

DEPARTMENT OF CONSUMER AFFAIRS  
TITLE 16. BOARD OF PHARMACY

**NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:  
SELF-ASSESSMENTS FORMS  
(Pharmacy, Hospital, Wholesaler)**

**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.

**PUBLIC HEARING**

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. A hearing may be requested by making such request in writing, addressed to the individuals listed under "Contact Person" in this notice.

**WRITTEN COMMENT PERIOD**

Written comments relevant to the action proposed, 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 no later than February 24, 2025, or must be received by the Board at the hearing, should one be scheduled.

Authority and Reference: Pursuant to the authority vested by sections 4005 and 4127 of the Business and Professions Code (BPC), and to implement, interpret, and make specific BPC sections 4005, 4019, 4021, 4022, 4022.5, 4022.7, 4029, 4030, 4036, 4037, 4038, 4040, 4043, 4044.5, 4045, 4050, 4051, 4052, 4053, 4053.1, 4059, 4070, 4081, 4101, 4105, 4110, 4113, 4115, 4119, 4120, 4127, 4160, 4161, 4201, 4301, 4305, 4305.5, 4330, 4332, and 4333, of the Business and Professions Code, the Board is proposing to amend sections 1715 of Article 2 and 1784 of Article 10 of Division 17 of Title 16 of the California Code of Regulations (CCR).

**Informative Digest/Policy Statement Overview**

Existing law requires that pharmacies be licensed by the Board in order to operate. (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 at 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 laws and regulations change, the form must be updated through the rulemaking process.

Existing law requires that wholesalers and third-party logistics providers (3PL) be licensed by the Board in order to operate (or operate into the state, as is the case for nonresident wholesalers and 3PLs). (BPC sections 4160 and 4161.) There are some distinctions between wholesalers and 3PLs, although these businesses are subject to the same general requirements. Each business must designate a designated representative-in-charge (DRIC) or responsible manager (RM) who is responsible for ensuring the business' 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 at 16 CCR section 1784, require the DRIC of a wholesaler or RM of a third-party logistics provider to complete a self-assessment every odd-numbered year, and within 30 days of specific occurrences. The self-assessment form assists with ensuring (and increasing, when necessary) 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 laws and regulations change, this form must also be updated through the rulemaking process.

The Board proposes amending section 1715 of Article 2 of Division 17 of Title 16 of the CCR, and the self-assessment forms incorporated by reference therein (*Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment* [17M-13] and *Hospital Pharmacy Self-Assessment* [17M-14]) to reflect current laws and regulations. Additionally, the Board proposes amending section 1784 of Article 10 of Division 17 of Title 16 of the CCR, and the self-assessment form incorporated by reference therein (*Wholesaler/Third-Party Logistics Provider Self-Assessment* [17M-26]) following recent changes in laws and regulations.

The forms incorporated by reference are being updated to include questions the PIC, DRIC, or RM will answer about the respective facility's compliance with specific laws and

regulations. The self-assessment forms assist the PIC, DRIC, or RM in ensuring that the licensed facility is operating in compliance with federal and state requirements. Having PICs, DRICs, and RMs complete these self-assessment forms also make the Board inspection process more meaningful and efficient because it informs the Board inspectors of each facility's compliance and any corrective measures (to be) implemented.

### **Anticipated Benefits of the Proposal**

Protection of the public is the Board's highest priority in exercising its licensing, regulatory, and disciplinary functions. This regulatory proposal benefits the health and welfare of California residents, and worker safety. This proposal does not impact the state's environment.

This proposal will update the self-assessment forms incorporated by reference so that the forms reflect current laws and regulations. Therefore, the PICs of pharmacies, DRICs of wholesalers, and RMs of third-party logistics providers throughout California will conduct self-assessments using up-to-date forms, thereby ensuring compliance with current laws and regulations. Ensuring facilities comply with current laws and regulations will better protect consumers, as it will create accountability and improve facility operations. This will benefit the health and welfare of California consumers, as well as employee safety. The proposal does not impact the state's environment.

### **Evaluation of Consistency and Compatibility with Existing State Regulations**

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

### **Incorporation by Reference**

For the purpose of 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. 1/24)
- Hospital Pharmacy Self-Assessment (Form 17M-14, Rev. 1/24)

For the purpose of amending section 1784 of Article 10 of Division 17 of Title 16 of the CCR, the following form is incorporated by reference:

- Wholesaler/Third Party Logistics Provider Self-Assessment (17M-26, Rev. 1/24)

## **Disclosures Regarding the Proposed Action, Including Fiscal Impacts**

### **FISCAL IMPACT ESTIMATES**

**Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State:** The proposed regulations do not result in a fiscal impact to the state. The Board currently requires PICs, DRICs, and RMs to complete self-assessments, as specified. The regulation does not increase the number of self-assessments reviewed or require additional Board workload or costs from the current process.

Any workload to update the forms was completed within normal business operations and without incurring additional costs.

The regulations do not result in costs or savings in federal funding to the state.

**Nondiscretionary Costs/Savings to Local Agencies:** None

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

**Mandate on Local Agencies and School Districts:** None

**Significant Effect on Housing Costs:** None

### **Business Impact Estimates:**

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.

As discussed below under Effect of Small Business, the requirement to complete these self-assessments already exists, and this regulatory proposal updates the statutes and regulations listed within the self-assessment forms (incorporated by reference in the regulations) so that the forms are up-to-date. Because the Board currently requires PICs, DRICs, and RMs to complete the 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.

## **Results of Economic Impact Assessment/Analysis:**

### **Impact on Jobs/New Businesses:**

The Board has determined that this proposal will not:

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

The Board determined that this proposal will not create or eliminate jobs or businesses. This proposal will update the self-assessment forms to include current laws and regulations, which will help PICs, DRICs, and RMs ensure that facilities are operating in compliance with state and federal laws and regulations. This will benefit the health and welfare of California residents, and worker safety. The proposal does not impact the state's environment.

### **Benefits of Regulation:**

This regulatory proposal benefits the health and welfare of California residents, and worker safety. This proposal does not impact the state's environment.

This proposal will update the self-assessment forms incorporated by reference, so that the forms reflect current laws and regulations. Therefore, the PICs of pharmacies, DRICs of wholesalers, and RMs of third-party logistics providers throughout California will conduct self-assessments using up-to-date forms, thereby ensuring compliance with current laws and regulations. Ensuring facilities comply with current laws and regulations will better protect consumers, as it will create accountability and improve facility operations. This will benefit the health and welfare of California consumers, as well as employee safety. The proposal does not impact the state's environment.

### **Business Reporting Requirements**

Businesses will not be required to submit any additional reports/forms. Businesses are already required to complete and maintain (for three years after completion) these self-assessment forms and make them available to the Board during inspections, as is necessary for the health, safety, and welfare of California consumers.

### **Effect on Small Business:**

The Board has determined that the proposed regulatory action will not have a significant adverse economic impact directly affecting small businesses. While the Board does not have specific data to determine if any of 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.

Existing regulations require the self-assessment forms to be completed biennially and when certain events occur; additionally, the completed forms are to be maintained for three years after they are completed, and are to be made available to the Board during inspections. This regulatory proposal updates these self-assessment forms. Some of the questions on the forms will change to keep the questions up-to-date with current laws and regulations, but the forms will not have significantly more questions. It is therefore not anticipated that pharmacies will use more time completing, or more space storing, the self-assessment forms. Businesses are already required—in regulation—to complete and maintain these forms, so this proposal will not have an impact on businesses.

### **CONSIDERATION OF ALTERNATIVES**

In accordance with Government Code section 11346.5(a)(13), 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 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 submit comments—relevant to the above determinations—in writing, at the address listed below for the Contact Persons, during the written comment period, or at the hearing if one is scheduled or requested.

### **AVAILABILITY OF INITIAL STATEMENT OF REASONS AND RULEMAKING FILE**

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information upon which the proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice.

### **TEXT OF PROPOSAL**

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website at [http://www.pharmacy.ca.gov/laws\\_regs/pending\\_regs.shtml](http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml).

### **AVAILABILITY OF CHANGED OR MODIFIED TEXT**

After considering all timely and relevant comments, the Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as

described below or may modify such proposals 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, with the modifications clearly indicated, will be available for review and written comment for 15 days prior to its adoption from the persons designated in this Notice as the Contact Persons and will be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

### **AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE**

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 Persons named below or by accessing the website listed below.

#### **Contact Persons**

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

Name: Lori Martinez  
Address: Board of Pharmacy  
2720 Gateway Oaks Drive, Ste. 100  
Sacramento, CA 95833  
Phone No.: (916) 518-3100  
Fax No.: (916) 574-8618  
E-Mail Address: PharmacyRulemaking@dca.ca.gov

The backup contact person is:

Name: Julie Ansel  
Address: Board of Pharmacy  
2720 Gateway Oaks Drive, Ste. 100  
Sacramento, CA 95833  
Phone No.: (916) 518-3100  
Fax No.: (916) 574-8618  
E-Mail Address: PharmacyRulemaking@dca.ca.gov

### **AVAILABILITY OF DOCUMENTS ON THE INTERNET**

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations with modifications noted, as well as the Final Statement of Reasons when completed, and modified text, if any, can be accessed through the Board of Pharmacy's website at: [https://www.pharmacy.ca.gov/laws\\_regs/pending\\_regs.shtml](https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml).