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HOUSE . . . . . No. 3915

The Commonwealth of Massachusetts

PRESENTED BY:

Peter J. Koutoujian

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the passage of the accompanying bill:

An Act regulating wholesale prescription drugs.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Peter J. Koutoujian	10th Middlesex

The Commonwealth of Massachusetts

In the Year Two Thousand and Nine

AN ACT REGULATING WHOLESALE PRESCRIPTION DRUGS.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. The General Laws are hereby amended by inserting after chapter 94C the following chapter:-

Chapter 94C1/2.

Section 1. As used in this chapter, the following words shall, unless the context clearly appears otherwise, have the following meanings:

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

"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, complies with any 1 of the following: (1) the wholesale distributor has a written agreement currently in effect with the manufacturer evidencing such ongoing relationship; or (2) 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.

"Board", the board of registration in pharmacy, established pursuant to section 22 of chapter 13.

"Chain pharmacy warehouse", 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.

"Co-licensed product", a prescription drug in which 2 or more parties have the right to engage in the manufacturing and marketing of such drug.

"Drop shipment", the sale of a prescription drug to a wholesale distributor by the manufacturer of the prescription drug, 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, and the pharmacy or chain pharmacy warehouse receives delivery of the

prescription drug directly from the manufacturer, or that manufacturer's third party logistics provider, or that manufacturer's exclusive distributor.

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

"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 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 pursuant to this chapter.

"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:

(1) a pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; (2) 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; (3) a wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intra-company pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient; or (4) an authorized distributor of record to a specialty wholesale distributor to a specialty pharmacy to a patient or other designated persons authorized by law to dispense or administer such drug to a patient.

"Pedigree", a document or electronic file containing information that records each distribution of any given prescription drug within the distribution channel.

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

"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.

"Repackager", a person who repackages.

"Specialty wholesale distributor", anyone who exclusively distributes a prescription drug to a specific group of specialty pharmacies or licensed practitioners and who has certified to the Board of Pharmacy that the distribution of such products will only occur in the limited situations described herein.

"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.

"Wholesale distribution", distribution of prescription drugs to persons other than a consumer or patient, but does not include: (1) 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; (2) 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; (3) the distribution of prescription drug samples by manufacturers' representatives; (4) drug returns, when conducted by a hospital, health care entity, or charitable institution in accordance with 21 C.F.R. § 203.23; (5) the sale of minimal quantities of prescription drugs by retail pharmacies to licensed practitioners for office use; (6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription; (7) the 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; (8) 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; (9) drop shipments of a prescription drug from the manufacturer of such prescription drug, or that manufacturer's co-licensed partner, or that manufacturer's third party logistics provider or that manufacturer's exclusive distributor, to a pharmacy, or chain pharmacy warehouse; (10) 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; or (11) 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.

"Wholesale distributor", anyone engaged in the wholesale distribution of prescription drugs, including, but not limited to, repackagers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses; manufacturer's 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.

Section 2. (a) Every wholesale distributor, including a third party logistics provider, who

engages in the wholesale distribution of prescription drugs shall be licensed by board and every non-resident wholesale distributor shall be licensed by the board if it ships prescription drugs into the commonwealth, in accordance with this chapter prior to engaging in wholesale distributions of wholesale prescription drugs provided, that, specialty wholesale distributors shall be separately licensed and designated as specialty wholesale distributors by the board or shall be inspected and accredited as a specialty wholesale distributor by a nationally recognized accreditation program approved by the board. Manufacturers shall be exempt from any licensing and other requirements of this section, to the extent not required by federal law or regulation, unless particular requirements are deemed necessary and appropriate following rulemaking. Such third party logistics provider shall be licensed as a wholesale distributor pursuant to this chapter.

(b) The board shall require the following minimum information from each wholesale distributor applying for licensure pursuant to paragraph (a): (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 persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs; (4) the specific type of ownership or operation, whether a partnership, corporation, or sole proprietorship or other form of ownership; (5) the name of any owner and operator of the licensee, 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 proprietorship, 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 board 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 subparagraph (8) for such person; (8) each person required by subparagraph (7) to provide a personal information statement and fingerprints shall provide the following information to the board: (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 each such office of the person was held or in which each such occupation or position of employment was carried on; (E) whether the person has been, during the past 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 7 years, the person has been enjoined, either temporarily or permanently, by a court of competent jurisdiction from violating any Federal or board 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, during the past 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 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 contendere or after a plea of not guilty and admission to sufficient facts to warrant a plea of guilty. 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 must, within 15 days after the disposition of the appeal, submit to the board a copy of the final written order of disposition; and (I) a photograph of the person taken in the previous 30 days.

(c) The information required pursuant to paragraph (b) 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 clause (1) of paragraph (b) of section 2; and (2) determines that the designated representative meets the following qualifications: (A) is at least 21 years of age; (B) has been employed full time for at least 3 years in a pharmacy or with a wholesale distributor in a capacity related to the dispensing and distribution of, and recordkeeping relating to, prescription drugs; (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 1 applicant at a time, except where more than 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 federal Internal Revenue Code; (G) 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 (H) does not have any felony convictions under Federal, State, or local laws.

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

(f) Every wholesale distributor applying for a license shall submit a bond to the board 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 a fund established by the board pursuant to paragraph (g). Such bond or security shall secure payment of any fines or penalties imposed

by the board and any fees and costs incurred by the board regarding that license, which the licensee fails to pay 30 days after the fines, penalties, or costs become final. The board may make a claim against such bond or security until 1 year after the licensee's license ceases to be valid. The bond shall cover all facilities operated by the applicant in the state.

(g) The board licensing authority 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 1 facility, the wholesale distributor shall obtain a license for each facility.

(i) Each calendar year, the board licensing authority shall send to each wholesale distributor licensed pursuant to section 2 a form setting forth the information that the wholesale distributor provided pursuant to paragraph (b). Within 30 days of receiving such form, the wholesale distributor shall identify and state under oath to the board all changes or corrections to the information that was provided pursuant to paragraph (b). Changes in, or corrections to, any information in paragraph (b) shall be submitted to the board as required. The board may suspend or revoke the license of a wholesale distributor if it determines that the wholesale distributor no longer qualifies for the license issued under this section.

(j) The designated representative identified pursuant to item (7) of paragraph (b) must receive and complete continuing training in applicable Federal and State laws governing wholesale distribution of prescription drugs.

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

Section 3. (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 and/or 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 requirement of section 4. Wholesale distributors shall be held accountable for policing their returns process and insuring 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. 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 board.

(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 or entity's credit to establish an account for the purchase of prescription drugs from any person other than the 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.

Section 4. (a) Each person who is engaged in wholesale distribution of prescription drugs, including repackagers, but excluding the original manufacturer of the finished form of the prescription drug, that leave the normal distribution channel shall, before each wholesale distribution of such drug, provide a pedigree to the person who receives such drug.

(1) 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.

(2) The board of shall determine by July 1, 2010, a mandated implementation date for electronic pedigree. Such a determination shall be based on consultation with manufacturers, distributors, and pharmacies responsible for the sale and distribution of prescription drug products. The implementation date for the mandated electronic pedigree will be no sooner than July 1, 2011.

(b) Each person who is engaged in the wholesale distribution of a prescription drug, including repackagers, 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 distribution of a prescription drug occurs that each transaction listed on the pedigree has occurred.

(c) The pedigree shall include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer through acquisition and sale by any wholesale distributor or repackager, until final sale to a pharmacy or other person dispensing or administering the prescription drug. The necessary chain of distribution information shall include, but not be limited to: name, address, telephone number, and if available, the electronic mail address, of each owner of the prescription drug, and each wholesale distributor of the prescription drug; name and address of each location from which the product was shipped, if different from the owner's; transaction dates; and certification that each recipient has authenticated the pedigree. The pedigree shall also include the: name of the prescription drug; dosage form and strength of the prescription drug; size of the container; number of containers; lot number of the prescription drug; and name of the manufacturer of the finished dosage form.

(d) Each pedigree or electronic file shall be maintained by the purchaser and the wholesale distributor for 3 years from the date of sale or transfer and available for inspection or use within 5 business days upon a request of an authorized officer of the law.

Section 5. (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 chapter, 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 paragraph (1) 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 distributors or retailers of the drug, to immediately cease distribution of the drug within that state.

(b) An order under paragraph (a) shall 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 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 6. It shall be unlawful for a person to perform or cause the performance of or aid and abet any of the following acts:

(a) failure to obtain a license in accordance with this chapter, or operating without a valid license when a license is required by this chapter;

(b) if the requirements of paragraph (a) of section 3are applicable and are not met, the purchasing or otherwise receiving a prescription drug from a pharmacy;

(c) if a state license is required pursuant to paragraph (b) of section 3, the sale, distribution, or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the prescription drug to receive the prescription drug;

(d) failure to deliver prescription drugs to specified premises, as required by paragraph (c) of section 3;

(e) accepting payment or credit for the sale of prescription drugs in violation of paragraph (e) of section 3;

(f) failure to maintain or provide required pedigrees;

(g) failure to obtain, pass, or authenticate a pedigree;

(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 chapter;

(i) 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;

(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, 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;

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

(l) 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

(m) 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.

It shall not be unlawful for a prescription drug manufacturer, or agent of a prescription drug manufacturer, to obtain or attempt to obtain a prescription drug for the sole purpose of testing the prescription drug for authenticity.

Section 7. (a) Any person who engages in the wholesale distribution of prescription drugs in violation of this chapter shall be punished by imprisonment in the state prison for not more than 5 years or by a fine not more than $50,000, or both.

(b) Any person who knowingly or intentionally engages in wholesale distribution of prescription drugs in violation of this chapter, shall be punished by imprisonment in the state prison for not more than 15 years, or by a fine not more than $500,000, or both.

Section 8. The fee for any permit or license granted under this chapter or renewal thereof shall be determined annually by the commissioner of administration under the provision of section 3 of chapter 7.

SECTION 2. The board of registration in pharmacy shall promulgate regulations regarding the requirements of chapter 94C1/2 of the general laws no later than 90 days after the effective date of this act.

SECTION 3. Sections 36A to 36D, inclusive, of chapter 112 of the General Laws are hereby repealed.