



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](mailto: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.<sup>1,2</sup> 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.

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<sup>1</sup> 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.

<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup> 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](mailto:Kristen.x.tjaden@viihealthcare.com).

Sincerely,



Kristen Tjaden  
Government Relations Director  
ViiV Healthcare

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<sup>3</sup> 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.

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

**From:** Maria Lopez <[maria@missionwellness.com](mailto:maria@missionwellness.com)>  
**Sent:** Tuesday, November 5, 2024 9:51 AM  
**To:** Sodergren, Anne@DCA <[Anne.Sodergren@dca.ca.gov](mailto:Anne.Sodergren@dca.ca.gov)>; Damoth, Debbie@DCA <[Debbie.Damoth@dca.ca.gov](mailto:Debbie.Damoth@dca.ca.gov)>  
**Cc:** Peters, Philip@CDPH <[Philip.Peters@cdph.ca.gov](mailto:Philip.Peters@cdph.ca.gov)>  
**Subject:** Re: SB339 Education Requirements

Good morning Anne

My comments are regarding the SB339 pending regs as education requirements do not appear to be addressed within the regs.

Maria

**Maria Lopez, Pharm.D.**

Director of Pharmacy, President  
getSFcba Consultant  
Direct: 415.577.7840  
She/Her



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**From:** Sodergren, Anne@DCA <[Anne.Sodergren@dca.ca.gov](mailto:Anne.Sodergren@dca.ca.gov)>  
**Sent:** Tuesday, November 5, 2024 6:53 AM  
**To:** Maria Lopez <[maria@missionwellness.com](mailto:maria@missionwellness.com)>; Damoth, Debbie@DCA <[Debbie.Damoth@dca.ca.gov](mailto:Debbie.Damoth@dca.ca.gov)>  
**Cc:** Peters, Philip@CDPH <[Philip.Peters@cdph.ca.gov](mailto:Philip.Peters@cdph.ca.gov)>  
**Subject:** Re: SB339 Education Requirements

Good morning, Dr. Lopez,

Can you please confirm if your comments are in response to the Board's pending regulations or the Board's discussion later this week on updates to the Board's training program?

Thank you,

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**From:** Maria Lopez <[maria@missionwellness.com](mailto:maria@missionwellness.com)>

**Sent:** Monday, November 4, 2024 9:03:22 PM

**To:** Damoth, Debbie@DCA <[Debbie.Damoth@dca.ca.gov](mailto:Debbie.Damoth@dca.ca.gov)>

**Cc:** Sodergren, Anne@DCA <[Anne.Sodergren@dca.ca.gov](mailto:Anne.Sodergren@dca.ca.gov)>; Peters, Philip@CDPH <[Philip.Peters@cdph.ca.gov](mailto:Philip.Peters@cdph.ca.gov)>

**Subject:** SB339 Education Requirements

Dear Anne,

The intent of SB159 and SB339 has been to expand access to PrEP via pharmacists in accordance with the CDC guidelines.

Last spring we held an Office of AIDS stakeholder call and the topic of the BOP creating education for pharmacists HIV prevention was brought up. While the belief is that Betty Dong is an excellent person to create training, the consensus was that the BOP sponsoring educational clinical training is really outside the purview of the BOP as regulators, and clinical training should be completed by the traditional bodies which educate post graduate pharmacists. It appears to be impossible for the BOP to keep updated clinical training in line with best practice guidelines given that such education programs are costly and require full time staffing of educational experts.

While the updated legislation of SB339 is being addressed, it is important for the BOP to update the education language referenced in the regulations. The prior education language has been a barrier to educate CA pharmacists--mainly because the language under 1747 regs are too narrow in scope such that CA pharmacists intending to practice under SB339 must complete CA specific training. This is despite the fact that the CDC has created pharmacists specific training and APHA (American Pharmacists Association-- the national umbrella pharmacy association) has created a pharmacists' specific HIV prevention certificate program. Both programs are much more comprehensive and up to date. Additionally, the APHA HIV prevention certification is similar to the APHA immunization certificate program, which has been demonstrated to successfully educate post graduate pharmacists' competency on a national level. The APHA HIV prevention certificate program included staff from the CDC and the Health and Human Services department who advised and created the certificate training program with national experts.

I implore the BOP to consider to update the regs addressing the HIV education prevention requirements for California pharmacists and remove barriers for pharmacists. At present

the language states pharmacists must complete ACPE training which includes training on specific CA requirements. I propose that the language under 1747 include ACPE training for HIV prevention according to the CDC with the additional California specific training to be separate. The additional specific California training requirements can be met by completing a training that is posted at the Office of AIDS and/or the BOP regarding reimbursement and SB339. The additional CA specific training could be as simple as reading a slide deck and self-certifying (similar to how pharmacists must self-certify for DEA self certification—i.e. review slides and print a self-certifying certificate on the CA specific requirements). Accommodating the updated SB339 language while keeping training in line with CDC guidelines as the regulation requires pharmacists to practice when initiating PrEP would permit CA pharmacists to complete a number of national and more robust and up to date HIV prevention training programs available, therefore decreasing the training barriers currently in place for CA pharmacists.

Sincerely

Maria

**Maria Lopez, Pharm.D.**

Director of Pharmacy, President  
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