DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. BOARD OF PHARMACY

Finding of Emergency
Independent HIV Preexposure Prophylaxis Furnishing

The California State Board of Pharmacy (Board) is proposing an emergency action to amend the regulation related to the independent initiation and furnishing of HIV preexposure prophylaxis (PrEP) and HIV postexposure prophylaxis (PEP) as recommended by the federal Centers for Disease Control and Prevention (CDC) to patients, as authorized by Senate Bill (SB) 339 (Wiener, Chapter 1, Statutes of 2024). HIV is a deadly virus spread through specific bodily fluids; however, transmission can be prevented with treatment of the antiretroviral medications of PrEP and PEP, based on the type of exposure.

The proposed regulation would establish the requirement that 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 (BPC) sections 4081 and 4105.

The emergency regulation is proposed pursuant to the Board's general rulemaking authority in BPC section 4005 and specific emergency rulemaking authority in BPC section 4052.02(h). In Senate Bill 339 and BPC section 4052.02(h), the legislature deemed the adoption of regulations implementing BPC section 4052.02 to be "an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare." The proposed emergency regulation implements, interprets, and makes specific the newly amended BPC section 4052.02.

The Board approved the emergency rulemaking on April 24, 2024.

The Board will also pursue the non-emergency rulemaking process (to make these regulatory changes permanent). However, to preserve the peace, health, safety, and general welfare, as stated in BPC section 4052.02(h), the Board seeks to adopt this regulation on an emergency basis.

On February 6, 2024, SB 339 was approved by Governor Gavin Newsom. SB 339 authorizes a pharmacist to furnish up to a 90-day course of preexposure prophylaxis, or preexposure prophylaxis beyond a 90-day course, if specified conditions are met. Further, the Board is required to adopt emergency regulations to implement the updated BPC provisions by October 31, 2024. BPC 4052.02(e)(7) specifies that a pharmacist cannot furnish more than a 90-day course of preexposure prophylaxis to a single patient more than once every two years (unless directed otherwise by a prescriber).

BPC section 4052.02(h) requires the Board to adopt emergency regulations to implement the requirements by October 1, 2024, and directs the Board to develop the regulations in consultation with the Medical Board of California. The Board complied with the above consultation provision.

The Legislature has deemed the adoption of the proposed emergency regulation to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. (BPC section 4052.02(h).) Delay in the implementation of the proposed regulatory changes would conflict with the statutory directive found in SB 339 and BPC section 4052.02(h) that emergency regulations be adopted:

> (h) The board, by October 31, 2024, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

Additionally, the proposed regulatory changes will extend the maintenance of patient records related to the furnishing of preexposure prophylaxis, and delay in the implementation of these regulatory changes could result in the loss of patient records necessary to ensure 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.

Authority and Reference

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

INFORMATIVE DIGEST

Policy Statement Overview

Clinical trials have demonstrated PrEP to be safe and effective in reducing the risk of HIV infection if an at-risk individual adheres to the CDC-recommended PrEP regimen—a daily oral dose of tenofovir disoproxil fumarate with emtricitabine (TDF/FTC, commonly known by the brand name Truvada)—at the time of their exposure to HIV.

In addition, data indicates that adherence to a 28-day course of the “preferred” or “alternative” three-drug regimens recommended by the CDC is safe and effective in reducing the risk of infection after exposure to HIV when taken as soon as possible, but no later than 72 hours after exposure.

Creating access points to CDC-recommended PrEP and PEP consultation and treatment in pharmacies is critical to the health, safety, and general welfare of California residents and helps save lives. Pharmacists are well positioned to independently initiate and furnish PrEP and PEP as they are trusted healthcare providers who are highly accessible to patients within their communities. Further, access to pharmacist-initiated PrEP and PEP treatment enables at-risk individuals seeking PrEP to start the treatment sooner, enabling their body to build maximum protection from HIV infection sooner, and enables individuals who have been exposed to HIV to start PEP sooner within its 72-hour window of effectiveness post exposure, improving outcomes for those individuals.

However, pharmacists cannot provide adequate PrEP consultation and treatment without having access to the necessary patient records. The proposed regulatory changes will extend the maintenance of patient records related to the furnishing of preexposure prophylaxis, 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.

Necessity Statements

The proposed emergency regulation amends section 1747 to Title 16 of the California Code of Regulations (CCR) as follows:

Subdivision (b), which specifies the documentation retention of completion of a training program, is amended to add “of training” to the last sentence, so that the sentence reads “Documentation of training maintained pursuant to this subdivision must be made available upon request of the board.” This change is necessary to ensure clarity to the regulated public with respect to what documentation the subdivision is identifying that must be made available upon request of the Board, and to avoid confusion given the documentation/records maintenance requirement (related to the furnishing of preexposure prophylaxis) that is being added to subdivision (c).

Subdivision (c) is added to specify the requirement that documentation of preexposure prophylaxis furnished and services provided must be maintained in patient records, within the record system maintained by the pharmacy, for a minimum of three years from the date the preexposure prophylaxis was furnished. This addition will extend the maintenance of patient records related to the furnishing of preexposure prophylaxis, 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. The Board selected three years for consistency with the other records requirements throughout the Boards statutes and regulations, including 4081 and 4105. Finally, the subdivision specifies that the records must be made available upon request of the Board, as required by BPC 4081 and 4105. This requirement is added to the regulation to provide clarity to licensees, helping ensure they know that these records (are included in the categories of records that) must be available when requested by the Board, and is consistent with the language related to the training documentation in subdivision (b).

Consistency and Compatibility with Existing Regulations

During the process of developing this regulatory proposal, the Board conducted a search of any similar regulations on this topic and concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

Underlying Data

1. Senate Bill 339 (Wiener, Chapter 1, Statutes of 2024)
2. Relevant meeting materials and minutes from Board Licensing Committee meeting held April 10, 2024
3. Relevant meeting materials and minutes from Board meeting held April 24-25, 2024
4. Letter from the California State Board of Pharmacy to the Medical Board of California, dated May 1, 2024

Fiscal Impact Estimates

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Cost to any Local Agency or School District for which Government Code Sections 17500 – 17630 Require Reimbursement: None

Mandate Imposed on Local Agencies or School Districts: None

Significant Effect on Housing Costs: None

Contact Persons

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Website Access:

Materials regarding this proposal can be accessed through the Board of Pharmacy's website at: https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.