



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 V. 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

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. 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 the revised text for a 15-day comment period on April 29, 2024, which ended on May 14, 2024. Two comments were received during this comment period.

Attached following this memo are the following:

1. The modified text released for the 15-day public comment period.
2. Board staff prepared summarized comment with recommendation.
3. Comments received during the 15-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 April 29, 2024.
2. Amend the regulation to address concerns expressed by stakeholders and notice a second 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 April 29, 2024. 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.

Modified regulation text to the proposed regulation text are indicated with double strikethrough for deletions and double 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 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 15-day Comments Regarding Designation of Pharmacist-in-Charge with Board Staff Recommendations:

Written Comments from Lorri Walmsley, Walgreens

Comment 1: 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.

Response to Comment 1: Board staff does not recommend any changes to the text based upon the comment. Board staff note 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, Board staff notes that the Board previously considered the timeline for completion of the training course 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 2: 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 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 2: Board staff does not recommend any changes to the

text based upon the comment. Board staff note that this comment is outside the scope of the 15-day comment period. Further, Board staff notes that the Board previously considered the timeline for completion of the training course 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 3: 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 3: Board staff does not recommend any changes to the text based upon the comment. Board staff note that the Board previously considered the timeline for completion of the training course 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.



Lorri Walmsley, RPh., FAzPA
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May 13, 2024
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 the Pharmacist-in-Charge (PIC) is appropriately trained, qualified, and willing to take on the responsibility of ensuring compliance and promoting a safe working environment in their pharmacy. However, in § 1709.1.(a) we feel that the requirement to complete the training program prior to the date of application is problematic and may result in pharmacies having gaps in PICs. Data from the American Association of Colleges of Pharmacy show that pharmacy school applications have decreased by more than 60% in the last decade.¹ Pharmacies have staffing plans to ensure continuity of the operation of the pharmacy, however, in today's environment with declining enrollments in schools of pharmacy¹, staffing challenges are becoming increasingly more widespread and the filling of the PIC role even more challenging. This leaves pharmacy owners and operators challenged to find qualified PICs that meet the board's requirements and may result in pharmacy closures due to a gap in PIC. Allowing an individual 90 days to complete the state-required exam will ensure that pharmacies can continue to operate during the transition of a PIC. Of note, California remains only one of very few states to impose additional requirements on a pharmacist before assuming the role of a PIC. 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.~~

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

1. America Associate of Colleges of Pharmacy. "Academic Pharmacy's Vital Statistics" <https://www.aacp.org/article/academic-pharmacies-vital-tatistics#> Accessed (30 November 2023)

May 13, 2024

Anne Sodergren
Executive Officer
California State Board of Pharmacy
Department of Consumer Affairs (DCA)
2720 Gateway Oaks Drive Suite 100,
Sacramento, CA 95833
Anne.Sodergren@DCA.CA.GOV

Re: Board of Pharmacy Proposed Rules – Designation of Pharmacist-in-Charge [Request Amendment]

Dear Executive Officer Sodergren and Board Members,

I am writing to request an amendment to the California State Board of Pharmacy proposed rulemaking of *section 1709.1 of Title 16, Division 17, Article 2 of the California Code of Regulations*, which creates a new mandatory requirement for a pharmacist-in-charge (PIC) and interim PIC to complete a board-provided PIC overview and responsibility training course within two years prior to the date of application. Albertsons Companies Inc. (“ACI”) family of pharmacies is one of the largest pharmacy providers in the state of California. We currently operate 370 locations in the state under both the Albertsons, Vons, Pavillions, and Safeway banners. Nationwide, ACI operates 1726 pharmacies across 34 states and the District of Columbia.

Our pharmacies provide critical support to California’s healthcare infrastructure and in some cases the only available access to a pharmacy in rural communities. As technology and patient demand for pharmacists increase the reach of healthcare services, the pharmacy profession must rethink its barriers to entry, including the barriers to aspiring pharmacist leaders through mandatory PIC training requirements. ACI contends the proposed regulations will create the unintended consequences of new administrative staffing hurdles and further contribute to professional burnout.

We agree the training program being proposed and provided by the Board, free of charge, is not an undue burden. Albertsons sees value in having these pharmacists go through a voluntary training program. However, we believe the mandatory timeline requirement needs to be buttressed with the common realities of business and professional pharmacist decisions that can with limited notice, create an immediate need to designate an interim or new PIC. Existing pharmacy law (BPC § 4305) provides that operation of a pharmacy for more than 30 days without the supervision or management by a PIC constitutes grounds for disciplinary action. By way of definitive law, the California State Legislature believes a 30-day grace period is a necessary allowance that permits pharmacies a limited timeframe to designate a PIC. The legislature recognized and ensconced the reality that access to pharmacy services and the timeframe of PIC designation must be balanced. For the same patient safety reasons, we contend the Board should afford the same 30-day grace period to PICs to complete a training program after appointment.

Alternative Language Amendment Request:

§ 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 30 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.

...

(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 or within 30 days of appointment. 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

...

Albertsons also believes it is important to recognize the diverging paths states have taken in the last five years to address PIC pharmacy oversight, compliance with state and federal pharmacy laws, and pharmacist supervision. Each of the foregoing state boards of pharmacy has the same statutory mission as the California State Board of Pharmacy – protection of the public.

State Trends in Pharmacist-in-Charge and Pharmacy Jurisprudence Exam Requirements

Maryland, Idaho, and New Hampshire have never required, no longer require a PIC, and are in the process of removing PIC requirements from law, respectively.¹ Further, Idaho has implemented a disciplinary expungement process for formerly disciplined PICs resolving the inequity of a pharmacist carrying permanent discipline for laws (e.g. PIC registration, mandatory ratio supervision) that no longer exist.²

In 2018, Idaho removed the requirement for a pharmacist to pass the MPJE as a condition of licensure qualification.³ The decision to remove the MPJE has been followed by Vermont, Michigan, and Alaska, and has sparked a conversation among several national pharmacy organizations, including the American Pharmacist Association (APhA) for the creation of a more easily transferable pharmacist license, highlighting the particular challenge presented by the state-specific pharmacy law exams as a barrier.⁴⁻⁶ Ohio and New Hampshire have eliminated and proposed to eliminate the law exam for license transfer candidates, respectively. Published research from Idaho reviewing Prescription Drug Monitoring Program (PDMP) and National Practitioner Data Bank (NPDB) statistics provides that abolishing the PIC designation and jurisprudence exam has not resulted in any adverse public safety outcomes. Instead, Idaho has seen a surge in the number of licensed pharmacists, outpacing the growth in neighboring states.³

Concluding Summary

As drafted, it is unclear what the anticipated benefits of the mandatory *“upon application”* timeline requirement and believe we are proposing alternative language that is less burdensome to pharmacies while providing the same regulatory benefit as evidenced by the current allowances afforded in BPC § 4305. If the California State Legislature believes that *“it is appropriate for the training program to be completed prior to serving in that capacity”* they would not have provided pharmacies a 30-day grace period to appoint a PIC.

Thank you for the opportunity to provide public comment, particularly a second 15-day comment period on the modified proposed text! If you have any questions as it relates to the impact of these rules, please reach out to me at Rob.Geddes@Albertsons.com or 208-513-3470.

Sincerely,

A handwritten signature in blue ink, appearing to read "Rob Geddes".

Rob Geddes, PharmD, MBA
Director, Pharmacy Legislative and Regulatory Affairs
Albertsons Companies Inc.

CC:

Lori Martinez: PharmacyRulemaking@dca.ca.gov

References:

1. Adams, Alex J. "Eliminating the board of pharmacy's role in designating a pharmacist-in-charge." *INNOVATIONS in pharmacy* 11.3 (2020).
2. Adams, Alex J., and Timothy P. Frost. "Expunging board of pharmacy disciplinary actions." *Innovations in Pharmacy* 14.1 (2023).
3. Adams, Alex J., Timothy P. Frost, and Deeb Eid. "The basis for elimination of the jurisprudence examination as a condition of pharmacist licensure in Idaho." *American Journal of Pharmaceutical Education* (2023): 100119.
4. Vermont Board of Pharmacy. Meeting Minutes May 26, 2021. Available from: <https://sos.vermont.gov/media/u0aevfjm/unapproved-pharmacy-meeting-minutes-5-26-21.pdf> (Accessed April 9, 2024).
5. Michigan Board of Pharmacy. Meeting Minutes June 7, 2023. Available from: <https://www.michigan.gov/lara/-/media/Project/Websites/lara/bpl/Pharmacy/Rules-Work-Group--Agendas-Minutes-Notices/2023/6-7-23-Pharmacy-Rules-Work-Group-minutes-with-attachment.pdf?rev=e24658d3f639462c9b18f41f1fba131f&hash=5510924114C1C02ED08609C4109D82B5> (Accessed April 9, 2024).
6. American Pharmacists Association. Actions of the March 15, 2021. Virtual House of Delegates. Available from: https://www.pharmacist.com/Portals/0/PDFS/HOD/March_15_2021_Virtual_HOD_Session_Actions_FINAL.pdf?ver=ixb_o_r0k5IG0UiHVosAg%3D%3D (Accessed April 9, 2024).