

DEPARTMENT OF CONSUMER AFFAIRS

TITLE 16. BOARD OF PHARMACY

Division 17

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:
DESIGNATION OF PHARMACIST-IN-CHARGE

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) proposes taking 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 January 2, 2024**, or must be received by the board at the hearing, should one be scheduled.

PUBLIC HEARING

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 that person's authorized representative, no later than 15 days prior to the close of the written comment period.

The board may, after holding a hearing if requested and 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 the 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: Section 4005 of the Business and Professions Code (BPC) authorizes the board to adopt this regulation. The proposed regulation implements, interprets, and makes specific sections 4081, 4113, 4305 and 4330 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

The board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, interns, and pharmacy technicians. The board's mandate and its mission is to protect the public (BPC 4001.1).

Existing pharmacy law establishes the requirement for a pharmacy to designate a pharmacist-in-charge (PIC). This section further provides that the proposed PIC shall be subject to approval by the board and sets forth the requirements for the PIC (BPC 4113).

Existing pharmacy law provides that operation of a pharmacy for more than 30 days without the supervision or management by a PIC constitutes grounds for disciplinary action. Further, this section provides that any person who has obtained a license to conduct a pharmacy, who willfully fails to timely notify the board that a PIC has ceased to act in that capacity shall be subject to summary suspension or revocation of the pharmacy license under specified conditions (BPC 4305).

Existing pharmacy law provides that any person who has obtained a pharmacy license and fails to designate a PIC is guilty of a misdemeanor. Further, a pharmacy owner who commits any act that would subvert or tend to subvert the efforts of the PIC is guilty of a misdemeanor (BPC 4330).

Title 16, California Code of Regulations (CCR) section 1709.1 provides that a PIC of a pharmacy shall be employed at the location and have responsibility for the daily operations of the pharmacy. The section further provisions that the pharmacy owner shall vest the PIC with adequate authority to assure compliance with the laws governing the operation of a pharmacy.

This proposal will amend CCR Section 1709.1 to establish a training requirement for a proposed PIC to ensure the individual has an understanding of the legal obligations of a pharmacist serving as a PIC and an attestation confirming the individuals understanding of the authorities vested in such an individual.

Anticipated Benefits of the Proposed Regulations

By establishing an attestation and training requirement, the board will have confirmation that the proposed PIC has a full understanding of the obligations set forth for a PIC prior to accepting such a position. The proposal is consistent with the board's consumer protection mandate by ensuring the appropriate knowledge needed of those vested with the authority to ensure a pharmacy operates in the compliance with pharmacy law to ensure appropriate patient care.

Consistency and Compatibility with Existing State Regulations

While developing these regulations and amendments, the board conducted a search of similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations. As noted above, these amendments make state law more consistent with federal law.

Fiscal Impact and Related Estimates

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: The board estimates it will take approximately 30 hours of staff time to develop the training module and to implement the training program with one-time costs of \$3,930. There are no cost or

savings to any other state agency, and there are no cost or savings in federal funding to the state.

The training module will be posted on the Board's website during routine information technology updates and will not result in additional costs.

The Board currently ensures compliance with its regulation through its inspection and enforcement programs. The board does not anticipate any added workload or costs associated with this regulatory change.

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 the initial determination that the proposed regulations will not have a significant statewide adverse economic impact directly affecting businesses including the inability of California businesses to compete with businesses in other States.

This initial determination is based on the following facts:

This initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed amendments to the regulation. The board provided training will be free to pharmacists.

Cost Impact on Representative Private Person or Business:

The board is not aware of any negative cost impacts that a representative private person or business would necessarily incur in reasonable compliance with proposed action.

Effect on Housing Costs: None

Effect on Small Business:

While the board does not have, nor does it maintain, data to determine if any of its licensees (pharmacies and clinics) are a "small business," as defined in Government Code section 11342.610, the board has made an initial determination that the proposed regulatory action will not affect small businesses. Although the proposed regulation will directly affect businesses statewide, which may include small businesses, the board does not anticipate any adverse economic impact. The board notes that the training requirement established in the proposed regulation will be provided by the board free of charge.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The board concludes that:

- (1) this proposal will not create jobs within California;
- (2) this proposal will not eliminate jobs within California;
- (3) this proposal will not create new businesses within California;
- (4) this proposal will not eliminate existing businesses within California; and,
- (5) this proposal will not expand businesses currently doing business in the State of California.

The board determined that this proposal will not cause any of the foregoing because the changes are not of sufficient magnitude to create those impacts. This proposal establishes a board provided, free training requirement for a proposed PIC to ensure the individual has an understanding of the legal obligations of a pharmacist serving as a PIC and an attestation confirming the individuals understanding of the authorities vested in such an individual..

Additionally, the board determined that this regulatory proposal will not impact worker safety, or the state's environment as these changes do not involve worker safety or the environment. The board has determined that this regulatory proposal benefits the health and welfare of California residents by ensuring that the PIC has the appropriate knowledge of their responsibility and authority to ensure a pharmacy operates in compliance with pharmacy law to ensure appropriate patient care.

Consideration of Alternatives

The board must determine that no reasonable alternative that 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.

The board considered if there was an alternative means to ensure a proposed pharmacist-in-charge including allowing training provided by other organizations; however, determined that board provided training would be provided both free of charge and would allow the board to ensure that necessary components are framing of the legal provisions is appropriate.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person during the written comment period, or at the hearing if one is scheduled or requested.

Availability of Statement of Reasons and Rulemaking File

The board has prepared an Initial Statement of Reasons for the proposed action and has available all the information upon which the proposal is based. Copies of the exact language of the proposed regulations, 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 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website at <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: 2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3078
Fax No.: (916) 574-8618
E-Mail Address: PharmacyRulemaking@dca.ca.gov

The backup contact person is:

Name: Julie Ansel
Address: 2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3100
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Website Access

Materials regarding this proposal can be found at the Board of Pharmacy's website: https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.