

TITLE 16. BOARD OF PHARMACY

Notice of Proposed Regulatory Action Concerning: Wholesaler Self-Assessments

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 on November 01, 2021.

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 (BPC) authorizes the board to adopt these regulations. The proposed regulations implement, interpret, and make specific sections 4022.5, 4022.7, 4043, 4044.5, 4045, 4053, 4053.1, 4059, 4120, 4160, 4161, 4201, 4301 and 4305.5 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

Existing law requires that a wholesaler and a third-party logistics provider (3PL) be licensed by the California State Board of Pharmacy (board) in order to operate. (BPC sections 4160 and 4161.) There are some distinctions between the two settings although they are subject to the same general requirements. They must designate a designated presentative-in-charge (DRIC) or responsible manager (RM) who is responsible for their compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. (BPC sections 4160(d) and 4160(e)). All wholesalers and 3PLs are subject to extensive state and federal laws and regulations including those governing the scope of practice; prescription and labeling requirements; record keeping requirements, including policies and procedures; cooperating with

inspections; duties related to storage, handling, and security of drugs and devices; duties related to compounding sterile drug products; and duties with respect to notices to the board about certain changes to staff, facilities, and operations.

Existing regulations, California Code of Regulations, title 16 (CCR) section 1784, requires the DRIC of a wholesaler to complete a self-assessment every odd-numbered year, and within 30 days when specific conditions are met. The self-assessment form assists with increasing compliance with federal and state requirements and makes the board inspection process more efficient. The self-assessment form is incorporated by reference within 16 CCR section 1784, so as law and regulations change, the form must be updated through the rulemaking process. This is a time-intensive process and the board has not been able to update the regulation and self-assessment form as frequently as necessary, with the last update being completed in 2014.

One example of this problem is the addition of the 3PL licensing category, which was established in 2014. Previously, the board licensed 3PLs as wholesalers. However, in response to a federal law change in 2013, the board successfully obtained legislation to establish 3PLs as a separate licensing category (Assembly Bill 2605, Bonilla, Chapter 507, Statutes of 2014).

To address this, the board further seeks to more clearly and directly state the requirements of the self-assessment form within regulation. By specifying the requirements in regulation, it will allow future updates to the self-assessment form to be expedited through the streamlined rulemaking process afforded for nonsubstantive changes in Section 100 of CCR (Title 1).

The board proposes to amend Section 1784 of Article 10 of Division 17 of Title 16 of the CCR for the purpose of updating the form incorporated by reference therein (*Wholesaler Dangerous Drugs and Dangerous Devices Self-Assessment (17M-26 Rev. 10/14)*) to include recent changes in law and regulation. Additionally, the proposal will add the requirement for the new licensing category, 3PLs and RMs, to complete the self-assessment, and will more clearly and directly state the requirements of the self-assessment form within regulation.

Anticipated Benefits of the Proposed Regulations

The self-assessment form aids licensees in assessing their compliance with federal and state pharmacy law. This proposal will update the form to include laws and regulations adopted since 2014, and remove any laws and regulations superseded or repealed since 2014. Additionally, this proposal will add the requirement for the RM of the 3PL to complete the self-assessment form. Requiring 3PLs to complete the self-assessment will maintain the same level of oversight as when they were licensed as wholesalers. As the DRIC or RM goes through the biennial process of completing the self-assessment form, they will be made aware of any areas where the wholesaler or 3PL may be out of compliance with laws and regulations. This awareness can increase self-correction and promote compliance with state and federal laws and regulations. This should assist

wholesalers and 3PLs in complying with current law; since the laws are designed for consumer protection, consumer protection will be advanced by the licensee's compliance. This proposal also allows for a streamlined process for updating the self-assessment form as changes to pharmacy law occur, which will provide a more effective and efficient use of board resources, by reducing the workload associated with the rulemaking process.

Evaluation of Consistency and Compatibility with Existing State Regulations

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

Incorporation by Reference

"Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment (17M-26 Rev. 10/14)" which is currently incorporated by reference in the same regulation, is being renamed and revised to "Wholesaler/Third Party Logistics Provider Self-Assessment (17M-26 Rev. 09/18)."

Disclosures Regarding the Proposed Action, Including Fiscal Impacts

The Board has made the following initial determinations:

Mandate on Local Agencies and School Districts: None

Cost to Any Local Agency or School District That Requires Reimbursement Pursuant to Government Code Sections 17500 – 17630: None

Costs/Savings to Any State Agency:

The proposed regulations do not result in a fiscal impact to the state. The board currently requires wholesalers and 3PLs to complete and submit self-assessments, as specified. The regulations do not increase the number of self-assessments to be submitted or require additional board workload or costs from the current process.

Nondiscretionary Costs/Savings to Local Agencies: None

Costs/Savings in Federal Funding to the State: None

Effect on Housing Costs: 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, including the ability of California businesses to compete with businesses in other states.

Cost Impact on Representative Private Person or Business:

The agency is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. The board currently requires wholesalers and 3PLs to complete and submit self-assessments. The proposed regulations do not increase the workload or costs for these licensees to comply.

Effect on Housing Costs: None

Effect on Small Business:

The board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. While the board does not have specific data to determine if its licensees are a “small business” as defined in Government Code section 11342.610, the board anticipates that 3PLs are, by their nature, rather large businesses. The proposal makes the regulatory oversight of 3PLs, previously licensed as wholesalers, consistent with the standards for wholesalers.

Completion of a self-assessment form is required by existing regulation biennially and based on certain events; the completed forms are also required to be maintained. The updates will change some of the questions on the forms, but do not ask significantly more questions, it is therefore not anticipated that the licensee will use more time completing, or more space storing, the self-assessment form. As the requirement to complete and maintain these forms already exists in regulations, this proposal, that updates the form used and places some of the requirements, currently contained only in the form, into regulations will not have an impact on businesses.

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:

The board has determined that this regulatory proposal benefits the health and welfare of California residents and worker safety because the DRICs and RMs in wholesalers and third-party logistics providers both in and outside California will be conducting self-assessments based on current and up-to-date laws, rather than outdated laws, which will make it more likely that they will follow current laws and regulations. When DRICs/RMs are actively engaged in assessing a facility's compliance with current laws and regulations, they are more likely to identify and remedy any violations of pharmacy law. The board believes this periodic review and accountability will result in increased consumer safety and improve facility operations with respect to employee safety and the state's environment. Additionally, this proposal will allow for a more efficient use of board resources during inspections, as compliance should be better, and in updating the forms for the future. The proposal does not impact the state's environment.

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 during the written comment period.

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

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

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 Drive, Ste. 100 Sacramento, CA 95833
Phone No.:	(916) 518-3078
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E-Mail Address:	Lori.Martinez@dca.ca.gov

The backup contact person is:

Name:	Debbie Damoth
Address:	2720 Gateway Oaks Drive, Ste. 100 Sacramento, CA 95833
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Website Access

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