

TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Off-Site Storage Waivers

Section Affected: Title 16 California Code of Regulations (CCR) section 1707

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 February 7, 2020, and ended on March 23, 2020. 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 comment period.

During the 45-day comment period, one comment was received. On May 7, 2020, the comment was reviewed and rejected. During a review of the regulation, the Board amended the regulation text to include the identification of items the Board may consider when making its determination on whether to grant approval to store records off-site. The Board determined space limitations within the pharmacy should be considered as a staff safety risk if the pharmacy does not have adequate space onsite to store records. The Board further determined that cost should be considered if the pharmacy has to expand to increase the available storage space. The Board also determined that previous compliance with records requirements and the ease of which the pharmacy can access the records should be considered. As subsection (b)(2) requires the pharmacy to be able to produce the records within two business days, if the pharmacy would be unable to comply with this requirement, the waiver should not be granted. Previous compliance with records requirements is the existing requirement. The Board determined that it should still be considered; however, it should not be a blanket rejection as previously required because space limitations could pose a risk to staff safety. Additionally, the Board determined that additional factors should also be considered based on the licensee's specific situation. The Board determined that allowing for the consideration of additional factors allows for flexibility for our licensees. If a licensee has a specific situation that would not apply to other locations the Board can consider it and the explanation of the impact that the licensee provides. This allows the Board to consider unusual circumstances that do not occur at every licensed facility. The amended language makes the regulation clearer to the regulated public with respect to what the Board may consider when reviewing requests to store records off-site.

The Board voted to initiate a 15-day public comment period. If no negative comments were received, the Board voted to delegate to the Executive Officer the authority to adopt the modified text.

Modified Text

The 15-day public comment period began on May 19, 2020, and ended on June 3, 2020. One comment was received. The 15-day public comment was the same comment received during the 45-day public comment period. Pursuant to the Board's May 7, 2020 motion, the Executive Officer adopted the modified text.

Local Mandate

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

Economic Impact

Under the proposed regulations, a pharmacy currently unable to be granted a waiver due to violations of Business and Professions Code (BPC) section 4081, as specified, will be able to attain a waiver. The Board indicates approximately 10 to 15 pharmacies are denied a waiver per year due to BPC 4081 violations and these pharmacies could be granted a waiver.

The Board notes, the proposed regulations do not require pharmacies to utilize off-site storage facilities and therefore do not have a direct economic impact. However, to the extent a pharmacy having violated BPC 4081 is granted a waiver under the proposed regulations, these entities may incur costs related to off-site storage.

According to the Board, off-site storage facilities typically charge between \$0.30 to \$0.95 per bankers box per month for storage. The Board does not have an estimate of the average number of bankers boxes used for storage purposes of these impacted pharmacies and therefore does not have an estimate of total storage costs.

However, any additional costs would be considered part of normal business processes and considered minimal.

Small Business Impact

While the Board does not have nor does it maintain data to define if any of its licensees are "small businesses" as defined in Government Code section 11342.610, the Board determined that any adverse economic impact will not be significant. The proposed regulation is not imposing a requirement on licensees. The proposal will allow the Board more discretion when

approving a waiver and clarify that a waiver will allow storage of these records outside of the licensed area of the pharmacy.

Fiscal Impact

The Board anticipates 10 to 15 pharmacies may be granted a waiver under the proposed regulations. The Board indicates it will ensure compliance through the current inspection process. As a result, the proposed regulations are not anticipated to increase workload or costs to the state.

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 implementing this proposal, but if it does not, the Board would not have the ability to grant waivers when a pharmacy has been found in violation of Section 4081 of the Business and Professions Code. This would result in a pharmacy having to store records on-site, which may create an unsafe work environment.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the public comment period from February 7, 2020, to March 23, 2020, the Board received one comment. The comment was provided in the meeting materials for the May 7, 2020 Board meeting, and was reviewed and considered by the Board. The Board rejected the comment and approved the response thereto.

Summary and Response to Written Comment from Elizabeth Marley, PharmD.

Comment 1: The commenter requested clarification on whether the regulation applies to nonresident pharmacies and whether she needed to apply for a waiver.

Response to Comment 1: The Board rejected this comment. The Board notes that the off-site storage requirements apply to non-resident pharmacies pursuant to Precedential Decision No. 2019-01 [In the matter of the Citation Against: ESI Mail Pharmacy, Inc. dba Express Scripts, (Case No. CI 2009 44657; OAH Case No. 2011060384)].

15-Day Public Comment Period

During the public comment period from May 19, 2020, to June 3, 2020, the Board received one comment. This comment was previously submitted during the 45-day public comment period.

Summary and Response to Written Comment from Elizabeth Marley, PharmD.

Comment 1: The commenter indicated that she was unclear if the regulation applies to nonresident pharmacies.

Response to Comment 1: The Board previously noted that the off-site storage requirements apply to non-resident pharmacies pursuant to Precedential Decision No. 2019-01 [In the matter of the Citation Against: ESI Mail Pharmacy, Inc. dba Express Scripts, (Case No. CI 2009 44657; OAH Case No. 2011060384)]. As this comment was previously submitted during the 45-day comment period and reviewed by the Board at the May 2020 Board meeting, this comment did not go before the Board a second time.

At its May 7, 2020 meeting, the Board delegated to the Executive Officer the authority to adopt the 15-day regulation text if no negative comments were received during the 15-day public comment period.

On June 8, 2020, after the conclusion of the 15-day public comment period, the Executive Officer adopted the regulation text.