Finding of Emergency
Independent HIV Preexposure and Postexposure Prophylaxis Furnishing

The California State Board of Pharmacy (board) is proposing an emergency action to add a regulation related to the independent initiation and furnishing of HIV preexposure prophylaxis (PrEP) and HIV postexposure prophylaxis (PEP) recommended by the federal Centers for Disease Control and Prevention (CDC) to patients, as authorized by Senate Bill (SB) 159 (Wiener, Chapter 532, Statutes of 2019). 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 criteria that a training program for participating pharmacists must meet for approval by the board and the recordkeeping requirements for a pharmacist who has completed the training program.

The emergency regulation is proposed pursuant to the board's general rulemaking authority in Business and Professions Code (B&P) section 4005 and specific emergency rulemaking authority in B&P sections 4052.02 and 4052.03. The proposed emergency regulation implements, interprets, and makes specific B&P sections 4052.02 and 4052.03.

The board approved the emergency rulemaking on January 29, 2020 and submitted the emergency rulemaking documents to the Department of Consumer Affairs (DCA) for review and approval on February 7, 2020. The emergency regulation became effective April 30, 2020 and was scheduled to expire on October 28, 2020. The Governor issued two executive orders, N-40-20 and N-66-20, each of which authorized 60-calendar-day extensions, which applied to emergency and emergency readopt actions. The end of the first 60-day extension was December 28, 2020, and the end of the second 60-day extension is February 26, 2021.

The board approved the non-emergency rulemaking on January 29, 2020 and submitted the non-emergency rulemaking documents to DCA for review and approval on February 7, 2020. The board received approval from DCA of the non-emergency rulemaking on January 19, 2021. The rulemaking was submitted to OAL for publication on January 19, 2021 and the 45-day public comment period began on Friday, February 5, 2021. The 45-day comment period ends on March 15, 2021.

Therefore, to preserve the peace, health, safety and general welfare of the residents of the State of California, the board seeks to again readopt this emergency regulation to ensure patients are not deprived access to needed medication while the board finalizes the non-emergency rulemaking. There are no changes to the text from the prior emergency regulation adoptions.

On October 7, 2019, SB 159 was approved by Governor Gavin Newsom. SB 159 created 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. (B&P

sections 4040(a)(2), 4052(a)(10)(A)(iv)-(v), and 4059.) Under the exception created by SB 159, a pharmacist who completes a training program approved by the board may independently initiate and furnish PrEP (B&P section 4052.02) and PEP (B&P section 4052.03) in specified amounts, under specific circumstances, and counsel a patient on the use of those drugs. B&P sections 4052.02 and 4052.03 require a participating pharmacist to furnish those drugs if certain conditions are met, including if the pharmacist determines the patient meets the clinical eligibility criteria for PrEP or PEP specified in those sections and consistent with specified CDC guidelines.

B&P sections 4052.02(g) and 4052.03(g) require the board to adopt emergency regulations to implement the requirements of each section in accordance with the CDC guidelines by July 1, 2020. Both sections direct the board to develop the regulations in consultation with the Medical Board of California, and to develop the provisions of each regulation pertaining to a training program in consultation with the Medical Board of California and relevant stakeholders, including the Office of AIDS within the State Department of Public Health. The board complied with the above consultation provisions.

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. (B&P sections 4052.02(g), 4052.03(g).)

INFORMATIVE DIGEST

Summary of Existing Laws and Regulations

The Pharmacy Law (Chapter 9 [commencing with section 4001] of Division 2, B&P) provides for the licensure and regulation of pharmacists in this state by the board.

B&P section 4005 generally authorizes the board to adopt and amend rules and regulations pertaining to the practice of pharmacy.

B&P section 4052 authorizes a pharmacist to independently initiate and furnish PrEP and PEP as provided in B&P sections 4052.02 and 4052.03, “[n]otwithstanding any other law.”

B&P sections 4052.02 and 4052.03 require the board to adopt regulations to establish the training requirements for pharmacists to independently initiate and furnish PrEP and PEP in accordance with CDC guidelines.

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 is adhering 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 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.

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

Necessity Statements

The proposed emergency regulation adds section 1747 to Title 16 of the California Code of Regulations (CCR). The specific additions are as follows:

Subdivision (a) (before paragraph (1)) requires a pharmacist to successfully complete a training program approved by the board or provided by a provider accredited by an approved accreditation agency prior to independently initiating and furnishing PrEP or PEP. (See B&P section 4052.02(d) and 4052.03(d).) The board determined that approving training programs offered by accredited providers would increase the number of approved training programs available, thereby enabling 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 would reduce barriers to patient access and benefit California residents. The board has established specific requirements within 16 CCR sections 1732.05 and 1732.1 that accreditation agencies must meet to accredit providers offering continuing education to pharmacists, which include providers that currently offer continuing education in PrEP and PEP. The board is satisfied that these requirements establish adequate safeguards to ensure that PrEP and PEP training programs accredited by an approved accreditation agency for the purposes of the proposed regulation will meet all the requirements specified within this proposal. Training programs that are not offered by an accredited provider but meet the specific requirements of this section may be submitted

for board approval and approval will be based solely on the criteria identified in subdivision (a).

Subdivision (a)(1) specifies that the training program shall cover both PrEP and PEP. (B&P sections 4052.02(d) and 4052.03(d).) The board determined that the training program should be comprehensive to both PrEP and PEP in order to encourage pharmacists to participate in the program.

Further, subdivision (a)(1) specifies that the training program shall consist of at least 1.5 hours of instruction. The board determined that 1.5 hours was the appropriate length based on discussions with stakeholders, who expressed concern that training requirements of two hours or longer would create a barrier to access, and by assessing 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. Therefore, the information will not be new to a large portion of pharmacists. Additionally, the board determined that the training program should establish a minimum competency for pharmacists providing PrEP and PEP and that 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 should they wish to do so.

Subdivision (a)(1)(A) requires a training program to cover, at minimum, the pharmacology of PrEP and PEP. As a pharmacist will be independently initiating and furnishing these medications, the pharmacist must 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, may not emphasize to a patient that adherence to the PrEP regimen is critical to HIV prevention and reduces the likelihood that an HIV infection will become drug resistant if unknowingly acquired while on PrEP.

Subdivision (a)(1)(B) requires a training program to provide the educational requirements to independently initiate and furnish PrEP and PEP as identified in B&P sections 4052.02 and 4052.03. The educational requirements ensure the pharmacist is trained and aware of the limitations on their authority to independently initiate and furnish PrEP and PEP, which is 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. (B&P 4052.02(e)(6), 4052.03(e)(1).) A pharmacist must be aware of these limitations, which, in the case of PrEP, 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, and will also prevent pharmacists from prescribing PEP in excess of, or otherwise inconsistent with, CDC recommendations. In the case of both PrEP and PEP, limiting the treatment a pharmacist may provide will encourage patients to continue treatment with a primary care provider, who will be better positioned to manage the patient's care.

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. Patient counseling is required by B&P 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 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) requires a training program to provide the pharmacist with sources to obtain 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. Additionally, federal resources are available through the CDC. 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) requires a training program to provide education on financial assistance programs, including the Office of AIDS' PrEP Assistance Program (PrEP-AP). This requirement is added as B&P sections 4052.02(d) and 4052.03(d) require that the training program provide information on financial assistance programs. The Office of AIDS' PrEP Assistance Program is the financial assistance program for California residents. This information is critical for pharmacists providing PrEP and PEP because cost of treatment can be a barrier to access.

Subdivision (a)(1)(F) requires a training program to provide education on the clinical eligibility recommendations provided in the CDC guidelines defined in B&P sections 4052.02(c) and 4052.03(c). B&P 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. (B&P 4052.03(e)(1)-(e)(3).)

Subdivision (a)(2) requires a training program to require an assessment with a score of 70% or higher to receive documentation of the successful completion of the course. This requirement was added 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. The board notes that minimum training is appropriate and trusts a professional pharmacist to seek out additional training if they determine it necessary.

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.

Consistency and Compatibility with Existing Regulations

The board conducted a search of the California Code of Regulations and determined that the proposed regulation is neither inconsistent nor incompatible with existing state regulations.

Underlying Data

1. Senate Bill (SB) 159 (Wiener, Chapter 532, Statutes of 2019)
2. Letter from California State Senator Scott Wiener to California State Board of Pharmacy, dated November 5, 2019
3. Board Meeting Materials and Additional Meeting Materials, January 29-30, 2020, https://www.pharmacy.ca.gov/about/meetings_full.shtml
4. Relevant meeting materials and minutes from board Licensing Committee meeting held January 9, 2020

5. Relevant meeting materials and minutes from board Licensing Committee meeting held December 12, 2019
6. CDC guidelines for PrEP: CDC, “Preexposure Prophylaxis for the Prevention of HIV infection in the United States—2017 Update: A Clinical Practice Guideline” (March 2018) https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf
7. CDC guidelines for nPEP: “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
8. California Department of Public Health, Office of AIDS, “Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP)” https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OA_prev_PrEP.aspx
9. Letter from the California State Board of Pharmacy to the Medical Board of California, dated February 21, 2020

Fiscal Impact Estimates

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

Fiscal Impact on Public Agencies Including Costs or 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

Effect on Housing Costs: None

Local Mandate: None

Mandate on Local Agencies or School Districts

This regulatory action does not impose a mandate on local agencies or school districts.

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Website Access: Materials regarding this proposal can be found at https://www.pharmacy.ca.gov/laws_regs/approved_regs.shtml.