Date of Hearing: June 20, 2017

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Evan Low, Chair
SB 752(Stone) – As Amended March 28, 2017

SENATE VOTE: 39-0

SUBJECT: Pharmacy: designated representative-reverse distributors

SUMMARY: Authorizes the Board of Pharmacy (Board) to issue a designated representative-reverse distributer license to a person qualified to supervise a licensed wholesaler, as specified; requires designated representative-reverse distributors and designated representative- third party logistics providers (3PLs), to notify the executive officer of the Board of a change of name or address; and authorizes persons who act as agents for pharmacies or other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or non-saleable dangerous devices to be recognized as reverse distributors.

EXISTING LAW:

1) Establishes the Board within the Department of Consumer Affairs to administer and enforce the Pharmacy Law. (Business and Professions Code Section (BPC) § 4001)

2) Defines a "designated representative" as an individual to whom a license has been granted, as specified, but that a pharmacist fulfilling the duties of a designated representative is not required to obtain a license as a designated representative. (BPC § 4022.5 (a))

3) Defines a "designated representative-in-charge" as a designated representative or a pharmacist proposed by a wholesaler or veterinary food-animal drug retailer and approved by the Board as the supervisor or manager responsible for ensuring compliance with all state and federal laws and regulations pertaining to practice in the applicable license category. (BPC § 4022.5 (b))

4) Establishes requirements for licensure as a designated representative and specifies that a designated representative provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer and shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.
(BPC § 4053)

5) Defines a "reverse distributor" as every person who acts as an agent for pharmacies, drug wholesalers, 3PLs, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or non-saleable dangerous drugs. (BPC § 4040.5)

THIS BILL:

1) Adds "designated representative-reverse distributor" to the definition of designated representative and specifies that a "designated representative-reverse distributor" means an

individual to whom a license has been granted, who is responsible for supervision over a licensed wholesaler that only acts as a reverse distributor.

2) Specifies that a licensed pharmacist shall not be required to obtain a license as a designated representative-reverse distributor.

3) Adds dangerous devices to the list of items that a specified entity can receive, inventory, warehouse, and manage the disposition of.

4) Permits the Board to issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing, and destruction of outdated or nonsaleable dangerous drugs and dangerous devices.

5) States that an individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

    a) He or she shall be a high school graduate or possess a general education development certificate equivalent.

    b) He or she shall meet one of the following requirements:

        i) Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third-party logistics provider, or pharmacy performing duties related to the distribution, dispensing, or destruction of dangerous drugs or dangerous devices.

        ii) Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs or dangerous devices pharmaceutical waste.

        iii) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

    c) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

        i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

        ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

        iii) Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.

        iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.

6) Permits the Board to promulgate regulations to require the training program to include additional material.

7) States that the Board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training to the Board.

8) Requires a reverse distributor to have at least one designated representative or designated representative-reverse distributor present at each of its licensed places of business.

9) Adds designated representative-reverse distributor as an individual who may sign for and receive deliveries of dangerous drugs or devices.

10) Specifies that each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business, at least one designated representative, in the case of a wholesaler, or designated representative-3PL in the case of a third-party logistics provider, shall be present. A wholesaler that only acts as a reverse distributor may use either a designated representative or a designated representative-reverse distributor to fulfill this requirement.

11) States that the fee for application, investigation, and issuance of a license as a designated representative, or as a designated representative-3PL, or as a designated representative-reverse distributor shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

12) States that the fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

FISCAL EFFECT: According to the May 1, 2017 Senate Committee on Appropriations analysis, this bill will likely result in ongoing costs of $50,000 to $100,000 per year for the Board to license the new category of licensee, and one-time costs of $50,000 for the Board to upgrade their information technology systems to issue the new licenses.

COMMENTS:

Purpose. This bill is sponsored by the *Board of Pharmacy*. According to the author, "Current law allows for reverse distributors. They are in charge of receiving, inventorying, warehousing, and managing the disposition of outdated or non-saleable dangerous drugs. However, it seems that some of the requirements for receiving a license for reverse distributor may not be necessary when the individual is working for a business whose sole business model is handling dangerous drugs and pharmaceutical waste for destruction. SB 752 establishes, through the creation of a new licensing category, a designated representative license for individuals working in a reverse distributor."

Background. *Pharmacist Practice and Regulation*. Pharmacists are healthcare professionals who understand the biochemical mechanisms and actions of drugs, drug uses, therapeutic roles, side effects, potential drug interactions, and monitoring parameters. Pharmacists provide counseling on the appropriate use and effects of prescribed drugs. In California, pharmacists are regulated by the Board. There are 42,691 pharmacists and 70,624 pharmacy technicians with active licenses in the state.

Regulation of Pharmacies. There are 7081 pharmacies regulated by the Board. Of these, 513 are hospital pharmacies. The Board reported it also regulates 506 non-resident pharmacies which generally include mail order pharmacies. The Board has additional licenses for those pharmacies that perform sterile compounding and are located in California (890) and ship into California from another state (91).

Reverse Distribution. In the course of normal operations, health care providers and pharmacies accumulate pharmaceuticals that they will not use or dispense. A reverse distributor is an individual who acts as an agent for pharmacies, drug wholesalers, 3PLs, manufacturers and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or non-saleable dangerous drugs. There are 568 wholesalers, 740 out of state wholesalers, 23 third party logistics providers, and 65 out of state 3PLs licensed by the Board.

Even though old, unused controlled substances constitute only 10% of all prescription drugs in the distribution system, they cause environmental problems when they're flushed down the toilet at home or at an institution. The environmental threat to lakes, streams, and rivers from discarded pharmaceuticals is a growing concern (Pharmacy and Therapeutics, 2009).

Federal Environmental Protection Agency (EPA) Proposed Regulations on Reverse Distribution. In 2015, "…in an attempt to bring consistency to the varying approaches taken by states" the EPA proposed rules to broaden the scope of regulation of reverse distribution. The EPA expanded the definition of pharmaceutical to include medication, dietary supplements, and any items containing pharmaceutical residuals, such as IV bags, unit dose packages, personal protective clothing contaminated with medications, and any spilled materials. The EPA also redefined waste to include all medications sent by a healthcare facility to a reverse distributor, regardless of whether they are eligible for credit. It also established numerous additional requirements for reverse distribution facilities, including notification to EPA; requiring all shipments be evaluated for hazardous waste content within 21 days of receipt; maintenance of records of all shipments received and maintenance of an inventory of all potentially creditable waste materials; and additional security, closure, and reporting requirements for such facilities were also proposed (Environmental Law Alert, 2015).

Designated Representatives. Wholesale operations that distribute dangerous drugs or dangerous devices must have a Wholesaler License and must be supervised by a registered pharmacist or an individual approved by the Board as a designated representative who is responsible for ensuring compliance with all state and federal laws and regulations pertaining to practice. These companies may not operate unless the pharmacist or designated representative is physically on the licensed premises. The designated representative must either demonstrate one year of paid work experience related to the distribution or dispensing of dangerous drugs or devices in a licensed pharmacy, drug wholesaler, drug distributor or drug manufacturer, or be eligible to take the pharmacy licensure examination. In addition, the designated representative must complete a training program approved by the Board and demonstrate knowledge of California and federal law regarding distribution of dangerous drugs and devices, controlled substances, pharmacopoeia standards relating to safe storage and handling of drugs, and knowledge of prescription terminology and dosages. There are 1,831 designated representatives, 35 veterinary food animal drug retailer designated reps, and 114 3PL designated representatives licensed by the Board.

Prior Related Legislation. AB 2605 (Bonilla, Chapter 507, Statutes of 2014) created a Board 3PL and nonresident 3PL provider license for an entity that handles and transports dangerous drugs and devices.

SB 1308 (Committee on Business and Professions, Chapter 655, Statutes of 1999) created the reverse distributor category.

ARGUMENTS IN SUPPORT:

The Board of Pharmacy (sponsor) writes in support, "The board believes there is benefit to creating specialized category of licensure for the designated representative that will oversee the operations of the reverse distributors. Currently, designated representatives are licensed based on their experience in the distribution of medication from manufacturers to pharmacies and practitioners. We believe that emerging efforts to destroy unwanted drugs through take-back programs warrants the board's efforts to create a licensing category that more clearly reflects the minimum qualifications someone must meet to perform the duties of disposal and destruction of medications from the supply chain."

ARGUMENTS IN OPPOSITION:

None on file.

REGISTERED SUPPORT:

Board of Pharmacy (sponsor)

REGISTERED OPPOSITION:

None on file.

Analysis Prepared by: Le Ondra Clark Harvey, Ph.D. / B. & P. / (916) 319-3301