

Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Notification of Temporary Closure

Section Affected: California Code of Regulations (CCR), Title 16, Division 17, Amend Section 1708.1

Hearing Date: None unless requested, see Notice of Proposed Action

The board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, hospital pharmacies, clinics, wholesalers, third-party logistics providers, and outsourcing facilities. The board's mandate and its mission is to protect the public Business and Professions Code (BPC) section 4001.1.

Problems Addressed

Existing pharmacy law does not establish a requirement for a pharmacy licensee to notify the board of a temporary closure of a licensed facility. For the past several years, typically in response to declared disasters, but also in response to construction issues, board licensed facilities must temporarily close. More recently, regrettably, a significant number of pharmacies were damaged or destroyed due to civil unrest. In many cases the damages occurred to several pharmacies in the same region. These closures can interrupt patient care by limiting access to prescription medication in that geographic area.

In order to provide clear and accurate information to the public, this proposal will require each permit holder to notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. Further, it specifies that the closure status will be public information.

Anticipated Benefits of the Proposed Regulations

Requiring notifications will ensure consistent reporting requirements for businesses licensed by the board and will allow the board to plan inspection activity and ensure licensees, other healthcare practitioners, and consumers have current operational status information when searching for a licensed facility on the board's website. Additionally, the notification will allow the board to maintain a more accurate operational history of its licensees.

Specific Purpose of Proposed Changes and Rationale

The section heading for 16 CCR 1708.1 is added to read "Notification of Temporary Closure," which provides clarity to the regulated public regarding the requirement of the regulation section.

The requirement is added with no subdivision label and reads: "A permit holder shall notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. Closure dates will be public information. The board determined that requiring notice to the board if a pharmacy is closed more than three consecutive days will allow some flexibility to the pharmacy by not requiring notice should the pharmacy be closed less than three consecutive days, with the need to provide accurate closure notice to the public and healthcare practitioners in the event patient care may be interrupted. Further, by sharing this information with the public, patients will be informed if their local pharmacy is closed, which will allow patients and healthcare practitioners to make informed decisions about the availability of prescription medications and the possible need to contact another pharmacy.

Underlying Data

1. Relevant Meeting Materials and Minutes from Board Meeting held July 29-30, 2020
2. Relevant Meeting Materials and Minutes from Board Licensing Committee Meeting held July 8, 2020

Business Impact

The board made a determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees. This initial determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over several months in numerous board and committee meetings.

Additionally, the board determined that the notification can be as simple as an email or a statement faxed or mailed to the board once the facility has been closed for three consecutive days. As a result, no additional costs are anticipated for businesses operating in the state.

Economic Impact Assessment:

The board has determined that:

- (1) this proposal will not create jobs within California;
- (2) this proposal will not eliminate jobs within California;
- (3) this proposal will not create new businesses within California;
- (4) this proposal will not eliminate existing businesses within California;
- (5) this proposal will not expand businesses currently doing business in the State of California.

The board determined that this proposal will not create, expand, or eliminate jobs or businesses. The proposal establishes the requirement for each permit holder to notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days, which can be a simple written statement faxed or emailed to the board.

The board has determined that this regulatory proposal may impact the health and welfare of California residents. The proposal establishes the requirement for licensees to notify the board when the facility will be closed for more than three consecutive days. This will be public information, which California residents can obtain from the board's website. This can help ensure that California residents can find an open licensed facility to obtain patient care. The proposal will not impact worker safety, housing, or the state's environment.

Fiscal Impact Assessment:

The proposed regulations may result in an increase in reports of facility closures to the board. In 2020, the board received approximately 300 reports of closures.

According to the board, a Staff Services Manager I, Specialist (SSMI) typically takes ten minutes to process each report of closure and ten minutes for each reopening at a cost of approximately \$15 per report or \$30 total (closing and opening), which results in total costs of approximately \$9,000 per year for 300 closures per year.

Specific Technologies or Equipment

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

DUPLICATION OR CONFLICT WITH FEDERAL REGULATIONS

None.

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 considered not requiring licensees to notify the board of temporary closures; however, the board determined that this was not appropriate as the board would continue to be unable to provide consumers with accurate notice of closed facilities.