

TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Notification of Temporary Closure

Section Affected: Amend Title 16 California Code of Regulations (CCR) section 1708.1

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on October 29, 2021 and ended on December 13, 2021. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the Board during the 45-day comment period.

During the 45-day comment period several comments were received. At its January 27, 2022 Board meeting, the Board voted to amend the regulation text and release the modified text for a 15-day comment period.

The regulation text was amended to exempt correctional pharmacies and to clarify that holiday closures and routine closures (of four consecutive days or less) also do not need to be reported. These exemptions preserve the intent of the Board, which is protecting the general public by advising them of pharmacy closures. The Board determined that the exemption for correctional pharmacies was appropriate because correctional pharmacies do not serve the general public, so reporting closures of these facilities would not provide beneficial information to the public. The Board determined that routine closures and closures for state and federal holidays do not need to be reported for clarity. The Board determined four days was appropriate due to the routine nature of state and federal holidays. Four days would eliminate the need for pharmacies to report closures over the Thanksgiving Holiday, which generally runs Thursday through Sunday.

As a result of amendment to the proposed text, the Board determined that the number of closure reports the Board would receive will be minimal and not exceed the quantity currently received by the Board, barring a natural disaster or other societal disturbance. As such, the Board determined that the fiscal impact previously identified in the Notice and Initial Statement of Reasons was no longer accurate. The Board amended the fiscal impact to zero.

The 15-day public comment period began on January 28, 2022 and ended on February 12, 2022. During the 15-day comment period no comments were received. As no comments were received, the regulation was adopted by the Executive Officer per the delegation issued by the Board on January 27, 2022.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

While the Board does not have, nor does it maintain, data to define if any of its licensees (pharmacies) are a “small business” as defined in Government Code section 11342.610, the Board has made the determination that this proposal will not have a significant adverse impact directly affecting small businesses. 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 four consecutive days. As a result, no additional costs are anticipated for businesses.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. 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.

Objections or Recommendations/Responses to Comments

During the public comment period from October 29, 2021 to December 13, 2021, the Board received several comments, which were provided in the meeting materials for the January 27, 2022 Board meeting, and the Board reviewed and considered them.

Summarized 45-day Comments Regarding Notification of Temporary Closure:

Written Comments from Greg Doe, CA Correctional Health Care Services

Comment 1: The commenter expressed concern about the requirement for Correctional Pharmacies to report temporary closures exceeding three days. The commenter indicated that Correctional Pharmacies are closed over the Thanksgiving holiday (Thursday – Sunday) which would require the reporting of 40 closures yearly. Further, the commenter indicated that patients continue to be served during these closures via

ADDS machines. Additionally, the commenter indicated that Correctional Pharmacies do not serve the general public.

Response to Comment 1: The Board reviewed this comment and made changes to the text based thereon. The Board amended the language to clarify that holiday and routine, short-term (four days or less) closures need not be reported, and to exempt Correctional Pharmacies, as they do not serve the general public. These changes preserve the intent of the Board in protecting the public. Additionally, CA Correctional Health Care Services indicated that it provides medications to its inmate patients twenty-hour hours a day, seven days a week, which obviates the need for reporting of closures.

Written Comments from Anthony Lorenzana, Clinicas del Camino Real

Comment 2: The commenter indicated that his pharmacy is closed over the Thanksgiving holiday (Thursday – Sunday) and he is unclear if he would need to report the closure to the Board. The commenter requested clarification on the definition of “temporary closure.”

Response to Comment 2: The Board reviewed this comment and did not amend the proposed text based on the comment beyond the changes made in response to Comment 1. The Board believed that the modified text addressed the commenter’s concern.

Written Comments from Lorri Walmsley, Walgreens

Comment 3: The commenter expressed concern about the requirement to report closures in the event of a natural disaster or when a pharmacy is closed on the weekends and would need to report after one day as it poses a burden on the pharmacy.

Response to Comment 3: The Board reviewed this comment and did not make any changes to the text based thereon due to natural disasters, etc. The Board made edits to clarify routine closures due to holidays, including routine closures of four days or less, do not need to be reported. The Board did not agree that reporting a closure is burdensome for a pharmacy as the report can be made by the pharmacist-in-charge via email to the Board, which takes only a minute or two. As discussed at previous Committee and Board meetings (July 2021 Committee and Board meeting), the Board determined that the public needs to know whether their local pharmacy is open during a state of emergency or if they need to seek services elsewhere. As such, it is necessary for pharmacies to report closures during a state or federal emergency as not all locations may be closed.

Written Comments from Marie Cottman, Pharm.D.

Comment 4: The commenter indicated that, as a small business owner, she occasionally closes her pharmacy for more than three days. The commenter indicated that she plans these closures in the advance and coordinates with patients and providers. The commenter requested that the language be amended to specify “unplanned” closures.

Response to Comment 4: While this comment was received after the closure of the comment period, the Board reviewed this comment and believes that the modified text addressed the commenter’s request, as discussed above.

The 15-day public comment period began on January 28, 2022 and ended on February 12, 2022. As no comments were received during the 15-day comment period, the regulation was adopted by the Executive Officer per the delegation issued by the Board on January 27, 2022.