

TITLE 16. BOARD OF PHARMACY, DEPARTMENT OF CONSUMER AFFAIRS
Initial Statement of Reasons

Hearing Date: None unless requested, see Notice of Proposed Action

Subject Matter of Proposed Regulation: Designation of Pharmacist-in-Charge (PIC)

Section Affected: California Code of Regulations (CCR), Title 16, Division 17, Amend Section 1709.1

Background

The California State Board of Pharmacy (board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, pharmacy interns, and pharmacy technicians. The board’s mandate and its mission is to protect the public (Business and Professions Code (BPC) section 4001.1).

Problems Addressed

Existing law, BPC section 4036.5 defines a “pharmacist-in-charge” as a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy’s compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

Existing law, BPC section 4113 provides in part that every pharmacy shall designate a pharmacist-in-charge (PIC). Further, the pharmacy is responsible for compliance with all state and federal laws and regulations pertaining to the practice of pharmacy. Section 41139(b) also specifically provides that the proposed PIC shall be subject to approval by the board.

Existing law, BPC 4330(b) provides that is it unlawful for any pharmacy owner to commit any act that would subvert or tend to subvert the efforts of the PIC to comply with the laws governing the operation of the pharmacy.

Existing law, CCR section 1709.1 further provides that a pharmacy shall employ a pharmacist and reiterates that the PIC shall have responsibility for the daily operations of the pharmacy. This section also provides that the pharmacy owner shall vest the PIC with adequate authority to assure compliance with the laws governing the operation of pharmacy.

In addition to the legal requirements referenced above, the board designated a precedential decision (Sternberg v. California State Board of Pharmacy (2015) 239 Cal.App.4th 1159 California Court of Appeal, Second District, Division Eight, Case No. B255856), which confirmed that a PIC is responsible and could be disciplined for a pharmacy’s noncompliance.

Regrettably, in spite of the legal provisions, precedential decision and general education by the board, it is not uncommon for investigations to substantiate violations where a pharmacist may be designated as a PIC in name only or the designated PIC fails to exercise appropriate oversight of the operations. Although the egregiousness of the violations may vary, there are instances where such an individual pharmacist ultimately is disciplined including losing their pharmacist license through the administrative process.

As part of its policy discussion and assessment of this issue, the board determined it appropriate to require, as part of the PIC approval process, which is subject to board approval, an attestation by the proposed PIC that affirms their acceptance of the responsibility for the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy and to further affirm that it is unlawful for any pharmacy owner to commit any act that would subvert or tend to subvert the efforts of a PIC to comply with all laws. Such attestations ensure that such an individual is aware of and accepts the responsibility for the legal obligations established. Additionally, it makes clear that the proposed PIC has an understanding of the obligations of the owner/manager to provide the PIC with sufficient authority to fulfill the PIC's responsibility.

Further, as part of its policy discussion, the board determined that completion of a training course would be appropriate for such individuals as well. The board determined that the training program would supplement the attestation and provide additional information beyond just the legal references included in the attestation to ensure education and awareness of the roles and responsibilities of the PIC. The board determined that it is appropriate to require completion of the training program within the last two years prior to appointment.

Anticipated Benefits of the Proposed Regulations

By establishing the attestation and training requirements for proposed PICs, it will ensure such an individual has a full awareness of the legal obligations of a PIC prior to accepting such responsibility. Such awareness and understanding will reduce violations of pharmacy law and improve public health by ensuring compliance with the law.

Specific Purpose of Proposed Changes and Rationale

Section 1709.1(a).

This section is amended to include a requirement for the pharmacy to submit its proposed PIC to the board for approval. Additionally, the proposed PIC shall have completed the board-provided training course, entitled Pharmacist-in-Charge Overview and Responsibility, within two years prior to the date of application. The board determined that development of a board provided training program and requiring completion of the training program would ensure a proposed PIC has a full understanding of the legal requirements and obligations of a PIC. Further, the training program will provide relevant information for the individual including the legal information related to the role of a PIC, the legal prohibitions for a pharmacy owner to

subvert or tend to subvert the efforts of the PIC, the legal requirements and overview of the self-assessment process, information on how to prepare for an inspection and the top violations that result in the issuance of a citation and fine. The requirement to completing the training within the past two years ensures recency of the knowledge.

Further, the PIC shall complete an attestation that includes the name of the proposed pharmacist-in-charge, the individual's license number, a statement that they have read Sections 4036.5, 4081, 4113, and 4330 of the Business and Professions Code and the proposed regulation section, a statement identifying the date that the proposed PIC took the board's training course, and a declaration signed under penalty of perjury of the laws of the State of California that the information provided by the individual is true and correct. As proposed, the attestation includes references to the relevant sections of the law, which ensures the individuals have an understanding of the requirements as well as the citations which allow the individual to read the language in its entirety. As the training will be board-provided, including the date of completion of the course will allow the board the ability to confirm compliance by a review of board records for that date. Finally, by requiring attestation under penalty of perjury, the board is communicating to the PIC the gravity of submitting false information to the board. Pursuant to BPC section 4301(g), the board has the statutory authority to discipline a licensee who knowingly made or signed any certificate or document that falsely represents the existence or nonexistence of facts. Should a PIC falsely certify to the completion of the training course and reading the required law sections, the PIC could be disciplined by the Board.

Underlying Data

1. Relevant portion of the Licensing Committee Meeting Materials and Minutes from Licensing Committee Meeting held January 19, 2022.
2. Relevant portion of the Public Board Meeting Materials and Minutes from Board Meeting held on January 27-28, 2022.
3. Relevant portion of the Public Board Meeting Materials and Minutes from Board Meeting held on October 26-27, 2022
4. Precedential Decision No. 2019-02.
(https://www.pharmacy.ca.gov/enforcement/precedential/no_2019_02.pdf)

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. Thus, despite stakeholder outreach, interested parties did not raise concerns regarding

any economic impact or hardship. Further, the board will be developing and providing the training free of charge.

Economic Impact Assessment:

The board has determined 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;
- (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 these 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 determined that this regulatory proposal benefits the health and welfare of California residents by improving education of proposed PICs and anticipated reduction in violations of Pharmacy Law.

Fiscal Impact Assessment:

The proposed regulation will result in a minor one-time fiscal impact to the state totaling \$3,930 for the development and implementation of the training program as follows:

Position	Task	Hourly Rate	Time	Costs
Supervising Inspector	Development of Training	\$137	24 hrs	\$3,288
Executive Officer	Edit & Review of Training	\$143	2 hrs	\$286
Public Information Officer	Training Voiceover	\$89	4 hrs	\$356
Total Costs:				\$3,930

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. Aside for the development of the course, the board does not anticipate any added workload or costs associated with this regulatory change that cannot be absorbed by the existing board staff.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment other than the ability to access the training materials online. Should someone need to access the materials differently (i.e., due to a disability), such individual can reach out to the board and the board will make arrangements to ensure that one who has a need to access to the materials is provided the opportunity to do so.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

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 and framing of the legal provisions is appropriate.