

## **TITLE 16. BOARD OF PHARMACY**

NOTICE IS HEREBY GIVEN that the Board of Pharmacy (Board) is proposing to take the action described in the Informative Digest. 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 not later than 5:00 p.m. on June 6, 2016.

The Board does not intend to conduct a Regulation Hearing on the matter, unless requested. Any interested person may submit a written request for a public hearing no later than 15 days prior to the close of the written comment period.

The Board, upon its own motion or at the instance 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 will be available for 15 days prior to its adoption from the person designated in this Notice as 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 of the Business and Professions Code, and to implement, interpret or make specific sections 4003, 4076.5, and 4311 of the Business and Professions Code, the Board of Pharmacy is proposing to amend section 1703 of Article 1 of Division 17 of Title 16 of the California Code of Regulations as follows:

### **INFORMATIVE DIGEST**

#### **A. Informative Digest**

The Board of Pharmacy (Board) proposes to amend section 1703 of Article 1 of Division 17 of Title 16 of the California Code of Regulations (CCR) and to update Authority and Reference citations for the purpose of amending the Board's regulations specific to the delegation of certain functions to the executive officer.

#### **B. Policy Statement Overview**

Existing regulation at section 1703 sets forth certain functions delegated and conferred upon the executive officer including filing accusations, setting cases for hearing, and issuing notices of suspension. This proposed regulatory change would update the regulation to increase the functions delegated to the executive officer to include the authority to make changes to its regulation without regulatory effect and to approve requests for waivers from the requirements for patient-centered labels pursuant to Business and Professions Code (B&P) section 4076.5(e).

Title 1, CCR section 100 specifies the requirements for regulatory changes that are without regulatory effect also known as “Section 100” changes. Currently, the board must vote to authorize or delegate the authorization of the adoption of these changes. This regulatory proposal would delegate to the executive officer the authority to adopt regulation changes that are deemed to be without regulatory effect without requiring additional motion by the board to vote to adopt the language.

B&P section 4076.5 specifies statutory requirements for patient-centered labels and contains a provision that allows the Board to provide a waiver from the requirements in certain circumstances. Currently, the process for a licensee requesting the waiver is to come before the Communication and Public Education Committee for approval of the waiver which is then ratified by the full board. It has been determined that approval of waivers can be performed at the board staff level as the requirements for waiver are clearly outlined in statute; therefore, approval by the board has been deemed unnecessary. This proposed change would delegate authority to approve waivers to the executive officer provided the licensee has demonstrated meeting the required elements of subdivision (e) of that section.

#### Anticipated Benefits of Proposal

The objective of this proposal is to enhance the efficiency of board operations thus adding to consumer protection. Delegating to the executive officer the authority to make changes without regulatory effect will shorten the timeframe for initiation of the rulemaking process for “Section 100” changes allowing these changes to become effective in a timely manner. In addition, delegating to the executive officer the authority to approve requests for waivers will facilitate and expedite review and approval of waiver requests as well as lesson agenda during board meetings and result in a minor savings of board members’ time.

#### C. Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the Board of Pharmacy 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.

### **FISCAL IMPACT ESTIMATES**

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

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 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.

The Board has determined that only the following types of businesses may be affected by the proposal:

For facility licensed by the Board that is requesting waiver from the patient-centered labels requirement, that business may experience minor cost avoidance as well as time saving as this proposal would allow this decision to be made by the executive officer. They would not have to wait to have the approval of the waiver approved by Board and this would ensure timely approval of waiver requests for eligible licensees that have demonstrated meeting the required elements of B&P section 4076.5(e).

Cost Impact on Representative Private Person or Business:

The board is not aware of any cost impacts that a representative private person would necessarily incur in reasonable compliance with the proposed action. This regulation proposal applies to the administrative operations of the board as well as facilities licensed by the board that dispense prescription medicine to patient in California; not individual licensees.

For facility licensed by the Board that is requesting waiver from the patient-centered labels requirement, that business may experience minor cost avoidance as well as time saving as this proposal would allow this decision to be made by the executive officer. They would not have to wait to have the approval of the waiver approved by board and this would ensure timely approval of waiver requests for eligible licensees that have demonstrated meeting the required elements of B&P section 4076.5(e).

Effect on Housing Costs: None

**EFFECT ON SMALL BUSINESS:**

The board has determined that the proposed regulations would not have a significant effect on small business. This initial determination is based on the fact that the

proposed regulatory changes are administrative in nature to ensure efficiency of board operations.

## **RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:**

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

The board has determined that this regulatory proposal will not have any impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California. This initial determination is based on the fact that the proposed regulatory changes are administrative in nature to ensure efficiency of board operations.

### **Benefits of Regulation:**

The Board of Pharmacy has determined that this regulatory proposal will have the following benefits to health and welfare of California residents, worker safety, and state's environment:

This proposal will enhance the efficiency of the board's operations thus adding to consumer protection. Delegating to the executive officer the authority to make changes without regulatory effect will shorten the timeframe for initiation of the rulemaking process for "Section 100" changes allowing these changes to become effective in a timely manner. In addition, delegating to the executive officer the authority to approve requests for waivers will facilitate and expedite review and approval of waiver requests as well as lesson agenda during board meetings and result in a minor savings of board members' time.

## **CONSIDERATION OF ALTERNATIVES**

The Board of Pharmacy 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.

## **INITIAL STATEMENT OF REASONS AND INFORMATION**

The Board of Pharmacy has prepared an initial statement of the 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 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's website <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:	Katrina Trinchera
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7946
Fax No.:	(916) 574-8618
E-Mail Address:	Katrina.Small@dca.ca.gov

The backup contact person is:

Name:	Anne Sodergren
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7910
Fax No.:	(916) 574-8618
E-Mail Address:	Anne.Sodergren@dca.ca.gov

Website Access: Materials regarding this proposal can be found at the Board of Pharmacy's website: [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).