

California State Board of Pharmacy 2720 Gateway Oaks Drive, Ste 100 Sacramento, CA 95833

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Business, Consumer Services and Housing Agency Department of Consumer Affairs Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item VIII. Discussion and Consideration of Adoption of Board Approved Regulations, Comments Pending Review by the Board

a. Proposed Regulation to Add Title 16, Section 1714.3, Community Pharmacy Staffing

Background:

At the July 2019 Board meeting, the Board approved proposed text to add Section 1714.3 of Title 16, CCR, related to community pharmacy staffing. This proposal will establish the criteria a pharmacy must meet to identify and ensure a person is assigned to assist the pharmacist as needed when the pharmacist is working as alone in compliance with B&P section 4113.5.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on February 28, 2020, which was scheduled to end on April 13, 2020. Due to Governor Gavin Newsom's Declaration of Emergency, the end of the comment period was extended to 5 p.m. on April 30, 2020.

To date the Board has received 5 comments. Any additional comments received will be provided to the Board at the Board meeting. Board staff and legal counsel will be available at the Board meeting to answer any questions. The proposed text and the comments received are attached following this memo.

At this Meeting

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

- 1. Adopt the regulation as approved at the July 2019 Board Meeting and noticed for 45-day comment on February 28, 2020.
- 2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

Possible Adoption Language: Adopt the regulatory language as noticed on February 28, 2020, and delegate to the executive officer the authority to make technical or non-substantive changes as may be required by Control agencies to complete the rulemaking file.

Possible Amendment Language: Approve the modified language and initiate a 15-day public comment period. Additionally, should no negative comments be received, 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.

Community Pharmacy Staffing 16 CCR § 1714.3

Title 16. Board of Pharmacy Proposed Regulation

Add section 1714.3 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1714.3. Community Pharmacy Staffing

This section applies to a community pharmacy that is required to comply with Business and Professions Code section 4113.5.

- (a) When a pharmacy is open to the public and a pharmacist is working without another pharmacy employee currently working, the pharmacy shall make another person who is an employee of the establishment within which the pharmacy is located available to assist the pharmacist. The pharmacy shall:
 - (1) Designate the name(s) of one or more persons who will be available to assist the pharmacist;
 - (2) Ensure that each designated person is able, at a minimum, to perform the duties of non-licensed pharmacy personnel as specified in section 1793.3;
 - (3) Ensure that each designated person qualifies to have access to controlled substances by conducting a background check on each person that is consistent with federal requirements for pharmacy employees with such access;
 - (4) Ensure that a designated person responds and is able to assist the pharmacist within five minutes after the pharmacist's request.
- (b) A pharmacy shall have and maintain policies and procedures that address the following:
 - (1) How a pharmacist on duty will be able to identify the person(s) designated as available to assist them, and the required criteria and training for those designated person(s), which shall be consistent with subdivison (a).
 - (2) The process for the pharmacist to request assistance and to document the response time between the request and arrival of the designated person at the pharmacy.
- (c) All impacted pharmacy employees and designated persons must read and sign a copy of the policies and procedures required by this section. For purposes of this section, "impacted pharmacy employees" means any employee of the pharmacy, whether the person works within or for the pharmacy owner, who has any duties to prepare for or to execute how or when a pharmacist may seek or obtain assistance pursuant to Business and Professions Code section 4113.5, including any pharmacist, any person who creates or approves

- pharmacy employees' work schedules, or who designates persons who may assist the pharmacist pursuant to this section.
- (d) The pharmacy must maintain the policies and procedures in the pharmacy premises in a readily retrievable format.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4110 and 4113.5, Business and Professions Code.

Community Pharmacy Staffing 16 CCR § 1714.3

45-Day Comments

45-Day Comments – Community Pharmacy Staffing

A hardcopy of the 45-day comments will be made available at the meeting or upon request. Requests may be emailed to Debbie.Damoth@dca.ca.gov.