

## TITLE 16. BOARD OF PHARMACY

### NOTICE OF PROPOSED REGULATORY ACTION CONCERNING: NOTIFICATION OF TEMPORARY CLOSURE

**NOTICE IS HEREBY GIVEN** that the California State Board of Pharmacy (board) proposes taking 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 December 13, 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 that person's 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 this regulation. The proposed regulation implements, interprets, and makes specific sections 4032 and 4312 of the BPC.

#### **Informative Digest/Policy Statement Overview**

The board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, hospital pharmacies, clinics, wholesalers, third-party logistics providers, and outsourcing facilities. The board's mandate and its mission is to protect the public (BPC §4001.1).

Existing pharmacy law does not establish a requirement for pharmacy licensees to notify the board of a temporary closure of a licensed facility. For the past several years, typically in response to declared disasters, but also in response to construction issues, board licensed facilities must temporarily close. More recently, regrettably, a significant number of pharmacies were damaged or destroyed due to civil unrest. In many cases the damages occurred to several pharmacies in the same region. This can interrupt patient care by limiting access to prescription medication.

This proposal will require each permit holder to notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. Further, it specifies that the closure status will be public information.

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

Requiring notifications will ensure consistent reporting requirements for businesses licensed by the board and will allow the board to plan inspection activity and ensure licensees, other healthcare practitioners, and consumers have current operational status information when searching for a licensed facility on the board's website. Additionally, the notification will allow the board to maintain a more accurate operational history of its licensees.

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

While 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.

### **Fiscal Impact and Related Estimates**

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: The proposed regulations may result in an increase in reports of facility closures to the board. In 2020, the board received approximately 300 reports of closures.

According to the board, a Staff Services Manager I, Specialist (SSMI) typically takes ten minutes to process each report of closure and ten minutes for each reopening at a cost of approximately \$15 per report or \$30 total (closing and opening), which results in total costs of approximately \$9,000 per year for 300 closures per year.

The proposed regulation will not have an impact on federal funding to the State or other State agencies.

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 determined that the proposed regulatory action will have no significant statewide adverse economic impact directly affecting businesses and/or employees, including the ability of California businesses to compete with businesses in other states. 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 in numerous Board and committee meetings. Additionally, the board determined that the notification can be as simple as an email or a statement faxed or mailed to the board once the facility has been closed for three consecutive days. As a result, no additional costs are anticipated for businesses operating in the state.

**Cost Impact on Representative Private Person or Business:**

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

**Effect on Housing Costs:** None

**Effect on Small Business:**

While the board does not have nor does it maintain data to determine if any of its licensees (pharmacies and clinics) are a “small business,” as defined in Government Code section 11342.610, the board has made an initial determination that the proposed regulatory action will not have a significant adverse economic impact directly affecting small businesses. The board determined that the notification can be as simple as an email or a statement faxed or mailed to the board once the facility has been closed for three consecutive days. As a result, no additional costs are anticipated for businesses.

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

**Impact on Jobs/New Businesses:**

The board concludes that:

- (1) this proposal will not create jobs within California;
- (2) this proposal will not eliminate jobs within California;
- (3) this proposal will not create new businesses within California;
- (4) this proposal will not eliminate existing businesses within California;
- (5) this proposal will not expand businesses currently doing business in the State of California.

**Benefits of Regulation:**

The board has determined that this regulatory proposal may impact the health and welfare of California residents. The proposal establishes the requirement for licensees to notify the board when the facility will be closed for more than three consecutive days. This will be public information, which California residents can obtain from our website. This can help ensure that California residents can find an open licensed facility to obtain patient care. The proposal will not impact worker safety or the state’s environment.

## **Business Reporting Requirement**

The board finds that it 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 that 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.

## **Initial Statement of Reasons and Information**

The board has prepared an Initial Statement of Reasons for the proposed action and has available all the information upon which the proposal is based.

## **Text of Proposal**

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of the Initial Statement of Reasons, 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>.

## **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 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  
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 Drive, 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:  
[https://www.pharmacy.ca.gov/laws\\_reqs/pending\\_reqs.shtml](https://www.pharmacy.ca.gov/laws_reqs/pending_reqs.shtml).