California Board of Pharmacy

Initial Statement of Reasons

Hearing Date:	None Scheduled unless Requested
Subject Matter of Proposed Regulation:	HIV Preexposure and Postexposure Prophylaxis Furnishing, Certificate of Compliance
Section(s) Affected:	Add Section 1747 of Article 5 of Division 17 of Title 16, California Code Regulations (CCR)

Specific Purpose of Each Adoption, Amendment, or Repeal:

1. **Problem Being Addressed:**

The California Board of Pharmacy (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 (BPC), § 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.

2. Anticipated Benefits of the Regulatory Action:

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 adheres 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.

Factual Basis and Rationale:

- **Adopt section 1747**

Subdivision (a)

Proposed subdivision (a) provides that a pharmacist must successfully complete a training program approved by the board, other accredited provider, or as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy before independently initiating and furnishing HIV PrEP and/or PEP to a patient pursuant to BPC sections 4052.02 and 4052.03. The subdivision enumerates the criteria a training program must satisfy to be approved by the board. The Board proposes to approve training programs by vote of all Board members at noticed meetings. The training program must cover both PrEP and PEP. (BPC, §§ 4052.02, subd. (d) and 4052.03, subd. (d).)

Pharmacists cannot provide adequate PrEP and PEP consultation and treatment on their own without training. This regulation is necessary to ensure pharmacists who independently initiate and furnish PrEP and PEP have all the training necessary to understand their responsibilities under California law, to identify indications and contraindications for PrEP and PEP, and to counsel patients on the appropriate administration of PrEP and PEP.

The board determined that approving training programs offered by accredited providers would increase the number of approved training programs available. This will enable more pharmacists to complete a training program than if the board developed its own training program or approved all training programs on a case-by-case basis. Increasing the number of pharmacists who are qualified to independently initiate and furnish PrEP and PEP will reduce barriers to patient access and benefit California residents.

The board determined that a pharmacist can also complete the training as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy. The board determined that pharmacists who attend a recognized school of pharmacy and receive PrEP and PEP as part of their course of study should not be required to complete additional training as the training would be duplicative. A recognized school of pharmacy must be accredited by the Accreditation Council for Pharmacy Education (ACPE), who is an approved accreditation agency per 16 CCR section 1732.05. Additionally, as specified in subdivision (b), the school of pharmacy will be responsible for confirming that the program meets the training requirements identified within the regulation.

The board has established specific requirements, in 16 CCR sections 1732.05 and 1732.1, accreditation agencies must meet to accredit providers offering continuing education in PrEP and PEP to pharmacists. These requirements will establish adequate safeguards to ensure that PrEP and PEP training programs accredited by approved accreditation agencies meet all the requirements specified in this proposal. The

approval process set forth in subdivision (a) will allow non-accredited programs to meet the board approval requirements of the statute and may increase the availability and access to training programs.

Subdivision (a)(1)

Proposed subdivision (a)(1) provides that the training program must consist of at least 1.5 hours of instruction. The board determined that 1.5 hours is the appropriate length based on discussions with stakeholders. Stakeholders expressed concern that training requirements of 2 hours or longer would create a barrier to access. The board also assessed the lengths of existing continuing education programs, which vary in length from one hour to three hours. HIV medicine is taught nationwide in pharmacy school. Because the information provided in the training program will not be new to many pharmacists, the board determined that 1.5 hours is an appropriate length for the training and will establish a minimum competency for pharmacists providing PrEP and PEP. Pharmacists seeking to provide the services authorized by the proposed regulation can use their professional judgment and obtain additional training beyond the 1.5 hours if they wish to do so.

Subdivision (a)(1)(A)

Proposed subdivision (a)(1)(A) requires a training program to cover, at minimum, the pharmacology (defined as the branch of medicine concerned with the uses, effects, and modes of action of drugs) of PrEP and PEP. As a pharmacist will be independently initiating and furnishing these medications, it is necessary for the pharmacist to understand the pharmacology of the medications and their interactions in the body with other medications the patient may be taking. A pharmacist unfamiliar with the pharmacology of PrEP, for example, would not know to emphasize to a patient that adherence to the PrEP regimen is critical to HIV prevention. This will reduce the likelihood that an HIV infection will become drug resistant if unknowingly acquired while on PrEP.

Subdivision (a)(1)(B)

Proposed subdivision (a)(1)(B) requires a training program to educate a pharmacist about the requirements for independently initiating and furnishing PrEP and PEP as identified in BPC sections 4052.02 and 4052.03. This requirement is necessary to ensure the pharmacist is trained on the conditions contained in BPC sections 4052.02(e)(1)-(7) and 4052.03(e)(1)-(4) and is aware of the limitations on their authority to independently initiate and furnish PrEP and PEP. Pharmacists are limited by statute to providing a maximum 60-day supply of PrEP once every two years and providing a full course of PEP within 72 hours of exposure when specific conditions are met. (BPC §§ 4052.02, subd. (e)(6) & 4052.03, subd. (e)(1).) A pharmacist must be aware of these limitations. In the case of PrEP, this will help minimize the harm to patients who may have a condition or circumstance without the pharmacist's knowledge that may indicate that PrEP should not be used. It will also prevent pharmacists from prescribing PEP in excess of, or otherwise inconsistent with, CDC recommendations. A training program

will also help educate pharmacists regarding other HIV test ordering and reporting requirements that they, as healthcare providers, must comply with, such as those found in Title 17, CCR, sections 2643.5 and 2643.10.

Subdivision (a)(1)(C)

Proposed subdivision (a)(1)(C) requires a training program to provide education on patient counseling techniques and information, including counseling on sexually transmitted diseases and sexual health. This is necessary because patient counseling is required by BPC sections 4052.02(e)(4) and 4052.03(e)(3). Training in this area is important to ensure patients are receiving accurate and consistent information. Risk factors for acquiring HIV often correspond with risk factors for other sexually transmitted infections of which a patient should be aware. Additionally, the training will help the pharmacist counsel patients on sensitive topics. Without counseling, a pharmacist's discomfort when asking about sexual history, or perceived discomfort of the patient, may prevent a pharmacist from accurately determining a patient's risk of HIV acquisition and eligibility for PrEP or PEP.

Subdivision (a)(1)(D)

Proposed subdivision (a)(1)(D) requires a training program to provide the pharmacist with information regarding patient referral resources and supplemental resources for pharmacists. This information is critical for pharmacists providing PrEP and PEP because pharmacists need to understand the type of resources available for patients, as well as themselves, and how and where to obtain the information. For example, the Office of AIDS, through the California Department of Public Health, provides HIV prevention resources and resources for those living with HIV and AIDS. Some examples for the resources available are financial assistance resources available through the California Department of Public Health, PEP patient care sources, and clinical counseling resources. Additionally, federal resources are available through the CDC. As there are numerous resources available and could be developed in the future, the board did not specify the resources within the language as to not limit the resources available to pharmacists and patients. The training on resources will ensure the pharmacist is aware of, and can share the information with, patients, and that a patient will be better situated to find help after a pharmacist becomes statutorily constrained from continuing PrEP treatment without a prescription or when the patient has completed PEP treatment.

Subdivision (a)(1)(E)

Proposed subdivision (a)(1)(E) requires a training program to provide education on financial assistance programs, including the Office of AIDS's PrEP Assistance Program (PrEP-AP). This requirement is necessary because BPC sections 4052.02(d) and 4052.03(d) require that the training program provide information on financial assistance programs. The Office of AIDS's PrEP-AP is the financial assistance program for California residents. This information is necessary for patients receiving PrEP and PEP because cost of treatment can be a barrier to access.

Subdivision (a)(1)(F)

Proposed subdivision (a)(1)(F) requires a training program to provide education on the clinical eligibility recommendations provided in the CDC guidelines defined in BPC sections 4052.02(c) and 4052.03(c). This requirement is necessary because BPC sections 4052.02 and 4052.03 require utilization of the CDC guidelines for PrEP and PEP, or any subsequent guidelines published by the CDC, to establish clinical eligibility for drug or drug combinations provided to patients. Additionally, the CDC guidelines provide clinical criteria patients must meet in order to receive PEP. (BPC, § 4052.03, subd. (e)(1)-(e)(3).)

Subdivision (a)(2)

Proposed subdivision (a)(2) requires a training program to require an assessment based on the criteria of (a)(1) with a score of 70% or higher for a pharmacist to receive documentation of the successful completion of the course. This requirement is necessary to ensure minimum competency upon completion of the course to independently initiate and furnish PrEP and PEP. The board determined that 70% was an acceptable score to demonstrate minimum competency. Minimum competency is necessary to ensure patient safety while improving access to these medications. Minimum training is appropriate and the board trusts pharmacists to seek out additional training if they determine it is necessary.

Subdivision (b)

Proposed subdivision (b) requires a pharmacist who independently initiates and furnishes PrEP and PEP to maintain proof of their successful completion of the training program for a period of four years. If a pharmacist completed the training as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy, the pharmacist can document that they completed the required training by maintaining a written certification from the registrar or training director stating that they completed the required training as part of their institution's curriculum or within coursework completed by the pharmacist. The pharmacist is not required to submit this documentation to the board. They need to maintain the written certification as proof of their successful completion of a PrEP and PEP training program. If training is completed as part of the pharmacist's pharmacy education, a certificate of completion would not typically be provided (as would be obtained for the training from a CE provider). Therefore, the board determined that a written certification from the registrar or training director stating that the required training was completed as part of their institution's curriculum or within coursework is an acceptable form of documentation of the necessary training.

The board determined that four years is the appropriate length of time to maintain documentation of successful completion of the training program for consistency with the period of time pharmacists are required to maintain their certificates of completion of their continuing education courses, as provided in 16 CCR section 1732.5(c). The board

believes that most pharmacists will complete the training course through an accreditation agency and receive a certificate of completion.

Maintaining consistency with the four-year recordkeeping requirement for continuing education will ensure that the records are maintained and will eliminate confusion with having different time frames. Additionally, maintaining proof of completion of the training program will allow the board to confirm compliance with the regulation during routine pharmacy inspections if pharmacists are independently initiating and furnishing PrEP and PEP pursuant to the proposed regulation and/or during an enforcement investigation.

Underlying Data

1. Senate Bill (SB) 159 (Wiener, Chapter 532, Statutes of 2019).
2. Relevant Meeting Materials and Minutes from Board Meeting held July 29-30, 2020.
3. Relevant Meeting Materials and Minutes from Board Licensing Committee Meeting held July 8, 2020.
4. Relevant Meeting Materials and Minutes from Board Meeting held January 29-30, 2020.
5. Relevant Meeting Materials and Minutes from Board Licensing Committee Meeting held January 9, 2020.
6. Relevant Meeting Materials and Minutes from Board Licensing Committee Meeting held December 12, 2019.
7. The CDC guidelines for PrEP (2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline) https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf
8. The CDC guidelines for PEP (Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV–United States, 2016). https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf
9. Office of AIDS: CA Department of Public Health: Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP). https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OA_prev_PrEP.aspx
10. Letter from the California State Board of Pharmacy to the Medical Board of California, dated February 21, 2020.

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 requirements for a voluntary program and schools of pharmacy. The board determined that existing continuing education providers and schools of pharmacy may have a minimal expense to develop or update their training programs to comply with the requirements of the proposed regulation, but only if they chose to do so.

Economic Impact Assessment:

The board has determined 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.

The board determined that this proposal will not create or eliminate jobs or businesses. The proposal states the requirements of a training program a pharmacist must complete prior to independently initiating and furnishing PrEP and PEP to patients. The board determined that existing continuing education providers and schools of pharmacy may have a minimal expense to develop or update their training programs or curriculum to comply with the requirements of the proposed regulation, but only if they choose to do so. As the proposed regulation establish the minimum standards for course curriculum and the providing the course curriculum is optional, this proposal does not create, eliminate, or expand jobs or businesses.

This proposal benefits the health and welfare of California residents. 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, which will benefit the health and welfare of California residents. The proposed regulation will not benefit workers' safety or the state's environment because they do not have any effect on worker safety or the 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 would be 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 the following alternative:

The board considered requiring a longer training program of two, three, or four hours; however, the board rejected this alternative. The board determined that a longer training program would pose a barrier to patient access as pharmacists may not have the additional time to complete the longer program. Additionally, the board determined the

pharmacists are professionals and, if in their professional judgement they would benefit from additional training, they can seek out the additional training.