



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 VI. Discussion, Consideration and Possible Action Related to Proposed Regulations, Title 16, California Code of Regulations Section 1709.1, Related to Designation of Pharmacist-in-Charge, Including Review of Comments Received During the 45-Day Comment Period

Background:

At the January 28, 2022, Board meeting, the Board approved 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. Several comments were received during the comment period.

Attached following this memo are the following:

1. The proposed text released for the 45-day public comment period.
2. Board staff prepared summarized comment with recommendation.
3. Comment received during the 45-day comment period.

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation text as noticed on November 17, 2023.
2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

Possible Adoption Language:

Accept the Board staff recommended comment response and adopt the regulation text as noticed on November 17, 2023. Additionally, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Title 16. Board of Pharmacy Proposed Text

Proposed changes to current regulation text are indicated with single strikethrough for deletions and single 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 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.
- (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 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 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: Board staff does not recommend any changes to the text based upon the comment. Board staff do 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. Board staff refer 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.

Response to Comment 2: Board staff does not recommend any changes to the text based upon the comment. Board staff 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. Board staff also note 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. Commenter provided an antidote about a PIC at CVS being issued a citation for numerous violations and he had received no training before taking the role. Mr. Raus indicates being PIC is a role he would not take again. In addition to his support of the proposed regulation, commenter encourages the Board to enforce current regulations.

Response to Comment 3: Board staff does not recommend any changes to the text based upon the comment. Board staff 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: Board staff notes that the proposed addition would expand the Board's policy direction in this area and Board staff request direction from the Board with respect to this comment.

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: Board staff does not recommend any changes to the text based upon the comment. Board staff notes that this comment is outside the scope of this regulatory change and comment period. Board staff notes Assembly Bill 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. Additionally, 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: Board staff notes that the proposed addition would expand the Board's policy direction in this area and Board staff request direction from the Board with respect to this comment.

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.

Response to Comment 7: Board staff does not recommend any changes to the text based upon the comment. Board staff acknowledges commenters support of the proposed regulation. Board staff 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: Board staff does not recommend any changes to the text based upon the comment. Board staff notes that this comment is outside the scope of this regulatory change, comment period, 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 Business and Professions Code (BPC) section 4113 be added to subdivision (a), as the section "more clearly describes the requirement to submit a PIC Change Application...."

Response to Comment 9: Board staff does not recommend any changes to the text based upon the comment. Board staff 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: 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 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: Board staff notes that the proposed addition would expand the Board's policy direction in this area and Board staff request direction from the Board with respect to this comment.



Mark Johnston, R.Ph
Executive Director,
Board of Pharmacy Regulatory Affairs

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Woonsocket, RI 02895

401-601-1968

Mark.Johnston@cvshealth.com

12/28/23

Lori Martinez

Address: 2720 Gateway Oaks Drive, Ste. 100

Sacramento, CA 95833

PharmacyRulemaking@dca.ca.gov

Dear Ms. Martinez,

I am writing to you in my capacity as Executive Director of Pharmacy Regulatory Affairs for CVS Health ("CVS") and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of California through our integrated offerings across the spectrum of pharmacy care that includes over 1,000 pharmacies located within California. We appreciate the opportunity to submit comments on the California Board of Pharmacy's ("Board") proposed amendments to 1709.1 of Article 2 of Division 17 of Title 16 of the California Code of regulations.

CVS is fundamentally opposed to Pharmacist-in-Charge (PIC) requirements that exceed licensure as a California pharmacist. Our opposition is based upon a declining pool of pharmacists available for hire and for potential promotion to a PIC position. At the 2023 National Association of Boards of Pharmacy, District VI, VII, and VIII meeting, which was attended by representatives of the Board, declining pharmacy student enrollment was unveiled. The number of pharmacy school students enrolled at all institutions who entered class in 2018 was 15,192, and this decreased by nearly 1,000 students a year until the 2022 class who enrolled 12,580 students. In 2023 only 9,324 students were enrolled. While other states such as New Hampshire are eliminating the PIC requirement, thus following Maryland who has never required a PIC, California is proposing to establish barriers to entry as a PIC.

CVS Health is also fundamentally opposed to incorporating by reference a "Pharmacist in Charge Overview and Responsibility training course" that does not currently exist, as it violates Title 1 of the California Code of Regulations pertaining to the publication of regulations. The proposed "board-provided Pharmacist-in-Charge Overview and Responsibility training course" ("Training Course"), found in § 1709.1(a), is an undefined course of an unknown length, unknown cost, unknown content, unknown availability, and unknown requirements, such as a final exam.

The provisions of the proposed regulation pertaining to the Training Course are not required by California statute or other applicable law specifically requiring the adoption or enforcement of the incorporated material by the Board. Therefore, the incorporated material requires review by the Office of Administrative Law ("OAL") as required under 1 CCR § 20(b). Furthermore, 1 CCR § 20(c)(4) requires the regulation text to state that the document is incorporated by reference and identifies the document by title and date of publication or issuance. This was not achieved in the proposed regulation. These requirements are in place to avoid regulatory agencies from re-interpreting or placing new requirements into incorporated

material, such as changes to course length, cost and frequency, and thus, running the risk of statutory overreach or unjustly placing fiscal burdens on the regulated community without a proper fiscal analysis or an opportunity for the regulated community to provide public comment.

In summary, CVS believes that this proposed amendment should be returned to committee to consider the reduction of barriers into a PIC role or, more effectively, the elimination of the PIC role, pharmacy student enrollment rates, and the legality of incorporation by reference. Feel free to contact me directly.

Sincerely,



Mark Johnston, R.Ph

CVS Health,

Executive Director,

Board of Pharmacy Regulatory Affairs

From: Mark Raus <markraus78@gmail.com>
Sent: Saturday, November 18, 2023 1:23 PM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Cc: Cudmore, Jessica@DCA <Jessica.Cudmore@dca.ca.gov>
Subject: Changes to Section 1709.1

Lori,

I have been a practicing pharmacist since I was licensed in 1984. I was a former PIC for many years and am currently working in the retail setting as well as President of the Independent Pharmacists' Association, a union of over 120 pharmacists and interns in the Northern California area. I personally support this addition to the regulations. I recall a story from a Board Inspector, who walked into a CVS pharmacy in California, and promptly wrote up the ill prepared, poorly trained, noncompliant, understaffed PIC for numerous violations. That PIC commented to the Board Inspector that he should never have allowed management to talk him into taking that position. No training, wet behind the ears, etc. As for me, with the training and skills, and a clean license, necessary to be a PIC, I won't do it again. I don't trust management to back me up. Just look at Raley's in Oroville ((PHY53490) where former Board Inspector Patricia Peterson literally walked off the job when she was deliberately understaffed (one tech retired and one tech went on paternal pregnancy leave with months to prepare for both) and 1 week behind in filling prescriptions. All we got from management was a shoulder shrug and "I'm sorry". Total failure on their part. When they posted the position, it took 70 days to fill. That's right, well beyond the 30 days. Management could not be trusted. The owners were fined the maximum of \$5000. Big deal. Chump change. And they continue to defy the board. See Complaints: CI2023 101952, CI2022 100978, CI2021 95408. CI2021 95409, CI2021 95217. I saw the recent newsletter and noticed this problem is pervasive with numerous citations. You should list them individually, so we can boycott those stores until they are in compliance. Store PHY53495 is well past 90 days without a PIC despite having options (a licensed supervisor can step down and take the spot) to remedy the situation. At store PHY53490, several years ago, the PIC there asked management for an extra clerk while they were going through a major software change. The Supervisor said NO. So the PIC quit. No one would take the job. After 30 days, that supervisor sent his name to the BOP as the new PIC, yet did not work a single shift there for 6 months, except when the pharmacy was closed due to a possible dam failure. You can't do a good job unless you have enough trained staff to safely fill prescriptions in a timely manner and comply with all the Board regulations.

So...yes, I support the regulation. But I encourage you to enforce the current regulations. Fines and citations are now just a cost of doing business in California, not notices for change and supporting compliance.

Mark Raus RPh
PHY38734



January 1, 2024

Lori Martinez
 2720 Gateway Oaks Drive Ste. 100
 Sacramento, CA 95833
 Email: lori.martinez@dca.ca.gov

RE: Title 16 CCR 1709.1 Designation of Pharmacist-in-Charge (PIC)

Ms. Martinez:

On behalf of the California Society of Health-System Pharmacists (CSHP) we are submitting comments to the regulatory rule making proposal to amend 16 CCR section 1709.1.

§ 1709.1. Designation of Pharmacist-In-Charge	Comments and Suggestions
<p>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. <u>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 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</u></p>	<p>While the proposed regulation adds administrative burden to pharmacists and pharmacies, it is recognized that there might be unawareness by some pharmacists of the responsibilities that are associated with the PIC role and their duty to be aware of the potential for subversion of their efforts in complying with pharmacy law. This proposed regulation has the benefit of potentially creating awareness.</p> <p>A substantial shortcoming of the proposed regulation is that there is no responsibility assigned to what the law refers to as the ‘pharmacy owner’. At times, PICs experience pressure from owners, executives, and administrators to violate and bend laws and regulations and there is general unawareness that their actions can be considered subversion of the efforts of the PIC. It is therefore suggested 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.</p> <p>It is our recommendation that this section be amended as follows (noted in red font):</p> <p>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. <u>Prior to approval of the board, and as</u></p>

<p><u>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.</u></p>	<p><u>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 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. 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.</u></p>
<p>(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.</p>	<p>Frequently PICs are confronted with lack of resources to execute their authority to assure compliance with pharmacy related laws. As such we recommended the following language (noted in red font)</p> <p>(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority and resources to assure compliance with the laws governing the operation of a pharmacy.</p>
<p>(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.</p>	<p>No comment</p>
<p>(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.</p>	<p>No comment</p>
<p>(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</p>	<p>This section outlines who may be temporarily designated as PIC. We would like to request that training be mandated for individuals assuming this temporary role. This requirement would depend on the format of the training. For example, a prerecorded webinar would be more readily available to temporary PIC’s.</p>

<p>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 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-incharge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.</p>	
<p>(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.</p>	<p>No comment</p>
<p>(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.</p>	<p>No comment</p>

Sincerely,



Loriann De Martini, PharmD, MPH, BCGP
 Chief Executive Officer
 California Society of Health System Pharmacists



Lorri Walmsley, RPh., FAzPA
Director, Pharmacy Affairs
Walgreen Co.
5330 E. Washington St, Ste. 105
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lorri.walmsley@walgreens.com

December 22nd, 2023
California State Board of Pharmacy
Attention: Anne Sodergren, Executive Director
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Via Email:

RE: § 1709.1. Designation of Pharmacist-In-Charge

Dear Executive Director Sodergren and members of the California Board of Pharmacy,

On behalf of all pharmacies owned and operated by Walgreen Co. licensed in the State of California, we thank the Board for the opportunity to comment on the proposed rules. We ask the board to review our comments, concerns, and suggested edits to the proposed rules.

Walgreens supports and promotes the board's mission to ensure that a Pharmacist-in-Charge (PIC) is appropriately trained and qualified to ensure compliance in their pharmacy. However, in § 1709.1.(a) we feel that the requirement to complete the training program before the application is problematic and may result in pharmacies having gaps in PICs due to not having qualified candidates that have completed this in advance of an opening. We respectfully request the proposed change below.

§ 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 within two years prior to the date of application **or within 90 days of appointment.** ~~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.~~

In addition to the current proposed edits to § 1709.1. Designation of Pharmacist-In-Charge we also request the the Board consider removing the mileage requirement for a pharmacist-in-charge to oversee two locations. The 50-mile requirement is arbitrary and 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. Leaving it open allows the pharmacist the discretion to determine what is reasonable based on the specific circumstances. As such we consider that the Board consider the following amendment:

- (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.**

Walgreens thanks the Board for the opportunity to comment on these proposed regulations. If the Board would like additional information, please feel free to contact me.

Sincerely,

Lorri Walmsley, RPh, FAzPA



December 21, 2023

Lori Martinez
California State Board of Pharmacy
2720 Gateway Oaks Dr., Ste 100
Sacramento, CA 95833

Submitted via electronic mail to: Lori Martinez, California State Board of Pharmacy

RE: *Proposal to amend §1709.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations*

Dear Ms. Martinez:

Kaiser Permanente appreciates the opportunity to respond to the California Board of Pharmacy's request for comments on the proposed amendments to the Board's regulations pertaining to the designation of a Pharmacist-in-Charge (PIC) of a California-licensed pharmacy. Kaiser Permanente comprises the non-profit Kaiser Foundation Health Plan, the non-profit Kaiser Foundation Hospitals; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan. These entities work together seamlessly to meet the health needs of Kaiser Permanente's nine million members in California. Kaiser Permanente's pharmacy enterprise in California is comprised of hundreds of licensed pharmacies that are staffed by thousands of individual pharmacy licentiates.

Kaiser Permanente believes that requiring PICs to complete a Board-developed training program and attestation is a commonsense approach to strengthen pharmacists' understanding of the authorities and obligations placed upon a PIC. Based on the narrative in the Initial Statement of Reasons, we believe that the Board intends for a PIC to complete the training program and attestation both when the initial PIC is designated as part of pharmacy facility license application and when a subsequent PIC is designated using the Board's Change of PIC Application. Although the reference in the regulation to California Code of Regulations section 1709 is probably sufficiently broad to include both the initial designation of a PIC and subsequent PIC changes, we encourage the Board to consider whether the regulation could be modified to make the intent clearer. One possible approach would be to modify the regulation (see proposed modification in red underlined font below) to reference section 4113 of the Business and Professions Code, which more clearly describes the requirement to submit a PIC Change Application to the Board.

(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") and in Section 4113 of the Business and Professions Code, a pharmacy shall submit its proposed PIC....

Kaiser Permanente appreciates the opportunity to provide feedback in response to the proposed amendments to the Board's regulations pertaining the designation of a PIC of a California-licensed pharmacy. If you have questions, please contact John Gray (562.417.6417; john.p.gray@kp.org) or Rebecca Cupp (562.302.3217; rebecca.l.cupp@kp.org).

Respectfully submitted,



A handwritten signature in black ink, appearing to read "JP Gray", with a long, sweeping horizontal line extending to the right.

John P. Gray, PharmD, MSL
Director, National Pharmacy Legislative and Regulatory Affairs
Kaiser Permanente

Late Comments:

Received After the
Closure of the
Comment Period

From: Compliance Department <compliance@slnsupport.com>
Sent: Wednesday, January 3, 2024 11:37 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Amendment Section 1709.1 of Title 16, Div. 17, Art. 2 - Designation of Pharmacist-in-Charge

Good afternoon.

I'm contacting you to inquire about the proposed amendment to Section 1709.1 regarding the designation of pharmacist-in-charge. Said amendment states that, prior to approval of the BOP, the proposed PIC must comply with the BOP provided training within two (2) years prior to the date of application and corresponding attestation.

It is not clear if the new requirements will apply to non-resident pharmacies or specifically to in-state pharmacies. Will you be so kind and let us know if non-resident pharmacies will have to comply with these requirement? Thank you very much in advance.

Kind Regards,

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From: Sandra Bardas <sandbar1343@gmail.com>

Sent: Tuesday, January 30, 2024 12:33 PM

To: Damoth, Debbie@DCA <Debbie.Damoth@dca.ca.gov>

Subject: . Discussion and Possible Action Related to Proposed Regulations, Title 16, California Code of Regulations, Section 1709.1, Related to Designation of Pharmacist-in-Charge,

Members of the Board of Pharmacy,

Unfortunately, I missed the 45 day comment period for this topic. However, please consider my comments at this time.

I am a Pharmacist-in-Charge under Pharmacy Clinic Permits for free standing, physician owned ambulatory surgery clinics. These clinics are accredited by an Ambulatory Surgery Accreditation Agency. I am classified as a consultant, not an employee. I am not on the premises except for site visits. I do comply with providing the quarterly inventory count and a written report of my visit detailing areas of compliance and areas which need attention. It has been challenging to implement compliance with the newest regulations involving sterile compounding and the Drug Supply Chain Security Act (DSCSA).

It would be helpful to amend the proposed regulation 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 as described. However, I would clearly specify that this requirement includes holders of a Pharmacy Clinic Permit. Since the PIC for a Clinic Pharmacy Permit does not have the range of duties that a PIC in a pharmacy has, I would suggest that there be a special course addressing the duties and responsibilities in these circumstances.

It may be helpful to include those pharmacists who work in this area to help design and update these required courses. We are sensitive to the issues involved.

Respectfully,

Sandra Leigh Bardas RPH32539