

**TITLE 16: BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS**

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Independent HIV Preexposure
Prophylaxis Furnishing

Sections 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 September 20, 2024, and ended on November 4, 2024. The Board's notice stated that it 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, and one was not held.

During the 45-day comment period, the Board received two comments. At the December 4, 2024, Board meeting, the Board reviewed the comments received and voted to adopt the regulation as noticed for public comment on September 20, 2024.

The Board consulted with the Medical Board of California in the development of this proposal.

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 determine if any of its licensees are "small businesses", as defined in Government Code section 11342.610, the Board determined that the proposed regulatory action may impact small businesses. The pharmacy may have a minimal expense related to the records retention requirement; however, the Board believes the expense to be minimal, as the records can be maintained electronically, and their retention is necessary to ensure compliance with BPC section 4052.02.

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, as effective and less burdensome

to affected private persons than the adopted regulation, or more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Board considered not adopting the proposed regulation; however, the Board determined that alternative was not reasonable, as ensuring pharmacists have the information they need to comply with BPC section 4052.02(e)(7) and provide patients with the medication and services they need is necessary and benefits public health.

Objections or Recommendations/Responses to Comments

45-Day Comment Period

During the 45-day comment period, which began on September 20, 2024 and ended on November 4, 2024, the Board received two comments. At the December 4, 2024 Board meeting, the Board reviewed the comments received and voted to adopt the regulation text as noticed on September 20, 2024.

Summarized 45-day Comments with Board Staff Recommendations:

Written Comments from Kristen Tjaden, ViiV Healthcare

Comment 1: The commenter expressed support for the Board's proposed permanent regulation; however, the commenter urges the Board to allow the use of the CDC-recommended long-acting injectable PrEP, consistent with the CDC guidelines.

Response to Comment 1: The Board reviewed the comment and made no changes to the text based on it. The Board notes that this comment is outside the regulation's scope. The regulation does not address the types of products that can be dispensed and is specific to training and documentation requirements. The authority to dispense specific PrEP medication is specified in Business and Professions Code section 4052.02.

Written Comments from Maria Lopez, Mission Wellness Pharmacy

Comment 2: The Commenter expressed concern that the Board's regulation requires pharmacists to complete ACPE training, which includes training on specific CA requirements. The commenter believes this creates a barrier to pharmacists' education and that providing training is outside the purview of the Board as a regulator. The commenter recommends that the regulation be amended to allow ACPE training for HIV prevention according to the CDC and have a separate California-specific training.

Response to Comment 2: The Board reviewed the comment and made no changes to the text based upon the comment. The Board notes that Business and Professions Code section 4052.02(d) requires that pharmacists complete a training program approved by the Board in consultation with the Medical Board of California and other

relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health. Further, the Board notes that requiring the completion of multiple training programs (one ACPE training and one California-specific training) instead of the single board-provided training course may result in confusion and non-compliance, which may decrease the number of trained pharmacists. Finally, the Board notes that the Board’s mission statement is to “protect and promote the health and safety of Californians by pursuing the highest quality of pharmacist’s care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement.” Providing education to licensees is within the purview of the Board.