



California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item XI. Discussion and Possible Action related to Proposed Amendment to California Code of Regulations, Title 16, Section 1709.1 Related to Designation of Pharmacist-in-Charge, Including Review of Comments Received During the 15-Day Comment Period Initiated to Address Issues Raised by the Office of Administrative Law

Background:

At the January 28, 2022, Board meeting, the Board approved the proposed regulation text to amend Section 1709.1 related to the Designation of Pharmacist-in-Charge. This proposal amends the board's regulations regarding the designation of a pharmacist-in-charge and required training.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on November 17, 2023, which ended on January 2, 2024. The Board reviewed the comments at the February 2024 Board meeting and voted to amend the text in response to the comments received.

Following review by DCA Legal, Board staff released revised text for a 15-day comment period on April 29, 2024, which ended on May 14, 2024. The Board reviewed the comments at the July 2024 Board meeting and voted to adopt the staff-proposed comment responses and the text as noticed.

The final rulemaking package was submitted to the Office of Administrative Law (OAL) for formal review on September 4, 2024. Following their review, OAL requested amendments to the regulatory text to ensure compliance with the Administrative Procedure Act (APA). Specifically, OAL requested that the training subject matter, approximate length, and administration method be added. The modified text was released on public comment on October 17, 2024, which ended on November 1, 2024.

The Board will have the opportunity to discuss the regulation and the amendments requested by OAL at this meeting. The modified text released for the 15-day public comment period, staff-recommended comment responses, and comments received are attached following this memo.

Possible Adoption Language:

Move to ratify the modifications to the regulatory text published during the second 15-day comment period from October 17, 2024, through November 1, 2024, and accept Board staff-recommended comment responses [in line with today's discussion]. Additionally, direct Board staff to take all steps necessary to complete the rulemaking process.

Title 16. Board of Pharmacy Second Modified Text

Proposed changes to current regulation text are indicated with a ~~single strikethrough~~ for deletions and a single underline for additions.

Modified regulation text to the proposed regulation text is indicated with a ~~double strikethrough~~ for deletions and a double underline for additions.

The second modified regulation text to the regulation text is indicated with a ~~bold double strikethrough~~ for deletions and a bold wavy underline for additions.

Amend Section 1709.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1709.1. Designation of Pharmacist-In-Charge

- (a) The pharmacist-in-charge (PIC) of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy. Prior to approval of the board, and as part of the application and notice process set forth in Section 1709 of this Division (“application”), a pharmacy shall submit its proposed PIC. The PIC shall have completed the board-provided Pharmacist-in-Charge Overview and Responsibility training course, available on the board’s website, within two years prior to the date of application. The PIC shall complete an attestation statement in compliance with this section. For purposes of this section, a completed attestation statement shall include all of the following: 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 this section, ~~and~~ 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. **The board-provided Pharmacist-in-Charge Overview and Responsibility training course shall be approximately 1 hour and shall cover:**
- (1) Legal requirements of the role of a PIC**
 - (2) Legal prohibitions for a pharmacy owner to subvert the PIC**
 - (3) Legal requirements/Overview of the self-assessment process**
 - (4) How to prepare for an inspection**
 - (5) Top violations that result in a Cite and Fine**
- (b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
- (c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.
- (d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.
- (e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The interim PIC shall have

completed the board-provided Pharmacist-in-Charge Overview and Responsibility training course, identified in subdivision (a) within two years prior to the date of application. The interim PIC shall complete the attestation statement as identified in subdivision (a). The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.

- (f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.
- (g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4036.5, 4081, 4113, 4305 and 4330, Business and Professions Code.



Proposed Regulation to Amend Title 16 CCR Section 1709.1, Designation of Pharmacist-in-Charge

Summarized 45-day Comments Regarding Designation of Pharmacist-in-Charge with Board Staff Recommendations:

Written Comments from Tony Park, California Pharmacy Lawyers

Comment 1: 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 1: Board staff have reviewed this comment and do not recommend any changes. Board staff note 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 2: Commenter requests clarification on whether the required training applies to non-resident pharmacies.

Response to Comment 2: Board staff does not recommend any changes to the text based upon the comment. Board staff notes 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 3: 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 3: Board staff does not recommend any changes to the text based on the comment. Board staff note that this comment is outside the scope of the comment period. Additionally, Board staff do 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.

From: Tony J. Park, Pharm.D., J.D. <tpark@capharmacylaw.com>
Sent: Thursday, October 17, 2024 12:21 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Notice of Modified Text - Designation of Pharmacist-in-Charge
Importance: High

Good morning.

I am writing the Board today as a concerned Californian, offering my unique perspective: (1) as legal counsel for pharmacists in their defense against the Board of Pharmacy's enforcement and disciplinary actions; (2) as an educator who teaches CA Pharmacy Laws and Ethics at multiple pharmacy schools (UOP, USC, KGI, and others), and (3) as General Counsel for CPhA, the largest state pharmacist association in the nation.

To be clear, this communication is NOT on behalf of any of the aforementioned organizations. I only write on behalf of myself.

In short, I strongly believe that mandatory PIC training should NOT be Board-provided, but rather Board-approved, for the following reasons:

1. There are many, many different types of pharmacy businesses and operations, both inpatient and outpatient, and therefore a single, 1.0 hour, Board-provided CE will not adequately address any unique aspects of the PIC position relevant to any particular type of practice.
2. In fact, I have seen no evidence whatsoever that the currently required Board-provided Pharmacy Laws update and Ethics course have increased compliance, decreased violations, or increased more ethical behavior amongst pharmacists.
3. In stark contrast, however, I have seen the mandatory Board-approved cultural competency course positively impact pharmacists' perspectives on dealing with patients and coworkers with greater cultural competency.

With all due respect, the Board should allow the numerous practice types in the pharmacy industry to self-determine the most appropriate content for PIC training necessary for their respective fields. Therefore, I strongly suggest that the Board merely provide specific learning objectives, as it already successfully does for its mandatory cultural competency CE, and allow the industry to determine their content.

Thank you, and please contact me at your convenience for any questions or for more information on this matter.

Tony.

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Tony J. Park, Pharm.D., J.D.

Principal Attorney
California Pharmacy Lawyers



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From: Compliance Department <compliance@slnsupport.com>
Sent: Monday, October 21, 2024 7:18 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Fwd: [#235053] California non-resident PIC

Ticket ID : 235053

Hello,

I hope this message finds you well. Our office has been tracking the progress of the proposed amendment to Rule 1709.1 that establishes, among other things, some training requirements for the pharmacist-in-charge ("PIC"). We have a question regarding this rule and we hope you can be of assistance.

Could you clarify how is the training requirement going to apply to non-resident pharmacies?

Kind Regards,

Ambar Cosme Pabon
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November 1, 2024

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95834

Submitted electronically via email to PharmacyRulemaking@dca.ca.gov

Dear Ms. Martinez:

This letter is in response to the notification of proposed modifications to Title 16 CCR § 1709.1, related to the designation of pharmacist-in-charge. CenterWell Pharmacy Inc. (CenterWell Pharmacy) appreciates the opportunity to provide comments to the California State Board of Pharmacy (Board).

The proposed language states in part, "For purposes of this section, a completed attestation statement shall include all of the following: name of the proposed pharmacist-in-charge, the individual's license number...."

To add additional clarity to this language, we suggest changing "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."

Conclusion

Thank you for the opportunity to provide feedback to the Board on the proposed rules. Please feel free to contact me if you have any questions related to the comments.

Sincerely,

A handwritten signature in black ink that reads "Scott Clark".

Scott Clark
Vice President, Professional Practice
sclark8@humana.com

CenterWell Pharmacy is a full-service home delivery pharmacy serving patients across all 50 states. CenterWell Pharmacy provides personalized and coordinated holistic care with easy-to-use options so our patients can receive the care and prescriptions that they need when they need them. These services include prescriptions delivered straight to patients, as well as retail and specialty pharmacy services. Our pharmacies employ many pharmacists and pharmacy technicians who are critical to ensuring that patients across the country, including those in California, have access to necessary medications.