

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 December 7, 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, 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 4076 and 4076.5 of the Business and Professions Code, the Board of Pharmacy is proposing to amend Section 1707.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations as follows:

Informative Digest/Policy Statement Overview

The Board of Pharmacy (Board) proposes to amend Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of amending the Board's regulations specific to the requirements for patient-centered labels for prescription drug containers.

Existing law sets forth the requirements for a prescription drug container label for any drug dispensed to a patient in California (Business and Professions Code (B&P) section 4076). B&P section 4076.5 required the Board to consider the following factors when developing requirements for the patient-centered prescription label requirements:

- Medical literacy research that points to increased understandability of labels.
- Improved directions for use.
- Improved font types and sizes.
- Placement of information that is patient-centered.
- The needs of patients with limited English proficiency.
- The needs of senior citizens.
- Technology requirements necessary to implement the standards.

Title 16 CCR section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. When the Board promulgated these requirements, it included in subdivision (e) a requirement that the Board re-evaluate the requirements by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

Further specifications to the patient-centered label requirements went into effect on April 1, 2015 following promulgation of a regulation in 2014. The new specifications included a standardized, patient-centered prescription drug container label. These specifications mandated the format of all prescription drug container labels for prescription drugs dispensed in California, including: font type, font size, and placement of words. These changes were necessary to ensure patient safety and compliance of prescription medications through patient-centered labels that consider the following: medical literacy research that points to increased understandability of labels; improved directions for use; improved font types and sizes; placement of information that is patient-centered; the needs of patients with limited English proficiency; the needs of senior citizens; and technology requirements necessary to implement the standards.

This proposal further specifies the patient-centered prescription drug container label in 16 CCR section 1707.5(a)(1)(B) by clarifying the meaning of “name of the drug.” By requiring the brand name when a generic drug is dispensed, patients will be further educated as to what medications they are taking. This may reduce incidence of and/or prevent accident drug overdoses. Additionally, by amending 1707.5(d) to include translation services, pharmacies will be required to include means of providing translation services to patients with limited or no English proficiency. Having policies and procedures in place that identify how to provide translation services will make the services more readily available to those patients that need them.

B&P section 4005 generally authorizes the Board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy.

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.

Anticipated Benefits of Proposal

As one patient may have three prescriptions for the same medical condition, the Board determined that requiring the brand name when a generic drug is dispensed will further educate the patient and may prevent accidental drug overdoses. If a patient has a prescription issued in the brand name and then refilled in the generic name, the patient may not be aware that the two bottles contain the same medication. This could cause them to take double or triple the dose in error. Additionally, according to the United States Census Bureau, in 2011 approximately 8.7 million California residents had little or no English proficiency. This means that approximately 8.7 million California residents are unable to read and understand the prescription label and may rely on non-medically trained individuals to translate the information. The Board determined that pharmacies need to have policies and procedures in place to provide translation services in order to better educate and serve those patients with limited or no English proficiency.

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 of Pharmacy (Board) has made a 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. This initial determination is based on the fact that the proposed changes will help protect the public health based on the proposed changes described in the proposed text and are consistent with patient-centered labeling for prescription drug requirements meeting national and industry standards.

The proposed amendment is intended to protect the people of California by ensuring consumers receive their prescription drugs with respective labels that are centered around the consumers' needs so that each consumer is able to understand the prescription drug is for them, the name of the prescription drug (and the brand name if a generic drug is dispensed), the directions for use of the prescription drug, and the condition or purpose for which the prescription drug was prescribed is indicated on their prescription. Additionally, the proposed regulation would require pharmacies to have policies and procedures in place to respond to patients with limited or no English proficiency, which will ensure that pharmacies have the ability provide accurate information regarding prescription drugs in a language appropriate for the patient.

As a result, there may be a one-time cost to implement these regulations; however, the Board does not anticipate a statewide adverse economic impact directly affecting businesses. The Board concludes that the economic impact, including the ability of California businesses to compete with businesses in other states will not be significant.

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's proposal may affect small businesses; however, the Board does not have nor does it maintain data to determine if any of its licensed pharmacies, nonresident pharmacies, or clinics are "small businesses" as defined in Government Code section 11342.610.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses

The Board of Pharmacy 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 that patient-centered labeling is currently required under 16 CCR 1707.5. This proposal amends the regulation to require the brand name of the drug with the generic drug is dispensed. Additionally, this proposal requires that policies and procedures be updated to include translation services for patients with limited or no English Proficiency.

Benefits of Regulation

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents, worker safety, and the state's environment because the proposed amendments are intended to protect the people of California by ensuring consumers receiving prescription drug containers are thoroughly educated as to what prescription drugs they are receiving. This education may prevent the incidence of accidental drug overdose. Additionally, the proposal requires translation service methods be established in the pharmacies policies and procedures; this will allow California residents with limited or no English proficiency access to prescription drug education from medical professionals.

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 be more effective in carrying out the purpose for which the action is proposed or 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 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 Web site <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 Board of Pharmacy's Web site (www.pharmacy.ca.gov).

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
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The backup contact person is:

Name:	Anne Sodergren
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Website Access

Materials regarding this proposal can be found on the Board of Pharmacy's website: www.pharmacy.ca.gov.