

TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED RULEMAKING

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) is proposing to take 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 September 30, 2019.

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 his or her authorized representative, no later than 15 days prior to the close of the written comment period.

The board may, after 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 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, 4076, and 4112 of the Business and Professions Code authorize the board to adopt these regulations. The proposed regulations implement, interpret, and make specific sections 4005, 4076, and 4112 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

The board proposes to clarify and make specific the standards that apply to all pharmacies, including mail order pharmacies or pharmacies that deliver medications, to fulfill their patient consultation requirements.

Business and Professions Code (BPC) section 4001.1 specifies that protection of the public is the highest priority for the board 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.

BPC section 4005 generally authorizes the board to adopt and amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy. It also specifically authorizes the board to adopt regulations: relating to the sanitation of persons and facilities licensed by the board; pertaining to licensed facilities wherein any drug is

compounded, prepared, furnished or dispensed; pertaining to minimum equipment for licensed facilities; and for the proper and effective enforcement and administration of Pharmacy Law.

BPC section 4037 establishes the definition of a pharmacy to include an area, place or premises licensed by the board in which the professional of pharmacy is practiced and where prescriptions are compounded.

BPC section 4076 establishes the general labeling requirements for prescriptions.

BPC section 4112 generally establishes the licensing requirements for a nonresident pharmacy. Further, this section requires a nonresident pharmacy to provide a toll-free number to facilitate communication between patients in California and a pharmacist with access to the patient's record. Additionally, this section authorizes the board to adopt regulations that apply the same requirements or standards for oral consultation to nonresident pharmacies as those applied to resident pharmacies.

Title 16, California Code of Regulations (CCR) Section 1707.2 specifies the conditions under which a pharmacist must fulfill his or her duty to consult.

This proposal would amend the current "Duty to Consult" regulations to:

- Specify the minimum requirements a pharmacist must be available for patients to speak to, and the maximum time a consumer must wait before speaking to a pharmacist.
- Updates the authority and reference sections to comply with legal requirements and ensure readers' understanding of the underlying sections of pharmacy law that support the regulation.
- Expand the current requirements for when a pharmacist shall provide oral consultation and expand the requirements to all settings.

Anticipated Benefits of the Proposed Regulations

The broad objective of this proposal is to ensure that California consumers have timely access to a pharmacist to receive patient consultation. The specific benefits anticipated by the proposed amendments are to protect the public from risks of unsafe and or ineffective use of prescription medications through patient education. Providing access to a pharmacist ensures a patient is provided the opportunity to understand the appropriate use of the medications, drug warnings and interactions, and potential adverse effects if the medication is not taken as directed. Without such information patients are at risk.

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 and Related Estimates

The board has made the following initial fiscal impact determinations:

Local Mandate: None

Fiscal Impact on Public Agencies:

- Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None
- Costs/Savings to State Agencies: Minimal cost savings
- Nondiscretionary Costs/Savings to Local Agencies: None
- Costs/Savings in Federal Funding to the State: None

Significant Statewide Adverse Economic Impact Directly Affecting Businesses (If Any):

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.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The board concludes that it is:

- (1) Unlikely that the proposal will create or eliminate any jobs within California;
- (2) Unlikely that the proposal will create new, or eliminate existing, businesses in California;
- (3) Unlikely that the proposal will expand businesses currently doing businesses within the state; and,
- (4) The benefits to the public are for consumer protection and increased assurance that any patient consultation services are readily available to all California consumers irrespective of where the patient receives his or her medication.

Benefits of the Proposal:

The board has determined that this regulatory proposal will benefit the health and welfare of California residents. The legislature recognized the importance of patients having access to a pharmacist for purposes of providing patient consultation and created a mandate for the board to develop regulations specific to nonresident pharmacies. To fulfill this mandate, the board is ensuring patients have timely access to a pharmacist. The proposed amendments modify patient consultation requirements to specify how such consultation must be provided, irrespective of the care setting. This change will increase

patient access to pharmacists and result in better patient education surrounding the appropriate use of prescription medications. The proposed regulations will not benefit worker safety or the state's environment.

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. The board anticipates that the regulatory proposal will not result in any cost impacts to patients. Further, the board anticipates that this regulatory proposal will not result in any cost impacts to mail order pharmacies or pharmacies that have a medication delivery service. This determination is based on public comments received from representatives of mail order pharmacies operating both within and outside of California.

Business Reporting Requirement

The proposal requires pharmacies, including those that are nonresident, mail order, or that deliver medication to comply with patient consultation requirements. This proposal does not create any business reporting requirements.

Effect on Small Business:

The board believes this regulation will have no significant impact on small businesses. Although the board does not have nor maintain data to define if any of its licensees (pharmacies) are a "small business" as defined in Government Code section 11342.610, the board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. This is based on the determination that the regulatory proposal could result in existing mail order and nonresident pharmacies, some of which are likely small businesses, fulfilling patient consultation requirements already envisioned in statutory requirements.

Consideration of Alternatives

The board must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention (1) would be more effective in carrying out the purpose for which the action is proposed, (2) would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or (3) would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The board invites interested persons to present statements or arguments with respect to the alternatives to the proposed regulations during the public comment period.

Availability of Initial Statement of Reasons, Text of Proposed Regulations and Rulemaking File

The board will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the address above. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulations, the initial statement of reasons, and all of the documents upon which the proposal is based.

Availability of the Final Statement of Reasons

Upon its completion, you may obtain a copy of the final statement of reasons by accessing the website listed below or by contacting the person named below.

Contact Person

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Lori Martinez
Address: 2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833
Phone No.: (916) 518-3078
Fax No.: (916) 574-8618
E-Mail Address: Lori.Martinez@dca.ca.gov

The backup contact person is:

Name: Debbie Damoth
Address: 2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833
Phone No.: (916) 518-3090
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Website Access

Copies of this notice, the initial statement of reasons, and the text of the proposed regulations in underline and strikeout can be found at the California State Board of Pharmacy’s website: www.pharmacy.ca.gov.