

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 May 26, 2014.

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 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 Sections 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 section 4076). Business and Professions Code 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.

The patient-centered label requirements went into effect on January 1, 2011, and since that time the Board has worked to secure compliance by educating licensees, conducting surveys, distributing notices, and reviewing pharmacies' compliance with requirements. Accomplishments include conducting surveys of pharmacies for compliance with label requirements.

This proposal further specifies the requirements for a standardized, patient-centered prescription drug container label. This regulation would, among other things, mandate the format of all prescription drug container labels for prescription drugs dispensed in California, including: font type, font size, and placement of words. The board's proposal is 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.

As specified in Business and Professions Code Section 4001.1, 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.

Based on an initial evaluation, the board does not believe that the proposed regulation is inconsistent or incompatible with existing state or federal regulations.

FISCAL IMPACT ESTIMATES

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

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

Effect on Housing Costs: None

Significant Statewide Adverse Economic Impact Directly Affecting Business, Including Ability to Compete: 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. 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 Notice and are consistent with patient-centered label 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, the directions for use of the prescription drug, and the condition or purpose for which the prescription drug was prescribed if indicated on their prescription. Additionally, the font of the label is to be in 12-point sans serif typeface to allow for easy reading by all consumers.

While each of the items on the prescription drug label is currently required to comprise at least 50 percent, the existing law allows for additional items to be included in this part of the label. Additionally, the existing law requires a minimum font size of 10-point sans serif typeface, or if requested by the consumer, a 12-point sans serif typeface. As a result of both the items on the label and the typeface currently required in some capacity, all pharmacies should be currently able to meet the existing requirements in law. The board's proposal will make each item on the label and the 12-point sans serif typeface an independent requirement. As a result, there may be a one-time cost to implement these regulations but 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.

The board estimates this will impact the following types of businesses: pharmacies, nonresident pharmacies, and clinics. As of January 1, 2014, the board issued licenses to approximately 9,800 pharmacies, nonresident pharmacies, and clinics. Compliance with the proposed regulations will be conducted through routine inspections by the Board of Pharmacy.

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 new or elimination of existing jobs businesses. The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact creation of new business within California; the elimination of existing business within California; or the expansion of businesses currently doing business within the State of California.

Small Businesses: 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 are "small businesses" as defined in Government Code Section 11342.610.

Cost Impact on Representative Private Person or Business: The board understands that the requirements for patient-centered labels for prescription drug containers are required for prescriptions filled in California and shipped into California. In the event a pharmacy is filling prescription drug containers in California or that are shipped into California and do not meet the current requirements for labeling, the cost impacts a business could incur in becoming compliant with the proposed action are reasonable.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The proposed amendments to Section 1707.5 are intended to protect the people of California by ensuring consumers receiving prescription drug containers meet the requirements of the patient-centered labels.

The board does not have any information indicating that the proposed amendments will in and of itself have any effect on the (1) creation or elimination of jobs within the State of California, (2) creation of new businesses or the elimination of existing businesses within the State of California, or (3) expansion of businesses currently doing business within the State of California.

The board does not have any information indicating the adoption of proposed amendments to Section 1707.5 would actually have a positive effect on the creation of jobs and new businesses within California and the expansion of businesses currently doing business in California. Consideration was made by the board as to whether the benefit to the consumers of California outweighs any negative effect on affected businesses. Additionally, the board does not anticipate the elimination of jobs or existing businesses as a result of the proposed amendments to Section 1707.5. The board concludes that the economic impact, including the ability of California businesses to compete with businesses in other states will not be significant. 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 Notice and are consistent with industry standards.

Creation or Elimination of Jobs within California: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of new or elimination of existing jobs in the State of California. The assessment and conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

Creation of New Businesses within California: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of new businesses in the State of California. The assessment and conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

Elimination of Existing Businesses within California: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the elimination of existing businesses in the State of California. The assessment and

conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

Expansion of Businesses Currently Doing Business within the State: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the expansion of businesses currently doing business in the State of California. The assessment and conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment: The board's proposal demonstrates the board's anticipated benefit to ensure the health and welfare of California Residents, Worker Safety, and the State's environment to ensure California regulations reflect at minimum the labeling standards used in the profession. The patient-centered labeling requirements for prescription drug containers will be established and will provide uniformity for pharmacies and clinics.

Occupations/Businesses Impacted: The Board of Pharmacy has made an initial determination that this regulatory proposal will impact pharmacies and clinics. As of January 2014, the board had approximately 9,800 pharmacies and clinics with current licenses issued by the board.

Reporting Requirements: None

Comparable Federal Regulations: None

Benefits: Business and Professions Code section 4005 states that "the board may adopt rules and regulations....pertaining to the practice of pharmacy...." Further, Business and Professions Code 4001.1 states that the "protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount."

The board's proposal demonstrates the board's anticipated benefit to ensure California labeling regulations reflect at minimum the standards used in the profession.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy has determined 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 or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this Notice.

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:	Debbie Damoth
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7935
Fax No.:	(916) 574-8618
E-Mail Address:	Debbie.Damoth@dca.ca.gov

The backup contact person is:

Name:	Carolyn Klein
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
Fax No.:	(916) 574-8618
E-Mail Address:	Carolyn.Klein@dca.ca.gov

Website Access. Materials regarding this proposal can be found at www.pharmacy.ca.gov.