



California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item VI. Discussion and Possible Action Related Proposed Amendment to California Code of Regulations, Title 16, Section 1747 Related to Independent HIV Preexposure Prophylaxis Furnishing - Permanent, Including Review of Comments Received During the 45-Day Comment Period

Background:

At the April 25, 2024 Board meeting, the Board approved the proposed regulation text to amend Section 1747 related to Independent HIV Preexposure Prophylaxis Furnishing. This proposal amends the board's regulations regarding furnishing preexposure prophylaxis.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on September 20, 2024, which ended on November 4, 2024. One comment was received during the comment period.

Attached to this memo are:

1. The proposed text that was released for the 45-day public comment period.
2. Board staff-prepared summarized comment with staff's recommended response.
3. Comment received during the 45-day comment period.

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

1. Adopt the regulation text as noticed on September 20, 2024.
2. Amend the regulation to address the comment received and notice the modified text for a 15-day comment period.

Possible Adoption Language:

Accept the Board staff's recommended comment responses, adopt the regulation text as noticed on September 20, 2024, and authorize the Executive Officer to take all steps necessary to complete the rulemaking. Further, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Department of Consumer Affairs
Title 16. Pharmacy

PROPOSED REGULATORY LANGUAGE
Independent HIV Preexposure Prophylaxis Furnishing

Legend: Added text is indicated with an underline.
Deleted text is indicated by ~~strikeout~~.

Amend section 1747 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

- (a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the ~~h~~Board, provided by a provider accredited by an approved accreditation agency, or as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy. The training program shall satisfy the following criteria:
- (1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:
 - (A) HIV preexposure and postexposure prophylaxis pharmacology.
 - (B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.
 - (C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.
 - (D) Patient referral resources and supplemental resources for pharmacists.
 - (E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).
 - (F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).
 - (2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.
- (b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Training obtained as part of an equivalent curriculum-based training program, as identified in (a), can be documented by written certification from the registrar or training director of the

educational institution or program from which the licensee graduated stating that the training is included within the institution's curriculum required for graduation at the time the pharmacist graduated, or within the coursework that was completed by the pharmacist. Documentation of training maintained pursuant to this subdivision must be made available upon request of the ~~h~~Board.

(c) For the purposes of this section, documentation of preexposure prophylaxis furnished and services provided shall be maintained in patient records, in the record system maintained by the pharmacy, for a minimum of three years from the date when the preexposure prophylaxis was furnished. Such records shall be made available upon request of the Board, consistent with the provisions of Business and Professions Code sections 4081 and 4105.

NOTE: Authority cited: Sections 4005, 4052.02 and 4052.03, Business and Professions Code. Reference: Sections 4052, 4052.02, ~~and~~ 4052.03, 4081 and 4105, Business and Professions Code; and Section 120972, Health and Safety Code.



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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: Board staff does not recommend any changes to the text based upon the comment. Board staff notes that this comment is outside the regulation's scope, which is specific to training and documentation requirements. The authority to dispense specific PrEP medication is specified in Business and Professions Code section 4052.02.



October 21, 2024

Seung Oh, PharmD
President
California Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Submission email: Debbie.Damoth@dca.ca.gov

RE: Proposal to Make Permanent the Emergency Regulations Concerning Independent HIV Preexposure Prophylaxis Furnishing

Dear Dr. Oh and the Board of Directors:

ViiV Healthcare Company (“ViiV”) writes to the California State Board of Pharmacy (“Board”) regarding the proposal to make permanent the emergency regulations concerning independent HIV pre-exposure prophylaxis (PrEP) furnishing. Specifically, we write to:

- Support the Board’s proposal to make permanent the emergency regulations adopted on April 25, 2024, at section 1747 of Division 17 of Title 16 of the California Code of Regulations (CCR) for implementation of SB 339.
- Urge the Board to implement rules in full compliance with SB 339, which includes administration of FDA-approved and CDC-recommended long-acting PrEP.

ViiV is the only independent, global specialty company devoted, exclusively, to delivering advancement in HIV treatment and prevention to support the needs of people with HIV and those vulnerable to HIV. In collaboration with the HIV community, ViiV is committed to improving access to its HIV medicines and supporting the HIV community in securing enhanced care and treatment.

The Board Should Make Emergency Regulations Related to SB339 Permanent

Critical among the improvements to existing law is the authorization for eligible pharmacists to furnish up to a 90-day course of PrEP under specified circumstances. PrEP is an intervention in the form of a daily pill, or a once-every-two-month injection, to reduce the likelihood of HIV acquisition.

The new law directed the Board to adopt emergency regulations to implement the new provisions, in accordance with CDC PrEP Guidelines.^{1,2} The adoption of regulations was deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare.

¹ Centers for Disease Control and Prevention (CDC). Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2021 Update: A Clinical Practice Guideline. 2021. <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf>. Accessed October 8, 2024.

² Centers for Disease Control and Prevention (CDC). HIV Risk and Prevention: PrEP (Pre-Exposure Prophylaxis). July 5, 2022. <https://www.cdc.gov/hiv/risk/prep/index.html>. Accessed October 8, 2024.

The subsequent prompt implementation of the provisions of SB 339 and emergency rulemaking by the Board has supported nationwide efforts to end the HIV epidemic. In 2022, nearly 165,000 Californians were indicated for PrEP, but only about one-third were prescribed it.³ Promptly implementing permanent regulations can support efforts to reach more people who could benefit from PrEP.

SB 339 Requires the Board to Implement Rules in Accordance With CDC Guidelines, Which Include Administration of FDA-Approved and CDC-Recommended Long-Acting PrEP

ViiV reminds the Board that SB339 requires emergency regulations to implement the law in accordance with CDC guidelines, which includes recommendations for the use of long-acting injectable PrEP (i.e., APRETUDE™ (cabotegravir)) for certain patients, such as those who may not be able to adhere to daily oral PrEP.

In addition to being required under SB339, further amendment of the emergency regulations to explicitly include long-acting PrEP would also help to address disparities in PrEP use across vulnerable populations in the state. While California has one of the highest rates of PrEP coverage in the United States, Black and Hispanic Californians have disproportionately low rates of PrEP use when compared to the rate of PrEP use by white Californians with HIV. In 2022, Black Californians represented 14.6% of new diagnoses in 2022 but only 4.6% of PrEP users in the state; Hispanic/Latino Californians represented 57.0% of new diagnoses but only 28.6% of PrEP users in the state; and women represented 13.1% of new diagnoses in the state in 2021 but only 5.9% of PrEP users in the state.⁴ These disparities may indicate that daily oral PrEP has not effectively met the needs of key populations who could benefit from HIV prevention. A long-acting injectable formulation of PrEP may offer a valuable alternative to some. Importantly, this is consistent with CDC recommendations and guidelines.

In conclusion, the prioritized implementation of SB 339 by the Board has helped improve critically needed PrEP accessibility within the state's underserved populations vulnerable to HIV acquisition. ViiV firmly believes, however, that to fulfill the intent of the enacted law, the Board must ensure the inclusion of both daily oral PrEP and long-acting injectable PrEP.

We look forward to further engaging and are happy to assist the Board in any manner as you work to develop additional training. Please don't hesitate to contact me at Kristen.x.tjaden@viihealthcare.com.

Sincerely,



Kristen Tjaden
Government Relations Director
ViiV Healthcare

³ Centers for Disease Control and Prevention (CDC). NCHHSTP AtlasPlus. PrEP coverage and number of persons prescribed, 2022. <https://gis.cdc.gov/grasp/nchhstpatlas/tables.html>. Accessed October 8, 2024.

⁴ AIDSvu. California. <https://map.aidsvu.org/profiles/state/california/prevention-and-testing#1-1-PrEP>. Accessed October 8, 2024.