [*Penalties.*]

(A) Any person who commits any act prohibited by section 8(A)(1) through 8(A)(8) of this Act, is guilty of a [misdemeanor], which is punishable by not more than [one (1) year of imprisonment, or by a fine not exceeding five thousand dollars ($5,000)], or both.

(B) Any person who commits any act prohibited by section 8(A)(9) through 8(A)(16) of this Act, is guilty of a [felony], which is punishable by imprisonment for a term of [not less than five (5) years and not more than twenty (20) years, or by a fine not exceeding five hundred thousand dollars ($500,000)], or both.

(C) Any person who, with the intent to commit any of the acts prohibited by section 8(A)(9) through 8(A)(16) of this Act, commits any act prohibited by section 8(A)(1) through 8(A)(9) of this Act, is guilty of a [felony], which is punishable by imprisonment for a term of [not less than five (5) years and not more than twenty (20) years, or by a fine not exceeding five hundred thousand dollars ($500,000)], or both.

(D) Any criminal penalty imposed on a person who commits any act prohibited by section 8 of this Act, is in addition to, and not in lieu of, any other civil or administrative penalty or sanction authorized by law.

Section 10. [*Severability*.] [Insert severability clause.]

Section 11. [*Repealer*.] [Insert repealer clause.]

Section 12. [*Effective Date*.] [Insert effective date.]