

## TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy 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 of Pharmacy at its office not later than 5:00 p.m. on November 9, 2015.

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 of Pharmacy, 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 Sections 4005 of the Business and Professions Code to implement, interpret, and make specific section 4022 and 4074 of the Business and Professions Code, the Board of Pharmacy is proposing to amend Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

### INFORMATIVE DIGEST

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

The Board of Pharmacy (Board) proposes to amend Section 1744 of Article 5 of Division 17 of Title 16 of the California Code of Regulations (CCR).

Prior to July 1, 2014, Pharmacy Law required a pharmacist to inform a patient orally or in writing of the harmful effects of a drug: (1) if the drug posed a substantial risk to the person consuming the drug, when taken in combination with alcohol, or if the drug could impair a person's ability to drive a motor vehicle, and (2) the drug was determined by the Board of Pharmacy to be a drug or drug type for which the warning shall be given.

Assembly Bill 1136 (Levine, Chapter 304, Statutes of 2013), amended Business and Professions Code (B&P) section 4074 to require a pharmacist on or after July 1, 2014, to include a written label on a prescription drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel, if in the pharmacist's professional judgment, the drug may impair a person's ability to operate a vehicle or vessel. The required label may be printed on an auxiliary label that is affixed to the prescription container.

Existing regulation at CCR Section 1744 provides the specific classes of drugs which trigger a pharmacist's notice to patients where a patient's ability to operate a vehicle (and now a vessel) may be impaired. Additionally, the existing regulation identifies the specific drug classes that

may impair a person's ability to drive a motor vehicle or operate machinery or may have harmful effects if taken in combination with alcohol.

The proposed regulation amends CCR section 1744 to include the written label requirement. Additionally, the drug classes requiring the written label are being amended and updated based on discussions with industry professionals. The drug classes identified in this regulation have not been amended this 1983. As new drug classes have been established that may impair a person's ability to drive a motor vehicle or operate machinery or may have harmful effects if taken in combination with alcohol, it is necessary to amend and update the regulation.

B&P section 4001.1, specifies that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

B&P section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

B&P section 4022 generally defines dangerous drugs and dangerous devices.

B&P section 4074 generally authorizes the board to determine the drug or drug type requiring a drug risk warning.

### **Anticipated Benefits of Proposal**

This proposal will increase patient and consumer awareness regarding the potentially dangerous side-effects of certain prescription drugs. The use of a warning label on a prescription medication bottle will serve to remind and educate patients as to the possible adverse side effects of certain prescription drugs and the increased risks associated with consuming alcohol when taking specific drugs. This education will combat the growing epidemic of drugged driving and increase the safety of residents traveling within California and individuals performing work on the roadways.

### **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.

### **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 a determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees. 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. Additionally, existing law, implemented July 1, 2014, requires pharmacists to inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription. The proposed regulation amends the specific drug classes that require those written or oral instructions, based on feedback from industry professionals.

The proposed regulation affects any pharmacy licensed by the Board that dispenses the specific drug classes identified in the proposed text to patients. The Board is not including in its business impact those hospital pharmacies and licensed clinics that dispense prescription drug medications to inpatients, nor does it include licensed correctional facility pharmacies that dispense prescription drug medications to inmates.

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 Housing Costs: None

**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 existing law, implemented July 1, 2014, requires pharmacists to inform a patient orally or in writing of the harmful effects of a drug dispensed by prescription. The proposed regulation amends the specific drug classes that require those written or oral instructions, based on feedback from industry professionals.

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

Impact on Jobs/New Businesses:

The Board has determined that this regulatory proposal will not have a significant 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 pharmacies and pharmacists currently have to comply with these requirements. The proposed text modifies the specific drug classes requiring notice based on feedback from industry professionals.

### Benefits of Regulation:

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents, worker safety, and state's environment because it will increase patient and consumer awareness regarding the potentially dangerous side-effects of certain prescription drugs. The use of a warning label on a prescription medication container will educate patients on the possible adverse side effects of consuming alcohol when taking specific drugs. This education will combat the growing epidemic of drugged driving and increase the safety of residents traveling within California and individuals performing work on the roadways.

### 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 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: Lori Martinez  
Address: 1625 N. Market Blvd., N219  
Sacramento, CA 95834  
Phone No.: (916) 574-7917  
Fax No.: (916) 574-8617  
E-Mail Address: Lori.Martinez@dca.ca.gov

The backup contact person is:

Name: Anne Sodergren  
Address: 1625 N. Market Blvd., N219  
Sacramento, CA 95834  
Phone No.: (916) 574-7910  
Fax No.: (916) 574-8618  
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## **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).