

TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Independent HIV Preexposure and Postexposure Prophylaxis (PrEP and PEP) Furnishing

Section Affected: Title 16 California Code of Regulations (CCR) section 1747

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 January 29, 2021, and ended on March 15, 2021. The board's notice indicated that the board did not intend to hold a hearing on the matter unless requested. The board did not receive a request for a hearing during the comment period.

During the 45-day comment period, the board received one comment. At the March 18, 2021 board meeting, the board considered the comment submitted and determined that no modifications to the text were appropriate. The board voted to adopt the modified text as noticed for public comment on January 29, 2021.

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 are "small businesses" as defined in Government Code section 11342.610, the board determined that any adverse economic impact will not be significant. All pharmacists have the option of obtaining the additional training required to independently initiate and furnish PrEP and PEP prophylaxis, whether they work at a small community pharmacy or a large chain pharmacy.

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 requiring a longer training program of two, three, or four hours; however, the board rejected this alternative. The board determined that a longer training program would pose a barrier to patient access as pharmacists may not have the additional time to complete the longer program. Additionally, the board determined the pharmacists are professionals and, if in their professional judgement they would benefit from additional training, they can seek out the additional training.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the public comment period from January 29, 2021, to March 15, 2021, the board received one comment. The comment was provided in the meeting materials for the March 18, 2021 board meeting, and the board reviewed and considered it.

Summary and Response to 45-day Comments:

Written Comments from Rachel Michelin, California Retailers Association, and Steve C. Anderson, National Association of Chain Drug Stores

Comment 1: Commenters expressed strong support for the proposed regulation, specifically, the expanded training to include an equivalent curriculum-based training program completed from a recognized school of pharmacy.

Response to Comment 1: The board reviewed this comment and did not make any changes to the text based thereon. Further, the board acknowledged the support from the commenters for the regulation.

At its March 18, 2021 meeting, after reviewing and considering the comment in the record, the board voted to adopt the regulation text as noticed for public comment on January 29, 2021. Additionally, the board delegated to the Executive Officer the authority to make technical and nonsubstantive changes as necessary to complete the rulemaking file.