TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED RULEMAKING

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) is proposing to take the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the board at its office not later than July 13, 2020.

The board has not scheduled a public hearing on this proposed action. The board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period.

The board may, after considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as the contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Section 4005 of the Business and Professions Code (B&P) authorizes the board to adopt these regulations. The proposed regulations implement, interpret, and make specific sections 4022.5, 4022.7, 4025, 4043, 4045, 4051, 4053, 4053.1, 4054, 4059, 4059.5, 4080, 4081, 4105, 4120, 4160, 4161, 4161.5, 4163, 4164, 4165, 4304, 4332, and 4342 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

The California State Board of Pharmacy (board) proposes to amend Article 10 and Sections 1780, 1781, 1782, and 1783 of 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 pharmacy law specifies that protection of the public is the highest priority for the board in exercising its licensing, regulatory, and disciplinary functions and generally authorizes the board to adopt and amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy. Additionally, existing law establishes that the board is authorized to issue a wholesale license (B&P section 4160).

Dangerous drugs and dangerous devices are those available by prescription only.

(B&P section 4022.) 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 with similar expectations.

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 recognized 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 other things, B&P sections 4022.7, 4045, 4053.1, 4160, and 4161 to make 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.

In its current form, this proposal will formalize regulatory oversight of 3PLs in a manner consistent with the regulation of drug 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 necessary to prevent the sale of pharmaceutical preparations and 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 version. 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.

Anticipated Benefits of Proposal

This regulatory proposal will benefit the health and welfare of California residents because the proposed regulation will allow the board to maintain the regulatory oversight of 3PLs in a manner consistent with their previous oversight when 3PLs were licensed as drug wholesalers. 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 safely distributes prescription medication in California. Requiring 3PLs to meet minimum qualifications for licensure and operation, thus making it more likely that dangerous drugs will be transported, stored and otherwise handled under appropriate conditions, will allow the board to ensure, that the drug supply chain is safe and that the drugs being distributed to consumers are effective.

By making it clear that the board expects licensees to comply with current USP standards for safe and effective handling of each specific drug, it is making the regulation more current and logical. The board does not expect that licensees would be complying with 1990 standards in 2018.

Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the board has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

Fiscal Impact Estimates

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

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 establishes the regulatory requirements that apply to third-party logistics provider by extending existing regulations. Prior to 2014, these entities were licensed as a “wholesaler” in California; however, as the result of amendments to the Food, Drug, and Cosmetic Act and Pharmacy Law, the board now licenses these entities 3PLs.

Requiring drug distributors to examine all materials both upon receipt and before shipment is also not expected to have a cost impact as it is current industry practice to perform these examinations to ensure accurate receipt and shipment of drugs, and ensure containers have not been damaged or drugs contaminated during shipment or storage.

The updated reference standard is also not expected to have a cost impact. Despite the existing regulation’s current reference, the board anticipates that dangerous drug distributors (manufacturers, wholesalers, and 3PLs) already apply the most recent standards established by USP.

Cost Impact on Representative Private Person or Business:

The board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

Effect on Small Business

While the board does not have nor does it maintain data to define if any of its licensees are a "small business" as defined in Government Code section 11342.610, the board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. The board anticipates that manufacturers, wholesalers and 3PLs are, by their nature, rather large businesses. Additionally, this proposal establishes that the regulatory requirements that apply to wholesalers also apply to 3PLs. Prior to 2014, these entities were considered and licensed as "wholesalers" in California and subject to the same rules; however, as the result of the Federal Food, Drug, and Cosmetic Act, the board can no longer license these entities as wholesalers.

As noted above, the updated reference standard is also not expected to have a cost impact. Despite the existing regulation's current reference, the board anticipates that dangerous drug distributors (manufacturers, wholesalers, and 3PLs) already apply the most recent standards established by USP.

Results of Economic Impact Assessment/Analysis

Impact on Jobs/New Businesses:

The board has determined that it is:

(1) unlikely that this proposal will create jobs within California;
(2) unlikely that this proposal will eliminate jobs within California;
(3) unlikely that this proposal will create new businesses within California;
(4) unlikely that this proposal will eliminate of existing businesses within California;
(5) unlikely that this proposal will expand businesses currently doing business in the State of California.

Benefits of Regulation:

This regulatory proposal will benefit the health and welfare of California residents because the proposed regulation maintains the regulatory oversight of 3PLs in a manner consistent with their previous oversight when 3PLs were licensed as wholesalers. 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 complies with the standards established by the board for other drug distributors for safely

distributing prescription medication in or into California. Requiring 3PLs to meet minimum qualifications for licensure and operation, will allow the board to ensure, that the drug supply chain is safe and that the drugs being distributed to consumers are effective. The proposed regulations do not affect worker safety or the state's environment.

Business Report

The proposal would require a 3PL business to make a report upon request by board staff. The report is necessary for the health, safety, or welfare of the people of the state that the regulation apply to businesses.

Consideration of Alternatives

The board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person.

Availability of Rulemaking File, Including Initial Statement of Reasons, Text of Proposed Regulations, and Information

The board will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the address listed for, and from the person identified as, the contact person below. The rulemaking file currently includes this notice, the proposed text of the regulations, the documents incorporated by reference, the initial statement of reasons, and all the information upon which the proposal is based.

Availability of Modified Text

If the board proposes to substantively modify the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the board adopts the regulations as revised. Requests for copies of any modified regulations may be sent to the contact person below. The board will accept written comments on the modified regulations for 15 days after the date on which they are made available.

Availability of the Final Statement of Reasons

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

Contact Person

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Lori Martinez
Address:	2720 Gateway Oaks Dr., Ste 100 Sacramento, CA 95833
Phone No.:	(916) 518-3078
Fax No.:	(916) 574-8618
E-Mail Address:	Lori.Martinez@dca.ca.gov

The backup contact person is:

Name:	Debbie Damoth
Address:	2720 Gateway Oaks Dr., Ste 100 Sacramento, CA 95833
Phone No.:	(916) 518-3090
Fax No.:	(916) 574-8618
E-Mail Address:	Debbie.Damoth@dca.ca.gov

Website Access

Materials regarding this proposal can be found at the Board of Pharmacy's website: www.pharmacy.ca.gov.