

TITLE 16. Board of Pharmacy
DEPARTMENT OF CONSUMER AFFAIRS

Initial Statement of Reasons

Hearing Date: No hearing scheduled unless requested.

Subject Matter of Proposed Regulation: Discontinuance of Business

Section Affected: California Code of Regulations (CCR), Title 16, Division 17, Article 2, section 1708.2

Background and Statement of the Problem

The California State Board of Pharmacy (Board) is a state agency vested with the authority to license and regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (Business and Profession Code (BPC) section 4000, et seq.). The Board's mandate and mission are to protect the public (BPC section 4001.1).

The Board's current discontinuance of business regulations require a licensee to notify the Board and provide specified information; however, there are currently no provisions establishing requirements that help ensure continuity of patient care. The Board has received complaints from consumers and policy makers in two general areas:

1. A pharmacy has closed, and a patient cannot receive a refill because they are unable to contact the pharmacy to request a prescription transfer; and
2. A pharmacy has closed and transferred patient prescription refills to another pharmacy not of the patient's choosing.

In both such scenarios, patient care is impeded and many times, patients are required to seek a new prescription from their prescriber. The need to obtain a new prescription can delay treatment, which jeopardizes patient safety.

Additionally, the Board's Disciplinary Guidelines establish requirements that help ensure continuity of patient care in the event a premises license is surrendered or revoked. Specifically, the guidelines provide:

Respondent shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

This proposal establishes requirements that a closing pharmacy must comply with to ensure arrangements are in place to facilitate the continuity of patient care. At minimum, the pharmacy must provide a written notice to ongoing patients that includes the name of the patient, name and address of the pharmacy, name of the pharmacy where the patients' records will be transferred, and information on how to request a prescription transfer prior to the closure of the pharmacy. Additionally, the pharmacy must reverse all prescriptions for which reimbursement was sought but the prescriptions are not picked up by patients.

Anticipated benefits from this regulatory action:

The Board has determined that this regulatory proposal will have the following benefits to health and welfare of California residents and will not impact worker safety or the state's environment.

Protection of the public is the Board's highest priority in exercising its licensing, regulatory, and disciplinary functions. For many communities, the closure of a local pharmacy and loss of the pharmacist means that healthcare services and medications are interrupted and hard to reach. The proposed amendments to the existing regulations will help ensure that patients have seamless and continued access to their medications and other healthcare services.

A notice of the discontinuance of a pharmacy will increase patient awareness of planned pharmacy closures and mitigate destabilization in the patient's access to medications and healthcare services.

Specific Purpose of, and Rationale for, Proposed Changes

The Board's proposal makes the following changes:

A label has been added to the first paragraph to appropriately establish it at subsection (a). This change is nonsubstantive because it is "(1) renumbering, reordering, or relocating a regulatory provision" within the meaning of Title 1, CCR section 100(a)(1). This change is necessary for clarity. Additionally, Board has been capitalized at two locations within subdivision (a).

Further, subsection (a) is amended to add "individually or collectively referred to as a 'closure'" after the list of types of closures. The purpose of this addition is to identify and define a term that will be used in the subsequent subsection. This addition is necessary to provide clarity to the regulated public with respect to the use of term "closure" as used within subsection (b).

Subsection (b) adds the requirement that additional steps be completed when a pharmacy ceases operations due to a closure. The purpose of this addition is to introduce the information the closing pharmacy must include when informing patients of the closure. This addition is necessary to provide clarity to the regulated public by

informing them that they must comply with additional requirements (by providing certain information (that follows)) prior to a facility's closure.

Subsection (b)(1) through (b)(1)(D) adds the following:

- “(1) At least 30 days in advance of the closure, provide written notice to patients that have received a prescription within the last year. At a minimum, this notice shall include:
- (A) the name of the patient and if one exists and is known to the pharmacy, the name of the legal representative of the patient,
 - (B) the name and physical address of the pharmacy closure,
 - (C) the name of the pharmacy where patient records will be transferred and maintained, and
 - (D) information on how to request a prescription transfer prior to closure of the pharmacy.”

These requirements are similar to those found in the disciplinary guidelines for providing notice to patients in the event a premises license is surrendered or revoked. The purpose of these inclusions is to provide licensees with a list of the information they must (at minimum) include in a notice of closure, which must be in writing and provided at least 30 days prior to the closure. Providing this information in the notice of closure is necessary to inform licensees what information they must provide to help mitigate patient harm, so consumers do not have to wait additional and unexpected amounts of time for their medications. Further, the requirements protect a consumer's privacy, inform consumers of pharmacy closures, ensure consumers are informed regarding where they can receive their medication and healthcare services, and inform consumers about transferring their prescriptions prior to pharmacy closure so consumer are not delayed in getting their medications while ensuring the integrity of the prescriptions.

Subsection (b)(2) adds the requirement that the pharmacy reverse all prescriptions for which reimbursement was sought but the prescriptions are not picked up by patients. The purpose of this addition is to introduce the requirement that a closing pharmacy reverse all prescriptions for which reimbursement was sought if customers did not pick up their prescriptions. This is necessary to ensure pharmaceuticals are not dispersed to an unauthorized consumer and are disposed in accordance with California laws and regulations. Additionally, this ensures that, should prescriptions not be picked up by the consumers, the medications are not billed to any prescription coverage plan. Further, this will help ensure inappropriate billing does not occur and that patients are able transfer and receive prescription services at a different pharmacy.

Subsection (b)(3) adds the requirement that the facility provide the Board with a copy of the notice specified in subsection (b)(1). The purpose of this addition is to ensure the Board is able to verify that the closing pharmacy properly notified patients. This addition is necessary to ensure that the Board can verify the closing pharmacy (licensee) met the notice/reporting requirements by having the licensees provided these notices to the Board as well. This will allow the Board to maintain closure information and ensure that the facility is providing this information to its patients.

Subdivision (b)(4) adds the requirement that the pharmacist-in-charge certify compliance with the requirements in this section and, in the event the pharmacist-in-charge is no longer available, the owner must certify compliance, along with a pharmacist retained to perform these functions. The purpose of this subdivision is to outline who the responsible party or entity is for reporting purposes. This certification is necessary to provide the Board with the identity of the individuals who completed these tasks in the event there are questions or, if a complaint is received, inform the Board who to contact to obtain additional information.

Underlying Data

1. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held February 6, 2023 (Meeting Materials Agenda Item XII, Agenda.)
2. Relevant Meeting Materials and Minutes from Licensing Committee Meeting held January 24, 2023 (Meeting Materials Agenda Item VII, Meeting Minutes.)

Business Impact

The Board has made an initial determination that the proposed regulatory action will not have a significant statewide adverse economic impact directly affecting businesses or employees, including the ability of California businesses to compete with businesses in other states. The closing pharmacy can provide the required notice within normal business operations with no additional workload or costs. The Board does acknowledge there will be some steps to notify patients, but these requirements can (and should) be part of the (closing) pharmacy's normal business operations, i.e., part of the normal process to wind down and discontinue operations. The Board estimates that it would improve consumer protection outcomes when patients are notified of impending closures and continue to have the ability to access their medications in a timely manner.

Economic Impact Assessment

The Board has determined that this proposal will not:

- (1) create jobs within California;
- (2) eliminate jobs within California;
- (3) create new businesses within California;
- (4) eliminate of existing businesses within California;
- (5) expand businesses currently doing business in the State of California.

The Board determined that this proposal will not create or eliminate jobs or businesses. The proposed regulation provides clarity to consumers with respect to closure of pharmacies. Additionally, the proposal identifies the specific requirements for discontinuation of business. The estimated cost to the pharmacy would be the staff time spent alerting the consumer of the impending closure, arranging for the continuation of care for existing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients

This regulatory proposal benefits the health and welfare of California residents. Existing pharmacy regulations require a licensee to notify the Board of impending pharmacy closure and provide specified information; however, there are no provisions establishing conditions for continuity of patient care, including informing patients of the impending closure. Furthermore, the Board's Disciplinary Guidelines establish requirements for continuity of patient care in the event a premises license is surrendered or revoked, yet no similar requirements exist for licensees discontinuing business.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. The Board welcomes the public to comment and propose alternatives.

Description of reasonable alternatives to the regulation that would lessen any adverse impact on small business:

No such alternatives have been proposed, however, the Board welcomes comments from the public.