

TITLE 16: BOARD OF PHARMACY FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Designation of Pharmacist-in-Charge

Sections Affected: Title 16, California Code of Regulations (CCR) section 1709.1

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on November 17, 2023 and ended on January 2, 2024. The Board's notice stated that the Board did not intend to hold a hearing on the matter unless requested. The Board did not receive a request for a hearing during the comment period, and no hearing was held.

During the 45-day comment period, the Board received several comments. At the February 8, 2024 Board meeting, the Board reviewed the comments received and amended the draft regulation text to address concerns raised by stakeholders. The Board voted to initiate a 15-day public comment period, which commenced on April 29, 2024 and concluded on May 14, 2024.

Subdivision (e) of the regulation text was amended to establish the requirement for the interim pharmacist-in-charge (PIC) to also complete the required training course prior to becoming the interim PIC. The Board determined that it is important for any pharmacist agreeing to be the temporary or permanent PIC to understand what is required of them prior to serving in that capacity.

During the 15-day comment period, the Board received two comments. At the July 31-August 1, 2024 Board meeting, the Board reviewed the comments received and voted to adopt the regulation text as noticed for public comment on April 29, 2024.

The final rulemaking package was submitted to the Office of Administrative Law (OAL) for formal review on September 4, 2024. Following review, edits were necessary to ensure compliance with the Administrative Procedure Act (APA) and Business and Professions Code (BPC) sections 733 and 4122.

Specifically, the Board must clearly identify The Board amended the regulation text to include the training course location, cost, and subject matter. Specifically, the Board amended the regulation text to indicate that the training is available, free of charge, on the Board's website—additionally, the subject matter, previously identified in the Initial Statement of Reasons, was added for clarity about what would be covered in the training

program. A 15-day public comment period commenced on October 17, 2024, and concluded on November 1, 2024. Three comments were received.

At its November 6-7, 2024, Board meeting, the Board reviewed the comments and adopted the regulation text as noticed on October 17, 2024, and delegated to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

While the Board does not have nor does it maintain data to determine whether any of its licensees are “small businesses” as defined in Government Code section 11342.610, the Board determined that the proposed regulatory action will not have any adverse economic impact on 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.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, as effective and less burdensome to affected private persons than the adopted regulation, or 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 has the necessary training before taking on the role, including allowing training provided by other organizations; however, the Board determined that a Board-provided training would be provided free of charge and would allow the Board to ensure that the course includes all necessary components, including the legal requirements all PICs must meet while in the role.

Objections or Recommendations/Responses to Comments

45-Day Comment Period

During the 45-day comment period, which began on November 17, 2023 and ended on January 2, 2024, the Board received several comments. At the February 8, 2024 Board meeting, the Board reviewed the comments received and amended the draft regulation text to address an issue with a proposed definition within the draft regulation text. The Board voted to initiate a 15-day public comment period.

Summary and Response to 45-day Comments:

Written Comments from Mark Johnston, CVS Health

Comment 1: The commenter indicates that CVS Health is opposed to Pharmacist-in-Charge (PIC) requirements due to the declining pool of pharmacists available to hire and promote to PIC, as CVS Health views the required training as a barrier to entry as a PIC.

Response to Comment 1: The Board reviewed this comment and did not make any changes to the text based upon the comment. The Board does not agree that completion of a training program is a barrier, as the training program is being provided by the Board, free of charge, and ensures sufficient knowledge for individuals seeking to serve as a PIC, which protects consumers. As mentioned during Board and Committee meetings, 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. Further, the Board and Committee members previously discussed components, including legal requirements for a PIC and the Sternberg Precedential decision, legal requirements and overview of the self-assessment process, information on how to prepare for an inspection, legal prohibition for a pharmacy owner to subvert or tend to subvert the efforts of a PIC to comply with the laws governing the operation of a pharmacy, and the top violations that result in the issuance of a citation and fine. The Board refers commenter to the January 2022 Licensing Committee Meeting and the January 2022 Board Meeting, for which information and webcasts can be found at: https://www.pharmacy.ca.gov/about/meetings_full.shtml.

Comment 2: The commenter indicates that CVS Health is opposed to incorporating by reference a training course that does not currently exist due to its unknown length, unknown cost, unknown content, unknown availability, and unknown requirements, as it violates Title 1 of the California Code of Regulations. Additionally, this is not a statutory requirement and the incorporated material requires OAL review and violates section 20.

Response to Comment 2: The Board reviewed this comment and amended the language to add the approximate length, website availability, and subject matter. The Board notes that the training course is not being incorporated by reference. Incorporation by reference is specific to including (provisions of) another document as part of a regulation by referencing the other document. The training program is not another document that requires incorporation by reference. The Board also notes that the Board has two other training/education programs it provides required in regulation, including Law (1732.5) and Ethics (1732.5), which are also not incorporated by reference. In addition to the course being provided free of charge, the proposed regulation text includes the frequency with which the course must be taken, and any future changes would be based on and consistent with changes to pharmacy law.

Written Comments from Mark Raus, Pharmacist.

Comment 3: The commenter indicates that, as a pharmacist, he supports the addition of the regulations. He provided an anecdote about a PIC at CVS being issued a citation for numerous violations, and he had received no training before taking the role. Mr. Raus provided additional anecdotes about the risks of being a PIC and indicated that being a PIC is a role he would not take again. In addition to his support of the proposed regulation, the commenter encourages the Board to enforce current regulations.

Response to Comment 3: The Board reviewed this comment and did not make any changes to the text based upon the comment. The Board acknowledges commenters support of the proposed regulation.

Written Comments from Loriann De Martini, California Society of Health System Pharmacists.

Comment 4: The commenter indicates that the regulation does not establish responsibility to the “pharmacy owner.” Commenter states PICs may experience pressure from owners, executives, and administrators to violate and bend laws and regulations. Commenter recommends that the regulation also make mandatory that both a ‘pharmacy owner’ as well as the chief administrator and chief nursing administrator of a hospital also take part in training and make attestations. Specifically, commenter requests the following language be added to the end of subdivision (a): *“Additionally, the owner, officer, and partner of a pharmacy, wholesaler, third-party-logistics provider, or veterinary food-animal drug retailer and the chief administrator and the chief nursing manager of a facility licensed under Health and Safety Code 1250 that employs or contracts the services of a pharmacist-in-charge shall complete the board-provided Pharmacist-In-Charge Overview and Responsibility training course and complete an attestation statement in compliance with this section and every two years thereafter for the duration of their tenure as PIC.”*

Response to Comment 4: The Board reviewed this comment and did not recommend any changes to the text based upon the comment. The Board discussed requiring the owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer and the chief administrator and the chief nursing manager to complete the required training; however, the Board determined that the addition was outside of the policy discussion for this regulator package and requires additional consideration and discussion at future Board meetings.

Comment 5: The commenter recommends the subdivision (b) be amended to add “and resources” after “adequate authority,” as PICs frequently lack resources to execute their authority.

Response to Comment 5: The Board reviewed this comment and did not recommend any changes to the text based upon the comment. The Board notes that this comment is outside the scope of this regulatory change and comment period. Additionally, the Board

notes Assembly Bill (AB) 1286 included provisions to ensure the PIC has the authority to make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. Pursuant to AB 1286, a pharmacist on duty, if the pharmacist-in-charge is not available, is authorized to adjust staffing according to workload, if needed.

Comment 6: The commenter recommends that the required training be mandated for individuals designated as a temporary PIC in subdivision (e).

Response to Comment 6: The Board reviewed and accepted this comment. The Board discussed requiring the owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, the chief administrator, and the chief nursing manager to complete the required training. The Board amended the language to require temporary PICs to complete the training.

Written Comments from Lorri Walmsley, Walgreens

Comment 7: The commenter indicates that, while Walgreens supports the idea of a required training course, they believe requiring completion of the training course prior to appointment may result in some pharmacies having a gap between PICs due to not having pharmacists available that have completed the course. Commenter recommends that subdivision (a) be amended to add "*or within 90 days of appointment*" to allow appointed PICs additional time for completion of the course. Additionally, the commenter requested that the attestation requirement be removed.

Response to Comment 7: The Board reviewed this comment and did not recommend any changes to the text based upon the comment. The Board acknowledges commenters support of the proposed regulation. Additionally, the Board notes that the Board previously considered the timeline for completion of the training course. As the training program is intended to ensure that the individual has sufficient knowledge to serve as a PIC, it is appropriate for the training program to be completed prior to serving in that capacity.

Comment 8: The commenter requests that subdivision (c) be amended to remove the 50-mile driving limitation as "there are locations within the state of California that may be less than 50 miles which would take a longer commute than some locations that are more than 50 miles based on traffic patterns in the state and leaving it open will allow for pharmacist discretion."

Response to Comment 8: The Board reviewed this comment and did not recommend any changes to the text based upon the comment. The Board notes that this comment is outside the scope of this regulatory change and the policy discussion by the Board.

Written Comments from John Gray, Kaiser Permanente

Comment 9: The commenter indicates that Kaiser Permanente supports the completion of a Board-developed training course and attestation to strengthen pharmacists' understanding of their authority and obligations as a PIC. Commenter recommends that section 1709.1(a) be amended to add Business and Professions Code (BPC) section 4113, as the section 4113 "more clearly describes the requirement to submit a PIC Change Application....". This addition would clarify that the training is for initial and subsequent PIC appointments.

Response to Comment 9: The Board reviewed this comment and did not recommend any changes to the text based upon the comment. The Board notes that BPC section 4113 is identified within the language and listed as a reference section, and, as such, the additional language is not necessary.

COMMENTS RECEIVED OUTSIDE COMMENT PERIOD

Written Comments from Veronica Nunez, Pharmaregs, Inc.

Comment 10: Commenter requests clarification on whether completion of the training course will be required for non-resident pharmacies.

Response to Comment 10: The Board reviewed this comment and did not recommend any changes to the text based upon the comment. The Board notes that a non-resident pharmacy must identify a PIC that must be approved by the Board and all PICs must complete the training program.

Written Comments from Sandra Leigh Bardas, Pharmacist

Comment 11: Commenter requests that the regulation be amended to include the suggestion made by the California Society of Health-System Pharmacists (CSHP) to require the chief administration officer and the chief nursing manager to take the course. Commenter states they are specifically requesting that the requirements apply to PICs of a Clinic Pharmacy. Commenter recommends a specialized course addressing the duties and responsibilities for these individuals.

Response to Comment 11: The Board reviewed this comment and did not recommend any changes to the text based upon the comment. The Board discussed requiring the owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer and the chief administrator and the chief nursing manager to complete the required training; however, the Board determined that the addition was outside of the policy discussion for this regulatory package and requires additional consideration and discussion at future Board meetings.

Summary and Response to 15-day Comments:

Written Comments from Lorri Walmsley, Walgreens

Comment 12: The commenter indicates that, while Walgreens supports the idea of a required training course, they believe requiring completion of the training course prior to appointment may result in some pharmacies having a gap in a PIC due to not having pharmacists available that have completed the course. Commenter recommends that subdivision (a) be amended to add “*or within 90 days of appointment*” to allow appointed PICs additional time for completion of the course. Additionally, the commenter requested that the attestation requirement be removed.

Response to Comment 12: The Board reviewed this comment and did not recommend any changes to the text based upon the comment. The Board notes that this comment was previously submitted during the 45-day comment period and already reviewed and considered by the Board. Additionally, this comment is outside the scope of the 15-day comment period. Further, the Board notes that the timeline for completion of the training course was considered during several Board meetings. The training program is intended to ensure that the individual is prepared to serve as a PIC from the moment they assume the position of PIC, having gained the requisite knowledge to serve as a PIC before assuming the position, so it is appropriate for the training program to be completed *prior* to serving in that capacity.

Written Comments from Rob Geddes, PharmD, Albertsons

Comment 13: The commenter indicates that, while Albertsons supports the idea of a required training course, they recommend that subdivision (a) be amended to add “*or within 30 days of appointment.*” Commenter says this addition would allow appointed PICs additional time for completion of the course and mirror the “grace period” built into Business and Professions Code section 4305— which requires the appointment of a PIC within 30 days—indicating the California State Legislature believes a 30-day grace period is a necessary allowance that permits pharmacies a limited timeframe to designate a PIC.

Response to Comment 13: The Board reviewed this comment and did not recommend any changes to the text based on the comment. The Board notes that this comment is outside the scope of the 15-day comment period. Further, the Board notes that the timeline for completing the training course was considered during several Board meetings. The training program is intended to ensure that the individual is prepared to serve as a PIC from the moment they assume the position of PIC, having gained the requisite knowledge to serve as a PIC before assuming the position, so it is appropriate for the training program to be completed *prior* to serving in that capacity.

Comment 14: The commenter indicates that, while Albertsons supports the idea of a required training course, they recommend that subdivision (e) be amended to add “*or within 30 days of appointment.*” Commenter says this addition would allow appointed interim PICs additional time for completion of the course, and mirror the “grace period”

built into Business and Professions Code section 4305, which requires appointment of a PIC within 30 days.

Response to Comment 14: The Board reviewed this comment and did not recommend any changes to the text based upon the comment. Further, the Board notes that the timeline for completion of the training course was considered during several Board meetings. The training program is intended to ensure that the individual is prepared to serve as a PIC from the moment they assume the position of PIC, having gained the requisite knowledge to serve as a PIC before assuming the position, so it is appropriate for the training program to be completed *prior* to serving in that capacity.

Summary and Response to Second 15-day Comments:

Written Comments from Tony Park, California Pharmacy Lawyers

Comment 15: Commenter believes the mandatory PIC training should be Board-approved and not Board-provided. The commenter indicates that there are different types of pharmacy business practices, and, therefore, a single Board-provided CE would not adequately address the unique aspects of the PIC position. The commenter states he has not seen any “evidence that the Board-provided Pharmacy Laws update and Ethics course have increased compliance, decreased violations, or increased ethical behavior amongst pharmacists,” however, has seen that the mandatory Board-approved cultural competency course has “positively impacted pharmacists’ perspectives on dealing with patients and coworkers with greater cultural competency.” Commenter states that the Board should allow the pharmacy industry to self-determine the most appropriate content for the PIC training and suggest that the Board merely provide specific learning objectives.

Response to Comment 15: The Board reviewed this comment and did not recommend any changes. The Board notes that this comment is outside the scope of the comment period. Additionally, the Board notes that this issue was discussed at length at prior Board meetings. The Board determined that the Board must provide the training to ensure it is free of charge and that it would enable the Board to ensure the appropriate framing of the necessary components and legal provisions. Additional information is available on the Board’s website for the Licensing Committee (January 2022): https://www.pharmacy.ca.gov/about/meetings_licensing.shtml.

Written Comments from Ambar Cosme Pabon, Pharmaregs, Inc.

Comment 16: The commenter requests clarification on whether the required training applies to non-resident pharmacies.

Response to Comment 16: The Board reviewed this comment and did not recommend any changes to the text based on it. The Board noted that a non-resident pharmacy must identify a PIC that the Board must approve, and all PICs must complete the training program.

Written Comments from Scott Clark, CenterWell Pharmacy

Comment 17: Commenter recommends that the language in subdivision (a) be amended to change “the individual’s license number” to “the individual’s pharmacist license number of his/her resident state or the individual’s pharmacist license number of the state where the pharmacy is located.”

Response to Comment 17: The Board reviewed this comment and did not recommend any changes to the text based on it. The Board noted that this comment is outside the scope of the comment period. Additionally, the Board does not believe the additional language is necessary. As currently drafted, the language is clear that “license number” refers to the individual's pharmacist license number, as no other “license number” would fit the context of the subdivision.