

**State of California
Office of Administrative Law**

In re:
Board of Pharmacy

Regulatory Action:

Title 16, California Code of Regulations

Amend sections: 1709.1

NOTICE OF APPROVAL OF REGULATORY
ACTION

Government Code Section 11349.3

OAL Matter Number: 2024-1113-05

OAL Matter Type: Regular Resubmittal (SR)

This action proposes to require a Pharmacist-In-Charge to complete the Board of Pharmacy provided Pharmacist-In-Charge Overview and Responsibility training course and attestation prior to board approval.

OAL approves this regulatory action pursuant to section 11349.3 of the Government Code. This regulatory action becomes effective on 4/1/2025.

Date: December 23, 2024



Ashita Mohandas
Attorney

For: Kenneth J. Pogue
Director

Original: Anne Sodergren, Executive
Officer

Copy: Lori Martinez

NOTICE PUBLICATION/REGULATIONS SUBMISSION

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 10/2019)

RESUBMITTAL

OAL FILE NUMBERS	NOTICE FILE NUMBER	REGULATORY ACTION NUMBER	EMERGENCY NUMBER
	Z- 2023-1107-02	2024-1113-05	SR

For use by Office of Administrative Law (OAL) only

ENDORSED - FILED in the office of the Secretary of State of the State of California

DEC 23 2024

OFFICE OF ADMIN. LAW 2024 NOV 13 @ 4:59pm

Handwritten signature and initials

NOTICE	REGULATIONS
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AGENCY WITH RULEMAKING AUTHORITY CA Board of Pharmacy

AGENCY FILE NUMBER (If any)

A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
OAL USE ONLY <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn	NOTICE REGISTER NUMBER	PUBLICATION DATE	
	2023, 46-2	11/17/23	

B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)

1a. SUBJECT OF REGULATION(S) Designation of Pharmacist-in-Charge	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S) 2024-0904-01S
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)	ADOPT
SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	AMEND
TITLE(S)	REPEAL
16	1709.1

3. TYPE OF FILING	<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
	<input checked="" type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
	<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input type="checkbox"/> Other (Specify)	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)
October 17, 2024 - November 1, 2024

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)
 Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a)) Effective on filing with Secretary of State \$100 Changes Without Regulatory Effect Effective other (Specify)

6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY
 Department of Finance (Form STD. 399) (SAM §6660) Fair Political Practices Commission State Fire Marshal
 Other (Specify) Kimberly Kirchmeyer, Director, Department of Consumer Affairs

7. CONTACT PERSON Lori Martinez	TELEPHONE NUMBER (916) 244-6648	FAX NUMBER (Optional)	E-MAIL ADDRESS (Optional) Lori.Martinez@dca.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE <u>Anne Sodergren</u>	DATE 11/12/2024
TYPED NAME AND TITLE OF SIGNATORY Anne Sodergren, Executive Officer	

ENDORSED APPROVED For use by Office of Administrative Law (OAL) only DEC 23 2024 Office of Administrative Law

**Title 16. Board of Pharmacy
Order of Adoption**

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, 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.