

**Title 16, Division 17, Article 5, Section 1747
California Board of Pharmacy**

**NOTICE OF PROPOSED RULEMAKING
HIV Preexposure and Postexposure Prophylaxis**

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) is proposing to take 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 Person in this Notice, must be received by the board at its office by March 15, 2021.

The board has not scheduled a public hearing on this proposed action. The board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days prior to the close of the written comment period.

The board may, after 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 person designated in this Notice as the contact person 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, 4052.02, and 4052.03, and to implement, interpret, and make specific BPC sections 4052, 4052.02, and 4052.03, and Health and Safety Code section 120972, the Board proposes to adopt 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 regulate the pharmacy industry, including pharmacies and pharmacists. The board's mandate and mission is to protect the public. (Bus. & Prof. Code , § 4001.1.)

On October 7, 2019, Governor Gavin Newsom signed Senate Bill (SB) 159 (Wiener, Statutes of 2019, Chapter 532). SB 159 creates an exception to the general rule that a pharmacist may not furnish a dangerous drug to a patient without a prescription issued by a prescriber. (BPC, §§ 4040, subd. (a)(2), 4052, subd. (a)(10)(A)(iv)-(v), & 4059.)

Human immunodeficiency virus (HIV) is a deadly virus spread through specific bodily fluids. However, transmission can be prevented with treatment of the antiretroviral medications of preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP), based on the type of patient exposure. Under the exception created by SB 159, a pharmacist who completes a training program approved by the board may independently initiate and furnish HIV PrEP (BPC, § 4052.02) and HIV PEP. (BPC, § 4052.03) These medications may be furnished in specified doses under specific circumstances, as recommended by the federal Centers for Disease Control and Prevention (CDC). Pharmacists may also counsel a patient on the use of those drugs.

BPC sections 4052.02 and 4052.03 authorize a pharmacist to furnish PrEP and PEP, respectively, if certain conditions are met. These conditions require a patient to meet the clinical eligibility criteria for PrEP or PEP specified in these sections and other criteria consistent with specified CDC guidelines.

BPC sections 4052.02(g) and 4052.03(g) direct the board to develop the regulations in consultation with the Medical Board of California (MBC). BPC sections 4052.02(d) and 4052.03(d) require the board to develop a training program in consultation with the MBC and relevant stakeholders, including the Office of AIDS within the State Department of Public Health. The board complied with these consultation requirements.

BPC sections 4052.02(g) and 4052.03(g) required the board to adopt emergency regulations to implement the requirements of each section in accordance with CDC guidelines by July 1, 2020. The board did so, and approved text to be adopted as an emergency regulation at 16 CCR 1747 on January 29, 2020. The Office of Administrative Law (OAL) approved the text on April 30, 2020. The board takes this action to certify its compliance with Government Code section 11346.1(e) to make this regulation permanent, and makes certain revisions to the permanent text.

Section 1747 will permanently establish what criteria a training program must meet to be approved by the board and the recordkeeping requirements for a pharmacist who has completed the training program. The board proposes revisions to the emergency text to permit the training to be provided as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy.

On September 17, 2020, the Board approved a re-adoption of the regulation. The regulation will otherwise expire on October 27, 2020.

ANTICIPATED BENEFITS OF THE PROPOSED REGULATION

Protection of the public is the board's highest priority in exercising its licensing, regulatory and disciplinary functions. (BPC, § 4001.1.) This regulatory proposal will benefit the health and welfare of California residents. Clinical trials have demonstrated PrEP to be safe and effective in reducing the risk of HIV infection if an at-risk individual

is adhering to the CDC-recommended PrEP regimen - which includes 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. 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 additional access to CDC-recommended PrEP and PEP consultation and treatment in pharmacies is critical to the health, safety, and general welfare of California residents and will help 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 will enable at-risk individuals seeking PrEP to start the treatment sooner, enabling their body to build maximum protection from HIV infection sooner, and will enable 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.

CONSISTENCY AND COMPATIBILITY WITH EXISTING STATE REGULATIONS

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

FISCAL IMPACT ESTIMATES

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

The board already ensures licensees comply with current law and regulations related to continuing education (CE) compliance through inspections. As a result, the board does not anticipate any increase in workload or costs resulting from the proposed regulations.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

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

Business Impact:

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. This initial determination is based on the fact that the proposed regulation defines the training program and record maintenance requirements only for a pharmacist who chooses to furnish these medications. The board determined that existing CE providers and schools of pharmacy may have a minimal expense to develop or update their training programs or curricula to comply with the requirements of the proposed regulation, but only if they chose to do so.

Cost Impact on Representative Private Person or Business:

The board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. The board determined that existing CE providers and schools of pharmacy may have a minimal expense to develop or update their training programs or curricula to comply with the requirements of the proposed regulation if they chose to offer a program.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS:

The board does not have nor does it maintain data to define if any of its licensees are a “small business” as defined in Government Code section 11342.610. However, the board has determined that the proposed regulation will not affect small businesses. All pharmacists have the option of obtaining the additional training required to independently initiate and furnish PrEP and PEP prophylaxis, whether they work at a small community pharmacy or a large chain pharmacy.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/New Businesses:

The board concludes that:

- (1) this proposal will not create jobs within California;
- (2) this proposal will not eliminate jobs within California;
- (3) this proposal will not create new businesses within California;
- (4) this proposal will not eliminate existing businesses within California; and
- (5) this proposal will not expand businesses currently doing business in the State of California.
- (6) this proposal will not impact workers’ safety or the state’s environment.
- (7) this proposal benefits the health and welfare of California residents as the proposed regulation will ensure that pharmacists receive training consistent with CDC guidelines regarding the pharmacology of PrEP and PEP. This

training will ensure the pharmacist can provide more complete patient centered care.

CONSIDERATION OF ALTERNATIVES

The board must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person during the written comment period.

INITIAL STATEMENT OF REASONS

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, and any document incorporated by reference, and of 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 <https://www.pharmacy.ca.gov/>.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After holding a hearing, if requested, and considering all timely and relevant comments received, the Board may adopt the amendments as originally proposed, or with non-substantial or grammatical modifications. The Board may also adopt the proposed regulatory language with other modifications if the text as modified is sufficiently related to the originally proposed text that was noticed to the public. In the event that such modifications are made, the full regulatory text, with the modifications clearly indicated, will be made available to the public for review and or written comment at least 15 days before it is adopted. The public may request a copy of the modified regulatory text by contacting Ms. Martinez at the address above.

AVAILABILITY AND LOCATION OF FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file that 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 PERSON

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

Name: Lori Martinez
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The backup contact person is:

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WEBSITE ACCESS

Materials regarding this proposal can be found at the Board of Pharmacy's website: <https://www.pharmacy.ca.gov/>.