Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Dangerous Drug Distributors

Sections Affected: Amend Article 10 of Division 17 of Title 16, California Code Regulations
Amend Section 1780 of Article 10 of Division 17 of Title 16, CCR
Amend Section 1781 of Article 10 of Division 17 of Title 16, CCR
Amend Section 1782 of Article 10 of Division 17 of Title 16, CCR
Amend Section 1783 of Article 10 of Division 17 of Title 16, CCR

Problems Addressed

The California State Board of Pharmacy (board) is a state agency vested with the authority to regulate the pharmacy industry, including dangerous drug distributors. (Business and Professions Code (B&P) section 4000, et seq.) The board's mandate and its mission is to protect the public. (B&P section 4001.1.)

The board proposes to amend the title of, and sections 1780, 1781, 1782, and 1783 within, Article 10 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of updating the board's specific licensing requirements pertaining to dangerous drug distributors, including third-party logistics providers (3PLs).

Existing law establishes that the board is authorized to issue wholesaler and 3PLs licenses (B&P sections 4160 and 4161). Dangerous drugs and dangerous devices are those available by prescription only. (B&P section 4022, 4023, 4025.) National standards establish how various businesses in the pharmaceutical chain handle prescription drugs to ensure that, when they are ultimately received by the consumer, the prescription drugs are safe and effective. Generally, this is accomplished by ensuring that the prescription drugs are not damaged by the conditions under which they are transported, stored, or otherwise handled. Manufacturers, wholesalers, and third party logistic providers all handle the prescription drugs and are therefore similarly regulated as drug distributors.

Previously, the board licensed third-party logistics providers (3PLs) as wholesalers; however, effective November 2013, section 585, subdivision (b), of the Federal Food, Drug, and Cosmetic Act (21 United States Code Section 360eee-4, subdivision (b)(2)) no longer allows states to license 3PLs as wholesalers. As 3PLs are a member of the drug supply chain, the board successfully obtained legislation to establish 3PLs as a separate licensing category (Assembly Bill 2605, Bonilla, Chapter 507, Statutes of 2014).

AB 2605 added or amended, among others, sections that made the following changes:

- **B&P section 4022.7**:
    - Established the definition of a designated representative-3PL.

    - Established the definition of a responsible manager, who is also a designated representative-3PL.
- **B&P section 4045**:
    - Established the definition of a "third-party logistics provider." A 3PL provides or coordinates the warehousing of, or other logistics services for, a prescription drug or device on behalf of another person. The 3PL does not, however, take ownership, nor have responsibility to direct the sale or disposition of, the drug or device.
- **B&P section 4053.1**:
    - Established the board's authority to issue a license to a designated representative–3PL and specified that person's role as providing sufficient and qualified supervision of a 3PL's place of business by ensuring the safe handling, storage, warehousing, distribution, and shipment of drugs and devices.
    - Established the minimum qualifications to obtain said license.
- **B&P section 4160**:
    - Established the board's authority to issue a 3PL license and specifies that the location must operate with a designated representative-3PL present.
    - Established that, no person may act as a 3PL without, first, obtaining a license from the board.
- **B&P section 4161**:
    - Established the board's authority to issue a nonresident 3PL license for those performing the services outside California for drugs that ultimately come into California.
    - Requires board licensure for anyone operating as a nonresident 3PL.

Existing regulations specify how a wholesaler must operate, specifying conditions it must meet in the operation of its business. This proposal will modify those sections to reflect that 3PLs are held to the same standards as the wholesalers by specifying the conditions under which the drugs are secured, maintained, accessed, monitored, and handled. It will reimpose those regulations that applied to 3PLs before the change in federal and state law. It will specify when a 3PL must have a designated representative-3PL present and in control. It will require activity reporting to the board. It will also specify where and to whom a 3PL may furnish a dangerous drug or device, and require record keeping with respect to its functions.

Existing law permits the board to take action to prevent the sale of drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia (USP) or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code). Existing law requires designated representatives, individuals who are responsible for the safety wholesalers or 3PLs, to be knowledgeable and understand the safe storage, handling, and transport of dangerous drugs and dangerous devices. (B&P §§ 4053, 4053.1.)

In addition to the changes above, the proposal will update the references in regulation section 1780 to the storage and handling standards of the United States Pharmacopeia (USP), which currently refers to the standards in the 1990, 22nd Revision, to reference the most recent edition. This change will require that wholesalers and 3PLs follow the current version of the USP with respect to storage and handling standards. The United States Pharmacopeia is the international standard for handling drugs, including their storage conditions, to ensure that the drugs maintain their safety and efficacy. Not referencing the current standards could impact patient safety. For example, if storage conditions are too hot, a drug could lose potency, and the consumer could be harmed by taking a drug that does not provide the anticipated effect.

Benefits

This regulatory proposal will benefit the health and welfare of California residents because the proposed regulation will require 3PLs to transport, store and otherwise handle dangerous drugs under conditions that make it more likely that the drugs will be safe and effective when received by the consumer. Additionally, the standards are consistent with the standards for drug wholesalers, which is also how entities performing the same functions were previously regulated. Requiring 3PLs to meet minimum qualifications for licensure and operation, allows the board to ensure that the drug supply chain is safe and that the drugs being distributed to consumers are effective. As third-party logistics providers can no longer be licensed as wholesalers, by clearly specifying the minimum qualification for 3PLs, these regulations will ensure that the pharmaceutical drug supply chain is regulated consistently.

Specific Purpose of Proposed Changes and Rationale

The board's proposal would make the following changes:

Amend Article 10 of Division 17 of Title 16 of the CCR

The board is proposing to amend the title of Article 10 from "Wholesalers" to "Dangerous Drug Distributors," to reflect that this article applies to drug manufacturers, wholesalers, and 3PLs. The term "dangerous drug distributors" was selected because it is a broad term that can include the many functions these entities perform, including manufacturing, storing, transporting and selling dangerous drugs and devices.

Amend Section 1780 of Article 10 of Division 17 of Title 16 of the CCR

The board is proposing to amend the title of this section from "Minimum Standards for Wholesalers" to "Minimum Standards for Wholesalers and Third-Party Logistics Providers" which will provide clarity to whom the minimum standards apply. Within this entire section "and third-party logistics provider" has been added anywhere the terms "wholesale" or "wholesaler" is used. This change will require each of the existing minimum requirements that apply to a wholesaler, to now apply to 3PLs. As 3PLs perform similar functions as wholesalers, and they have the same responsibilities to

safeguard the drugs so that the drugs maintain their potency, efficacy, and safety, it is necessary to include their reference here and throughout this section. Dangerous drugs, generally, are those drugs that require a prescription under state or federal law. The drugs require a prescription because without direction by a medical professional, they pose a risk to a consumer.

Subsection (a) of the regulation will require a 3PL to store the dangerous drugs in a secured and lockable area, therefore keeping them from being taken and used without a prescription.

Subsection (b) will require a 3PL to maintain its premises clean and orderly, well ventilated, free from rodents and insects, adequately lighted, its plumbing in good repair, temperature and humidity at appropriate levels for the drugs, and its fixtures and equipment to be in a clean and orderly condition, all to ensure that the drugs do not become adulterated during storage, which would pose a risk to consumers.

Subsection (c) will require 3PLs to limit access to authorized personnel, to have an alarm and security system, and be well-lighted on the outside perimeter to minimize the risk of theft of dangerous drugs and, therefore their use by individuals without a prescription. The term "wholesaler" was removed as the section will apply to both wholesalers and 3PLs.

Subsection (d) will require 3PLs to examine shipments for identity, damage, contamination or other things that might make the drugs less safe for the public. The subsection is also amended to change "or" to "and" because it is necessary for wholesalers and 3PLs to examine the shipments upon receipt and before shipment as specified in subsections (d)(1) and (d)(2). It is necessary to examine the shipment upon receipt to ensure that the containers were not damaged or contaminated during shipment from the manufacturer. Additionally, it is necessary to examine the containers prior to shipment to ensure that the containers were not damaged or contaminated during storage at the facility. This amendment will eliminate possible confusion with the regulation and with industry standard practice.

Subsection (e) will specify how 3PLs handle returned, damaged, and outdated drugs, specifically to make sure they are physically stored separate from salable stock, making it less likely that they are inadvertently placed into the stream of commerce. It will also make the dangerous drugs or devices and 3PL facility easier to inspect.

Subsection (f) will require a 3PL to prepare written policies and procedures to address the receipt, security, storage, inventory and distribution of drugs, including losses; to correct errors and inaccuracies in inventories, and maintaining records of proper storage; to comply with federal regulation; to keep the records for three years; to maintain a list of officers, directors and managers, including their duties and qualifications; and to train its personnel to ensure compliance. This provision would make it more likely the drugs are being safely handled because the 3PL should be well

organized, and well run with trained personnel. It will also make the facility easier to inspect.

Subsection (g) will require the 3PL to certify that it meets the requirements of the section upon licensure or renewal. The affirmative statement that it complies with these provisions makes it more likely the 3PL will follow the provisions, and therefore more likely that the drug supply going to consumers is safe and effective. This section is further amended to add the requirement that the applicant for renewal certify under penalty of perjury that the requirements for renewal have been met. The requirement to certify under penalty of perjury is required because the potential consequence should make the individual signing the certification be truthful, take compliance seriously, and thereby making it more likely that they will comply with the substance of the board's regulation, and that the dangerous drugs will be stored and transported in a manner to keep them safe and effective. In addition, in the event enforcement action is necessary, the certifying individual may be held accountable for failing to be truthful.

Subsections (b) and (e)(3) are additionally amended to require wholesalers and 3PLs to apply the standards set forth in the latest edition of the United States Pharmacopeia (USP), rather than the standards from an outdated version (1990, 22nd Revision). This change will require that wholesalers and 3PLs follow the current version of the USP with respect to storage and handling standards. The United States Pharmacopeia is the international standard for handling drugs, including their storage conditions, to ensure that the drugs maintain their safety and efficacy. For example, if storage conditions are too hot, a drug could lose potency, and the consumer could be harmed by taking a drug that does not provide the anticipated effect. Compliance with the United States Pharmacopeia is also required by the U.S. Code (Section 321 of Title 21), the Code of Federal Regulations (Section 205.50 of Title 21), and Business and Professions Code section 4342. As compliance with the USP standards is established as a requirement of both federal and state law, the board determined removing the specific reference to a particular version of USP to be appropriate. The federal Food and Drug Administration has the ability to provide input in USP's maintenance, and numerous state and federal laws require compliance with official compendium, including USP, which explicitly incorporate any addendum thereto.

The Note's references are also updated to accurately reflect the appropriate law sections. Citations are also added for sections 4025, 4045, 4053.1, 4161.5, and 4342 of the Business and Professions Code; sections 109985 and 111280 of the Health and Safety Code; section 321 of Title 21 of the U.S Code; and section 205.50 of Title 21 of the Code of Federal Regulations.

Amend Section 1781 of Article 10 of Division 17 of Title 16 of the CCR

The board is proposing to amend the title of the section from "Exemption Certificate" to "Pharmacist or Designated Representative on Premises and in Control" to clearly describe the subject of the section. The section is additionally amended to add the heading "(a)" prior to the existing language. The existing language requires a

pharmacist or designated representative be present and in control of a manufacturer or wholesaler. New subdivision (b) was added to require a designated representative-3PL to be present and in control of the 3PL facility while business is being conducted. B&P section 4160, subdivision (e), requires a "responsible manager," who must be licensed as a designated representative-3PL, to be in charge. Like manufacturers and wholesalers, the person on the premises and in charge while business is being conducted should be a licensee. By having an appropriately licensed person on premises during any operations, it is more likely the dangerous drugs will be handled and stored appropriately, making the drug supply safer for the public.

Within the text and Note, references to section 4054 of the B&P is deleted; section 4054 refers to an exemption to what acts must be done by a pharmacist. The reference is not applicable to the pharmacists working at a manufacturer, wholesaler, or 3PL and it has therefore been deleted.

Additionally, the Note was updated to reference B&P sections 4022.5, 4022.7, 4160, and 4161, because those refer to the statute with the licensing requirements for a designated representative–3PL and to the wholesaler's and third-party logistics provider's requirements to have designated representatives.

Amend Section 1782 of Article 10 of Division 17 of Title 16 of the CCR

The board is proposing to amend this section to remove "and" before "wholesale" and add "and third-party logistics providers" to the first sentence to ensure the proper licensees are referenced in the section. Non-substantive changes were made to make the sentence more easily understood (making the subject singular, rather than plural). As amended, this section will require 3PLs to report to the board or its designee, up to 12 times a year, all sales of dangerous drugs subject to abuse as designated by the board. The 3PL will have to make the report within 30 days of the request in the form requested by the board. This will make the standard the same for 3PLs, manufacturers, and wholesalers. The reason for requiring the reports within a particular time frame is because the board uses the information to determine compliance with Pharmacy Law and it needs the records timely for inspections or investigations. The board requires the reports no more than 12 times a year to make sure that the demands are reasonable for the licensee. The board will determine, on a case by case basis, the drugs about which the information is needed, and the thresholds for reporting. While the board can review all distribution records at any time pursuant to Business and Professions Code section 3081 and regulation section 1783, this reporting requirement allows the board to obtain data between inspections from dangerous drug distributors where, on a case by case basis, the board determines there is a need to monitor one or more particular drugs. The board cannot always reliably anticipate which drugs are subject to abuse; in addition, the licensees may generally maintain more reliable records because they will not know which drugs the board will ask about in advance. Under these circumstances, the licensees' duty to respond to board requests for drugs identified on a case by case basis helps the board monitor the industry.

Additionally, the Note is updated to remove the outdated reference to Health and Safety Code section 26692, as this section has been repealed, and add references to B&P sections 4051.1, 4164, and 4165.

Amend Section 1783 of Article 10 of Division 17 of Title 16 of the CCR

The board is proposing to amend this section to add "or Third-Party Logistics Provider" to the section title to clearly identify to whom the section applies. This entire section is further amended to add "or third-party logistics provider" after "wholesaler" at all locations within the section and make grammatical changes to incorporate the addition of 3PLs to the entities subject to the section. These changes will require each of the existing requirements that apply to a manufacturer or wholesaler, to now apply to 3PLs. As 3PLs have the same statutory licensing requirements as wholesalers, and they have the same responsibilities to safeguard the drugs so that the drugs maintain their potency, efficacy, and safety, it is appropriate to include their reference here. The standards are required to keep the drugs safe and secure; applying the standards for wholesalers to 3PLs makes sense because they have been sufficient in the context of wholesalers, to keep industry expectations consistent, and to standardize board review.

Subsection (a) of the regulation will require that a 3PL can only furnish dangerous drugs or devices to authorized persons and require a 3PL, prior to furnishing the dangerous drugs or devices to an unknown person, to contact the board or other government entity to confirm that the person is authorized to receive the dangerous drugs or devices. By ensuring that only people with appropriate authority have access to the drugs and devices, the board can better monitor and control the safety and efficacy of the drugs. A controlled chain of custody makes it more likely that the patient receiving the drug receives a legitimate drug that is safe and effective.

Subsection (b) will require a 3PL to confirm that the recipient of dangerous drugs is a legally authorized person to receive the dangerous drugs or devices prior to furnishing the product. The existing regulation defines authorized person, which will apply to 3PLs, as someone who has a license from the board that allows the holder to obtain the drugs, or someone with similar authority authorized by another jurisdiction or the federal government. Similar to the prior requirement, controlling the chain of custody allows the board to monitor and control the drugs for a consumer.

Subsection (c) will require 3PLs to only deliver dangerous drugs or devices to the premises listed for the licensee. Additionally, it would allow for the 3PL to furnish dangerous drugs or devices to an authorized person or agent of said person at the 3PL location if specific parameters are met. Those parameters permit the 3PL to use this method only when (1) the identity and authorization of the recipient is established and (2) the method of receipt is only to meet the immediate need of a patient of the authorized person. These parameters ensure that the identity of the recipient is validated and that an unauthorized individual is not receiving the dangerous drugs or devices. Additionally, restricting the quantity that can be picked up at the 3PL facility reduces the quantity susceptible to diversion in transit and maintains a secure chain of

custody. The subsection will specify that 3PLs may provide dangerous drugs or devices to a hospital pharmacy receiving area if authorized personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or dangerous devices actually received. Finally, subsection (c) specifies the requirement of the authorized person to notify the 3PL should there be a discrepancy with the dangerous drugs or devices by the next business day. By ensuring the delivery location matches the authority, it makes it more likely that the drugs will not be diverted or stolen and delivered to people without a lawful prescription or who do not know how to handle the drugs to maintain their safety and efficacy. By ensuring the individuals receiving the drugs are affiliated with the person authorized to receive the drugs, the chain of custody of drugs remains secure. Receiving areas at hospitals must timely sign and identify what they received so that drugs stay secure and are not diverted or stolen. They must report discrepancies within one business day to readily identify any problems so that it can be corrected as soon as possible.

Subsection (d) will specify from whom a 3PL may accept payment, and extend credit to, for the purchase of dangerous drugs or devices. This again ensures the distributor knows who the drugs are being given to, that the person may lawfully obtain them, and creates a record that will dissuade a distributor from ignoring inconsistencies in a transaction in favor of a profit. This is one more way to prevent the drugs from getting to people without a prescription, or from being mishandled and therefore damaged and less safe, before the patient receives them. Additionally, a typographical error was corrected to change the term “mermit” to “permit”.

Subsection (e) will specify the retention of records for dangerous drugs or devices furnished by the 3PL. These records are to be maintained by both the authorized person and the 3PL. These records are currently maintained by the authorized person and the manufacturer or wholesaler. This change will require each of the existing requirements that apply to a manufacturer or wholesaler, to now apply to 3PLs. It will also make them easier to inspect. Specifically, the regulation will require the 3PL to maintain records for three years from when they were made, and the records must be made available for inspection during business hours. These requirements enable the board to trace and track each drug for three years. The three-year period for record keeping is a reasonable period given the time it might take to discover a problem at the consumer level and trace it back to its source(s) and to determine what, if any, problem occurred. The time period also mirrors other record keeping retention requirements created by the board, including in pharmacies, making it easier to implement for the board and its licensees.

Additionally, the Note is updated to add a reference to B&P sections 4025, 4105, and 4165 in compliance with section 11346.2(a)(2) of the Government Code.

Underlying Data

1. Assembly Bill 2605 (Bonilla, Statutes of 2014, Chapter 507).

2. Federal Food, Drug, and Cosmetic Act (Drug Quality and Security Act) https://www.gpo.gov/fdsys/pkg/BILLS-113hr3204enr/pdf/BILLS-113hr3204enr.pdf
3. 21 USC Chapter 9, Subchapter V, Part H: Pharmaceutical Distribution Supply Chain http://uscode.house.gov/browse/prelim@title21/chapter9/subchapter5/partH&edition=prelim
4. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held January 10, 2014 (Materials: Agenda Item I(b) Pages 1-6 plus Attachments 1 and 2, Minutes: Pages 1-6).
5. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held January 29-30, 2014 (Materials: Agenda Item XV(b) Pages 1-6 plus Attachments 2 and 3, Minutes: Pages 1, 33-36).
6. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held April 23-24, 2014 (Materials: Agenda Item VIII Pages 1-3 plus Attachment 2, Minutes: Pages 1 and 9).
7. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held July 30-31, 2014 (Materials: Agenda Item XI Pages 1-3 plus Attachment 1, Minutes: Pages 1, 15-16).
8. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held October 28-29, 2014 (Materials: Agenda Item V Pages 1-2 plus Attachment 1, Minutes: Pages 1and 4).
9. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held December 17, 2014 (Materials: Agenda Item II(f) and II(k) Pages 1,8-10 plus Attachments 6 and 10, Minutes: Pages 1,13-14,17-18)
10. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held January 27-28, 2015 (Materials: Agenda Item XIII(k) Pages 1 and 11 plus Attachment 10, Minutes: Pages 1, 45-46).
11. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held March 26, 2015 (Materials: Agenda Item II(h) Pages 1 and 8 plus Attachment 7, Minutes: Pages 1,16-18)
12. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held April 21-22, 2015 (Materials: Agenda Item XIII(h) Pages 1,10-11 plus Attachment 8, Minutes: Pages 1 and 16).
13. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held July 27-29, 2015 (Materials: Agenda Item X(f) Pages 1 and 10 plus Attachment 6, Minutes: Pages 1, 15-16).
14. Relevant Meeting Materials and Minutes from Board of Pharmacy Committee Meeting held September 27, 2016 (Materials: Agenda Item 6, Pages 1 and 5 plus Attachment 6, Minutes: Pages 1, 10-14).
15. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held October 26-27, 2016 (Materials: Agenda Item X(f) Pages 1 and 10 plus Attachment 6, Excerpt from Meeting Minutes).

Business Impact

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees. This initial determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over several months. Additionally, the proposed regulation applies the regulatory provisions that apply to wholesalers to third-party logistics providers. Prior to 2014, these entities were licensed as "wholesalers" in California; however, as the result of the Food, Drug, and Cosmetic Act, the board can no longer license these entities as wholesalers.

Economic Impact Assessment

The board concludes that this regulatory proposal will have the following effects:

(1) It is unlikely that the proposal will create or eliminate any jobs within California;
(2) It is unlikely that the proposal will create new, or eliminate existing, businesses in California;
(3) It is unlikely that the proposal will expand businesses currently doing businesses within the state

The board determined that it is unlikely that this regulatory proposal will impact jobs or businesses. This proposal establishes the regulatory expectations for 3PLs, who were previously licensed as drug wholesalers. The regulations expressly make the regulatory oversight of 3PLs consistent with the standards for wholesalers. As 3PLs were previously licensed as wholesalers, the board anticipates that they are already in compliance with the requirements specified within this proposal, as such there will not be an impact to jobs or businesses. Finally, the board determined that requiring wholesalers and 3PLs to comply with the current version of the USP with respect to storage and handling standards would also not impact jobs or businesses. The board anticipates that these entities are already complying with these standards as they are required by both federal and state law.

This regulatory proposal benefits the health and welfare of California residents because the proposed regulation establishes the regulatory requirements for third-party logistics providers. As third-party logistics providers can no longer be licensed as wholesalers, these regulations will ensure that the pharmaceutical drug supply chain is regulated and prescription medication is being safely distributed in California. Under the prior law, these entities were licensed as "wholesalers" in California and overseen by designated representatives. The new licensees are overseen by designated representative-3PLs, who have similar training and education requirements.

This regulatory proposal does not affect worker safety because the proposed regulation affects drug distribution practices between businesses, for the security of the drug supply and the benefit of consumers, but does not specify working conditions.

The regulatory proposal does not affect the state's environment. The proposed regulation establishes the requirements for drug distributors, but those requirements which should not impact the environment.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. The only alternative considered by the board would be to not amend the regulations to include this new licensing category. The board determined that this alternative was unacceptable because the board's regulations would not provide clear and consistent requirements to the regulated public.