

## TITLE 16. BOARD OF PHARMACY

### NOTICE OF PROPOSED REGULATORY ACTION CONCERNING: NOTICE TO CONSUMERS

**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 April 10, 2023.

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 holding a hearing if requested and 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: Sections 4005 and 4122 of the Business and Professions Code (BPC) authorize the board to adopt this regulation. The proposed regulation implements, interprets, and makes specific sections 733, 4005, 4076.5, and 4122 of the Business and Professions Code.

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

The board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, interns, and pharmacy technicians. The board's mandate and its mission are to protect the public (BPC 4001.1).

Existing pharmacy law specifies in general terms that a licentiate cannot obstruct a patient from obtaining a prescription drug (BPC 733). Further, this section provides that a notice to consumers shall include a statement that describes the rights established. Additionally, existing law requires every pharmacy to prominently post in a conspicuous place and readable by prescription drug consumers a notice that is produced and provided by the board (BPC 4122). The section also provides that a written receipt containing the same information may be provided in lieu of the posting of the notice. The board currently produces and distributes a "Notice to Consumers" poster (Notice)

and a “Point to your language” poster (Language) – the contents of which are specified in 16 California Code of Regulations (CCR) section 1707.6. The notices are produced and printed by the board and are distributed to pharmacies at no cost. The notices are also available on the board’s website in a portable document format (PDF) for utilization.

This proposal will revise the Notice and Language posters as part of the board’s consumer awareness initiative. The proposal will require the Notice to include a QR code that links consumers to a translation of the Notice in the top 16 languages spoken by Californians with limited English proficiency, as determined by the U.S. Department of Health and Human Services and the California Department of Health Care Services. Additionally, it will require pharmacies to place the Notice poster (or to display the notice to consumers on a video screen) in places that are conspicuous and physically accessible so consumers can scan a QR code to obtain a language translation of the notice when needed. Further, the proposal will require the Language notice to be printed in the top 16 languages as determined by the U.S. Department of Health and Human Services and the California Department of Health Care Services. Finally, the proposal will require pharmacies to either post or provide on the patient’s written receipt a statement describing patients’ rights per BPC 733 and BPC 4122.

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

The broad objectives of the regulation are reflected in the board’s mission statement, which is to “protect and promote the health and safety of Californians by pursuing the highest quality of pharmacist’s care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement.” The board seeks to educate consumers about the practice of pharmacy through a consumer education campaign of consumer-facing materials to improve consumers’ awareness of their rights and how to take their medications. The proposed action, as part of this consumer education campaign, will benefit consumers by promoting consumer awareness. This awareness will improve the health and welfare of California residents by encouraging consumers to discuss medications with their pharmacists, providing education on the importance of complying with prescription treatment regimens, and ensuring that consumers are better informed about their drug therapy and overall health.

### **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. These amendments make state law more consistent with federal law, which requires that taglines be posted in at least the top 15 languages (plus English) for individuals with limited spoken English.

## **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 board estimates this proposal could result in a fiscal impact to the board of approximately \$15,000 - \$20,000 to publish and distribute the revised posters to pharmacies. This is an important consumer education tool and the board will absorb these costs within its existing resources.

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 the initial determination that the proposed regulations will not have a significant statewide adverse economic impact directly affecting businesses including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation does not impose new requirements on licensees; rather, the proposal modifies the existing Notice and Language posters that are produced by the board and distributed to licensed pharmacies at no cost to a pharmacy. Under existing law, as an alternative to posting the posters provided by the board, pharmacies may utilize alternative means to display the required posters in an alternative format, display methodology or via video screen, as specified; however, this alternative format is not mandated. The proposal does require that pharmacies utilizing the alternative means to display the required poster must include a QR code so that consumers can utilize the QR translation technology. The inclusion of the QR code will not have a significant impact as the QR graphic will be printed on the posters by the board and can be embedded into the electronic file.

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 the proposed action as the board prints and provides the posters to licensees at no cost to the business.

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 affect small businesses. Although the proposed regulation will directly affect businesses statewide, which may include small businesses, the board does not anticipate any adverse economic impact as the board prints and provides the posters to licensees at no cost to the business.

### **Business Reporting Requirements**

The regulatory action does not require businesses to file a report with the board.

### **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; and,
- (5) this proposal will not expand businesses currently doing business in the State of California.

The board determined that this proposal will not cause any of the foregoing because these changes are not of sufficient magnitude to create those impacts. This proposal does not impose new requirements on licensees; rather, the proposal modifies the existing Notice and Language posters that are produced by the board and distributed to licensed pharmacies at no cost to pharmacies.

Additionally, the board determined that this regulatory proposal will not impact worker safety or the state's environment as these changes do not involve worker safety or the environment. The board has determined that this regulatory proposal benefits the health and welfare of California residents by educating consumers about their rights and fostering a quality dialogue between pharmacists and patients (or the patient's agent).

### **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 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 Text of Proposal and Initial Statement of Reasons**

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. Copies of the exact language of the proposed regulations, 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: Usha Mutschler  
Address: 2720 Gateway Oaks Drive, Ste. 100  
Sacramento, CA 95833  
Phone No.: (916) 518-3077  
Fax No.: (916) 574-8618  
E-Mail Address: PharmacyRulemaking@dca.ca.gov

The backup contact person is:

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: PharmacyRulemaking@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\\_regs/pending\\_regs.shtml](https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml).