FIRST REGULAR SESSION

HOUSE BILL NO. 339

94TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE HUNTER.

Read 1st time January 11, 2007 and copies ordered printed.

D. ADAM CRUMBLISS, Chief Clerk

1160L.01I

AN ACT

To repeal sections 338.330 and 338.370, RSMo, and to enact in lieu thereof seven new sections relating to wholesale distributors of prescription drugs, with penalty provisions.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Sections 338.330 and 338.370, RSMo, are repealed and seven new sections enacted in lieu thereof, to be known as sections 338.330, 338.370, 338.412, 338.414, 338.416, 338.418, and 338.420, to read as follows:

338.330. As used in sections 338.300 to **[**338.370**]** **338.420**, the following terms mean:

(1) **"Authentication", to affirmatively verify before any wholesale distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred;**

(2) "Authorized distributor of record", 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 of 1986, as amended, 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;

EXPLANATION — Matter enclosed in bold-faced brackets **[**thus**]** in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

(3) "Drop shipment", the sale of a prescription drug to a wholesale distributor 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;

(4) "Chain pharmacy warehouse", a physical location for drugs and devices that acts as a central warehouse and performs intracompany sales or transfers of the drugs or devices to a group of chain pharmacies that have the same common ownership and control;

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

(6) "Facility", a facility of a wholesale distributor where prescription drugs are stored, handled, repacked, or offered for sale;

(7) "Manufacturer", a person licensed or approved by the federal Food and Drug Administration to engage in the manufacture of drugs or devices;

(8) "Manufacturer's exclusive distributor", 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 a general responsibility to direct the sale or disposition of the manufacturer's prescription drug. Such manufacturer's exclusive distributor must be licensed as a wholesale distributor under sections 338.300 to 338.420, and to be considered part of the normal distribution channel must also be an authorized distributor of record;

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

(a) A pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;

(b) A wholesale distributor to a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;

(c) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or

(d) A chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient;

(10) "Out-of-state wholesale drug distributor", a wholesale drug distributor with no physical facilities located in the state;

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

[(2)**] (12)** "Pharmacy distributor", any licensed pharmacy, as defined in section 338.210, engaged in the delivery or distribution of legend drugs to any other licensed pharmacy where such delivery or distribution constitutes at least five percent of the total gross sales of such pharmacy;

(13) "Prescription drug", any drug, including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices, required by federal law, including 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 ("FFDCA");

(14) "Repackage", repackaging or otherwise changing the container, wrapper, or labeling to further the distribution of a prescription drug excluding that completed by the pharmacists responsible for dispensing product to the patient;

(15) "Repackager", a person who repackages;

(16) "Third-party logistics provider", 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 shall be licensed as a wholesale distributor under sections 338.300 to 338.420, and to be considered part of the normal distribution channel must also be an authorized distributor of record;

[(3)**] (17)** "Wholesale drug distributor", anyone engaged in the delivery or **wholesale** distribution of legend drugs from any location and who is involved in the actual, constructive or attempted transfer of a drug or drug-related device in this state, other than to the ultimate consumer**[**. This shall include, but not be limited to, drug wholesalers, repackagers and manufacturers which are engaged in the delivery or distribution of drugs in this state**]**, **including, but not limited to, manufacturers; repackagers; own-label distributors; private-label**

distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturers' exclusive distributors; and authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesale distributors; third-party logistics providers; and retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution with facilities located in this state or in any other state or jurisdiction. **To be considered part of the normal distribution channel such wholesale distributor must also be an authorized distributor of record.** A wholesale drug distributor shall not include any common carrier or individual hired solely to transport legend drugs. Any locations where drugs are delivered on a consignment basis, as defined by the board, shall be exempt from licensure as a drug distributor, and those standards of practice required of a drug distributor but shall be open for inspection by board of pharmacy representatives as provided for in section 338.360**;**

(18) "Wholesale distribution", a distribution of prescription drugs to persons other than a consumer or patient, but does not include:

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

(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, healthcare entity, or charitable institution in accordance with 21 C.F.R. Section 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 authorized distributor of record to one additional authorized distributor of record when the manufacturer has stated in writing to the receiving authorized distributor of record that the manufacturer is unable to supply such prescription drug and the supplying

authorized distributor of record states in writing that the prescription drug being supplied had until that time been exclusively in the normal distribution channel;

(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 to a third party returns processor.

338.370. Every person who violates any provision of sections 338.333, 338.337, **[**and**]** 338.340**, and sections 338.412 to 338.420** shall, upon conviction thereof, be adjudged guilty of a class C felony. **Every person who violates any provision of sections 338.412 to 338.420 may also upon conviction thereof be fined no more than five hundred thousand dollars.**

338.412. 1. The following minimum information shall be required from each wholesale distributor when applying for a license under sections 338.412 to 338.420:

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

(2) All trade or business names used by the applicant;

(3) 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;

(4) The type of ownership or operation, such as a partnership, corporation, or sole proprietorship;

(5) The name or names of the owner or owners or operator or operators of the applicant including:

(a) If a person, the name of the person;

(b) If a partnership, the name of each partner, and the name of the partnership;

(c) 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

(d) If a sole proprietor, the full name of the sole proprietor and the name of the business entity;

(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 under subdivision (8) of this subsection for such person;

(8) A personal information statement and fingerprints, required in subdivision (7) of this subsection which shall provide the following information to the board of pharmacy:

(a) The person's places of residence for the past seven years;

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

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

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

(e) Whether the person has been, during the past seven 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 years, the person has been enjoined, either temporarily or permanently, by a court 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 person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund 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 misdemeanor or felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendre. 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 fifteen days after the disposition of the appeal, submit to the state a copy of the final written order of disposition;

(i) A photograph of the person taken within the previous thirty days.

2. The information required under subsection 1 of this section shall be provided under oath.

3. The board of pharmacy shall not issue a wholesale drug distributor license to an in-state applicant, unless the board of pharmacy has conducted a physical inspection of the facility at the address provided by the applicant as required by subsection 1 of this section and determines that the designated representative meets the following criteria:

(1) Is at least twenty-one years of age;

(2) Has received a score of seventy-five percent or more on an examination given by the board of pharmacy regarding federal and state laws governing wholesale distribution of prescription drugs;

(3) Has been employed full time for at least three years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and record keeping relating to, prescription drugs;

(4) Is employed by the applicant full time in a managerial level position;

(5) Is actively in and aware of the actual daily operation of the wholesale drug distributor;

(6) 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;

(7) 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 such wholesale distributors are members of an affiliated group, as defined in Section 1504 of the Internal Revenue Code of 1986, as amended;

(8) 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

(9) Does not have any felony convictions under federal, state, or local laws.

4. The board of pharmacy shall have the authority to require and shall require every wholesale drug distributor applying for a license to submit a bond of at least one hundred thousand dollars, or the equivalent means of security acceptable to the board of pharmacy, 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 of pharmacy under subsection 5 of this section. 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 of pharmacy and any fees and costs incurred by the board of pharmacy regarding that license, which are authorized under state law and which the licensee fails to pay thirty days after the fines, penalties, or costs become final. The board of pharmacy shall have the authority to and may make a claim against such bond or security until one year after the licensee's license ceases to be valid. The bond shall cover all facilities operated by the applicant in the state.

5. The board of pharmacy shall establish a fund, separate from its other accounts in which to deposit the wholesale drug distributor bonds.

6. If a wholesale drug distributor distributes prescription drugs from more than one facility, the wholesale drug distributor shall obtain a license for each facility.

7. During the renewal cycle, the board of pharmacy shall send to each wholesale drug distributor licensed under this section a form setting forth the information the

wholesale drug distributor provided under subsection 1 of this section. Within thirty days of receiving such form, the wholesale drug distributor shall identify and state under oath to the board of pharmacy all changes or corrections to the information that was provided under subsection 1 of this section. Changes in or corrections to any information in subsection 1 of this section shall be submitted to the board of pharmacy as required by such board. The board of pharmacy may suspend or revoke the license of a wholesale drug distributor if such authority determines that the wholesale drug distributor no longer qualifies for the license issued under subsection 1 of this section.

8. The designated representative identified under subdivision (7) of subsection 1 of this section shall complete continuing education programs as required by the board of pharmacy in compliance with federal and state law governing wholesale distribution of prescription drugs.

9. Information provided under subsection 2 of this section shall not be disclosed to any person or entity 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.

10. The provisions of this section shall not apply to manufacturers who are distributing their own FDA-approved drugs and devices to the extent not required by federal law or regulation.

338.414. 1. A wholesale drug distributor shall receive prescription drug returns or exchanges from a pharmacy or chain pharmacy warehouse under the terms and conditions of the agreement between the wholesale distributor, the pharmacy, and chain pharmacy warehouse, including the returns of expired, damaged, and recalled pharmaceutical product to either the original manufacturer or a third-party returns processor, and such returns or exchanges shall not be subject to the pedigree requirements of section 338.416 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 shall be held accountable for administering their returns process and insuring their operations are secure and do not permit the entry of adulterated and counterfeit product.

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

3. Prescription drugs furnished by a manufacturer or wholesale distributor shall be delivered only to the premises 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 the particular patient of the authorized person.

4. Prescription drugs may be furnished to a 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 received. Any discrepancy between the 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 area.

5. A manufacturer or wholesale distributor shall not accept payment for or allow the use of a person 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 the person or entity legally authorized to receive prescription drugs. Any account established for the purchase of prescription drugs shall bear the name of the licensee.

338.416. 1. Each person who is engaged in wholesale distribution of prescription drugs shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of the prescription drugs. These records shall include pedigrees for all prescription drugs that leave the normal distribution channel. 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 or prescription drugs.

2. The board of pharmacy 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 or prescription drug products in the 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-year increments if it appears the

technology is not universally available across the entire prescription pharmaceutical supply chain.

3. Any person other than the original manufacturer of the finished form of the drug and any co-licensed products of the original manufacturer who is engaged in the wholesale distribution of a prescription drug, including repackagers, who is in possession of a pedigree for a prescription drug and attempts to further distribute that prescription drug shall affirmatively verify that each transaction listed on the pedigree has occurred before any distribution of a prescription drug occurs.

4. The pedigree shall:

(1) 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 drug. At a minimum, the necessary chain of distribution information shall include:

(a) The name, address, telephone number, and if available, the 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 product was shipped, if different from the owner's address;

(c) The transaction dates; and

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

(2) Include, at a minimum:

(a) The name of the prescription drug;

(b) The dosage form and strength of the prescription drug;

(c) The size of the container;

(d) The number of containers;

(e) The lot number of the prescription drug;

(f) The expiration date; and

(g) The name of the manufacturer of the finished dosage form.

5. Each pedigree or electronic file shall be:

(1) Maintained by the purchaser and the wholesale drug distributor, as required by law, from the date of sale or transfer; and

(2) Available for inspection, as required by law, upon request of an authorized officer of the law.

6. The board of pharmacy shall promulgate rules and a form relating to the requirements of this section no later than one hundred twenty days after August 28, 2007.

Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of the provisions of chapter 536, RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2007, shall be invalid and void.

338.418. 1. The board of pharmacy shall issue an order requiring the appropriate person, including the manufacturers, distributors, or retailers of a prescription drug, to immediately cease distribution of a prescription drug if the board of pharmacy determines that there is reasonable cause to believe that:

(1) A wholesale drug distributor, other than a manufacturer or their co-licensees, has:

(a) Violated a provision of sections 338.330 to 338.420; or

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

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

(3) Other procedures would result in unreasonable delay.

2. An order under subsection 1 of this section shall provide the person subject to the order with an opportunity for an informal hearing to be held not more than ten days after the date of the issuance of the order on the actions required by the order. If, after providing an opportunity for such hearing, the board of pharmacy determines that inadequate grounds exist to support the actions required by the order, the board of pharmacy shall vacate the order.

338.420. 1. No person shall perform or cause the performance of or aid and abet any of the following acts in this state:

(1) Failure to obtain a license in accordance with sections 338.330 to 338.420, or operating without a valid license when a license is required under sections 338.330 to 338.418;

(2) Purchasing or otherwise receiving a prescription drug from a pharmacy, unless the requirements in subsection 1 of section 338.414 are met;

(3) The sale, distribution, or transfer of a prescription drug to a person that is not authorized to receive the prescription drug, in violation of subsection 2 of section 338.414;

(4) Failure to deliver prescription drugs to specified premises as required by subsection 3 of section 338.414;

(5) Accepting payment or credit for the sale of prescription drugs in violation of subsection 5 of section 338.414;

(6) Failure to maintain or provide pedigrees as required by sections 338.330 to 338.420;

(7) Failure to obtain, pass, or authenticate a pedigree, as required by sections 338.330 to 338.420;

(8) Providing the board of pharmacy or any of its representatives or any federal official with false or fraudulent records or making false or fraudulent statements regarding any matter within sections 338.330 to 338.420;

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

(10) Except for the wholesale distribution by manufacturers or their co-licensees of a prescription drug that has been delivered into commerce under an application approved under federal law by the Food and Drug Administration, the manufacture, repacking, sale, transfer, delivery, holding, or offering for sale any prescription drug that is adulterated, misbranded, counterfeit, suspected of being counterfeit, or has otherwise been rendered unfit for distribution;

(11) Except for the wholesale distribution by manufacturers or their co-licensees of a prescription drug that has been delivered into commerce under an application approved under federal law by the Food and Drug Administration, the adulteration, misbranding, or counterfeiting of any prescription drug;

(12) The receipt of any prescription drug that is adulterated, misbranded, stolen, obtained by fraud or deceit, counterfeit, or suspected of being counterfeit, and the delivery or proffered delivery of such drug for pay or otherwise; and

(13) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded.

2. The prohibited acts under subsection 1 of this section shall not include a prescription drug manufacturer, a prescription drug manufacturer's co-licensees, or agent of a prescription drug manufacturer, obtaining or attempting to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

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