

**TITLE 16. BOARD OF PHARMACY**  
**NOTICE OF PROPOSED ACTION CONCERNING**  
**SELF-ASSESSMENTS FOR PHARMACIES**

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 **by Monday, December 27, 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: Pursuant to the authority vested by section 4005 and 4127 of the Business and Professions Code to implement, interpret, and make specific sections 4005, 4019, 4021, 4022, 4029, 4030, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4081, 4101, 4105, 4110, 4113, 4115, 4119, 4120, 4127, 4201, 4301, 4305, 4330, 4332 and 4333, of the Business and Professions Code, the Board is proposing to amend Section 1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations.

**Informative Digest/Policy Statement Overview**

Existing law requires that a pharmacy be licensed by the Board in order to operate. (Business and Professions Code (BPC) section 4110.) There are various types of pharmacies, including hospital pharmacies and community pharmacies. (See BPC sections 4029 and 4037.) There are some distinctions between settings, but all pharmacies are subject to some general requirements. Each pharmacy must designate a pharmacist-in-charge (PIC), who is responsible for the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. (BPC section 4113.) All pharmacies are subject to extensive state and federal laws and

regulations including those governing scope of practice for pharmacists and other personnel working in the pharmacy; 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 regarding certain changes to staff, facilities, and operations.

Existing regulations, California Code of Regulations, title 16 (CCR), section 1715, requires the PIC of a pharmacy licensed pursuant to BPC section 4029 or 4037 to complete a self-assessment using a designated form every odd numbered year and when certain changes occur that affect the location, organization, or management of the pharmacy. The self-assessment form is incorporated by reference within 16 CCR section 1715, 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.

The Board proposes to amend Section 1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR) to update the self-assessment forms that pharmacists-in-charge must complete (*Community Pharmacy Self-Assessment* [17M-12], *Hospital Outpatient Pharmacy Self-Assessment* [17M-13] and *Hospital Pharmacy Self-Assessment* [17M-14]) to reflect current laws and regulations. In addition, the Board proposes to incorporate many of the form's requirements into the regulation text itself.

The forms incorporated by reference are being updated to include questions to be answered by the pharmacy about the pharmacy's compliance with specific laws and regulations. The self-assessment forms assist the pharmacy's PIC to increase the pharmacy's compliance with federal and state requirements and also make the pharmacy inspection process more meaningful by providing relevant information from the PICs to the Board inspectors.

Existing law specifies that protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount. Existing law generally authorizes the Board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy.

### **Anticipated Benefits of the Proposed Regulations**

This proposal will update the forms incorporated by reference to reflect current laws and regulations. Therefore, the pharmacists-in-charge (PIC) of pharmacies throughout California will be conducting self-assessments based on current and up-to-date laws, rather than inaccurate references to laws on outdated self-assessment forms. This should assist pharmacies in complying with current law; since the laws are designed for consumer protection, consumer protection will be advanced by pharmacies' 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 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.

### **Incorporation by Reference**

For the purposes amending Section 1715 of Article 2 of Division 17 of Title 16 of the CCR, the following forms are incorporated by reference:

- Community Pharmacy Self-Assessment/Hospital Outpatient Self-Assessment (Form 17M-13, Rev. 07/18)
- Hospital Pharmacy Self-Assessment (Form 17M-14, Rev. 07/18)

### **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 pharmacies to complete and submit self-assessments, as specified. The regulation does 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 because, as discussed below under Small Business Effect, the requirement to complete these self-assessments already exists and these regulations are updating the statutes and regulations listed within the self-assessment forms incorporated by reference. Because the Board currently requires pharmacies to complete and submit self-assessments. The proposed regulations do not increase the workload or costs for these licensees to comply.

**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 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, as discussed below. While the Board does not have specific data to determine if its pharmacy licensees are a “small business” as defined in Government Code section 11342.610, a smaller community retail pharmacy may fall into that definition.

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 pharmacy 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 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 regulatory proposal will benefit the health and welfare of California residents because pharmacies who provide drugs to California consumers will be conducting self-assessments based on current and up-to-date laws, rather than outdated laws, which will make it more likely that pharmacies will follow current laws and regulations. When PICs are actively engaged in reviewing the current laws and regulations, they are more likely to identify and remedy any violations of pharmacy law and regulations, which exist primarily for consumer safety. Additionally, this proposal will allow for a more efficient use of Board resources during pharmacy inspections, since pharmacy 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: (1) would be more effective in carrying out the purpose for which the action is proposed, (2) would be as effective and less burdensome to affected private persons than the proposed action, or (3) 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 is invited to present statements or arguments in writing with respect to alternatives during the 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**

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  
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### **Website Access**

Materials regarding this proposal can be found at the Board of Pharmacy's website:  
[https://www.pharmacy.ca.gov/laws\\_regs/pending\\_regs.shtml](https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml).