

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

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing scheduled.

Subject Matter of Proposed Regulation: Independent HIV Preexposure Prophylaxis
Furnishing

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

Background and Statement of the Problem

The California State Board of Pharmacy (Board) is a state agency vested with the authority to license and regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (Business and Profession Code (BPC) section 4000, et seq.). The Board's mandate and mission are to protect the public (BPC section 4001.1).

The Board is proposing to amend CCR section 1747 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 using 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 sections 4081 and 4105.

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. BPC section 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) directs the Board to develop emergency regulations, in consultation with the Medical Board of California, to implement the updated BPC provisions by October 31, 2024. The Board complied with this consultation provision and approved text on April 25, 2024 (to be adopted as an emergency regulation at 16 CCR 1747). The Office of Administrative Law (OAL) approved the text on August 14,

2024. The Board takes this action to certify its compliance with Government Code section 11346.1(e) to make the emergency amendments to the regulation permanent, and makes additional nonsubstantive revisions to the permanent text.

The proposed regulatory changes will extend the maintenance of patient records related to the furnishing of preexposure prophylaxis, ensure pharmacists have the information they need (found in the patient records) to comply with BPC section 4052.02(e)(7), and provide patients with the medication and services they need.

Anticipated benefits from this regulatory action:

Protection of the public is the Board’s highest priority in exercising its licensing, regulatory, and disciplinary functions. The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents.

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 bodies 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.

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, thereby benefiting the health and welfare of California residents.

This regulatory proposal does not affect employee safety or the state’s environment.

Specific purpose of, and rationale for, each proposed change

The Board is amending CCR section 1747 as follows:

The Board proposes capitalizing the “B” in “Board” in subdivisions (a) and (b). This change is non-substantive because it is a grammatical change as part of an effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4). This is necessary for consistency throughout the Board’s regulations. Inconsistent capitalization/lowercasing may result in misinterpretation and confusion.

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.” The purpose of this change is to specify that this records retention requirement applies to training documentation (to distinguish this records retention requirement from the one for patient records, proposed to be added to the regulation section as subdivision (c) below). 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. The purpose of this addition is to extend the maintenance of patient records related to the furnishing of preexposure prophylaxis. This addition is 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. The Board selected three years for consistency with the other records retention requirements throughout the Board’s 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 sections 4081 and 4105. The purpose of this addition to the regulation is to establish the requirement that the records be made available upon request of the Board. This addition is necessary 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 training documentation retention in subdivision (b).

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

Business Impact

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

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 section 4052.02(e)(7) and provide patients with the medication

and services they need. 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.

Economic Impact Assessment

The Board concludes that this proposal will not:

- (1) create jobs within California;
- (2) eliminate jobs within California;
- (3) create new businesses within California;
- (4) eliminate existing businesses within California; and
- (5) expand businesses currently doing business in the State of California.

The Board determined that this proposal will not create or eliminate jobs or businesses. This proposal will 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, which benefits the health and welfare of California residents and does not impact jobs or businesses.

This regulatory proposal does not affect employee safety or the state's environment.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. 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.

Description of reasonable alternatives to the regulation that would lessen any adverse impact on small business

No such alternatives have been proposed, however, the Board welcomes comments from the public.