

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. BOARD OF PHARMACY

**NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:
Independent HIV Preexposure Prophylaxis Furnishing**

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (Board) proposes taking the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. Any person interested may present statements or arguments, relevant to the action proposed, in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Persons in this Notice, must be received by the Board at its office by November 4, 2024.

PUBLIC HEARING

The Board has not scheduled a public hearing on this proposed action. However, the Board will hold a hearing if it receives a written request for a public hearing from any interested person, or that person's authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request in writing addressed to the individuals listed under "Contact Persons" in this notice.

The Board may, after holding a hearing if requested and considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the persons designated in this Notice as the Contact Persons and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Business and Professions Code (BPC) sections 4005 and 4052.02, the Board proposes amending section 1747 of Division 17 of Title 16 of the California Code of Regulations (CCR).

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

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

Clinical trials have demonstrated HIV preexposure prophylaxis (PrEP) to be safe and effective in reducing the risk of contracting HIV infection if an at-risk individual adheres to the Centers for Disease Control and Prevention-recommended (CDC) 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.

The Board is proposing to amend CCR section 1747 related to the independent initiation and furnishing of PrEP and HIV postexposure prophylaxis (PEP) as recommended by the 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 BPC 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).

The Board was required to adopt emergency regulations to implement the updated BPC provisions by October 31, 2024, and the Board did so, approving text (to be adopted as

an emergency regulation at 16 CCR 1747) on April 25, 2024. 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.

Anticipated Benefits of Proposal

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 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.

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.

Evaluation of Consistency and Compatibility with Existing State 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.

DISCLOSURES REGARDING THIS PROPOSED ACTION

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs/Savings to State Agencies or Costs/Savings in Federal Funding to the State: The regulations do not result in a fiscal impact to the state.

The regulations do not result in a fiscal impact to the state in the form of federal funding

or any cost or savings to any state agency.

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

Business Impact Estimates:

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

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.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any negative cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/New Businesses:

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.

Business Reporting Requirements

This regulatory proposal does not require businesses to file a report with the Board.

Effect on Small Business:

While the Board does not have, nor does it maintain, data to determine if any of its licensees (pharmacies and clinics) are a “small business”, as defined in Government Code section 11342.610, the Board has 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

In accordance with Government Code section 11346.5(a)(13), the Board has determined that no reasonable alternative it considered to the regulation, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed, as effective and less burdensome to affected private persons than the proposal described in this Notice, or more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may submit comments—relevant to the above determinations—in writing, at the address listed below for the Contact Persons during the written comment period, or at the hearing if one is scheduled or requested.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND RULEMAKING FILE

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information upon which the proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, the Initial Statement of Reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy’s website at http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments, the Board, upon its own motion or at the request of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal, with the modifications clearly indicated, will be available for review and written comment for 15 days prior to its adoption from the persons designated in this Notice as the Contact Persons and will be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file, which is available for public inspection by contacting the person named below.

You may obtain a copy of the Final Statement of Reasons, once it has been prepared, by making a written request to the Contact Person named below or by accessing the website listed below.

Contact Persons

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Lori Martinez
Address: Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3100
Fax No.: (916) 574-8618
E-Mail Address: PharmacyRulemaking@dca.ca.gov

The backup contact person is:

Name: Julie Ansel
Address: Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3100
Fax No.: (916) 574-8618
E-Mail Address: PharmacyRulemaking@dca.ca.gov

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations with modifications noted, as well as the Final Statement of Reasons when completed, and modified text ,if any, can be accessed through the Board of Pharmacy's website at: https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.