MEDICAL BOARD OF CALIFORNIA LEGISLATIVE ANALYSIS

BILL NUMBER: AUTHOR: BILL DATE: SUBJECT:

SPONSOR:

SB 339 Wiener March 14, 2023, Introduced HIV Preexposure Prophylaxis and Postexposure Prophylaxis California Pharmacists Association Equality California San Francisco AIDS Foundation

DESCRIPTION OF CURRENT LEGISLATION

Authorizes a pharmacist to furnish up to a 90-day course of preexposure prophylaxis (PrEP), or beyond 90-days if specified conditions are met and requires the Board of Pharmacy (BOP) to adopt emergency regulations to implement these provisions by July 1, 2024.

Requires a health care service plan and health insurer to cover PrEP and postexposure prophylaxis (PEP) furnished by a pharmacist, including costs for the pharmacist's services and related testing ordered by the pharmacist.

BACKGROUND

Business and Professions Code (BPC) section 4052.02 authorizes a pharmacist to initiate and furnish up to a 60-day supply of HIV PrEP medication under certain conditions, including:

- The pharmacist has <u>completed a training program</u> approved by the BOP (and in consultation with the Medical Board of California (Board)).
- The patient is HIV negative (based upon a test completed within at least the last seven days) and has no self-reported HIV-related signs or symptoms.
- The patient is not taking any contraindicated medications and the pharmacist provides counseling on the use of PrEP medication, including side effects, and informs the patient they must see a primary care provider to receive more than a 60-day supply once every two years.
- The pharmacist documents the services provided by the pharmacist and seeks consent to notify the patient's primary care provider. If the patient has no primary care provider, the pharmacist shall provide them with a list of providers.

<u>BPC section 4052.03</u> authorizes a pharmacist to initiate and furnish HIV PEP under certain conditions, including:

• The pharmacist has completed a training program approved by the BOP (and in consultation with the Board).

- The pharmacist screens the patient and determines the exposure occurred within 72 hours and the patient meets clinical criteria consistent with CDC guidelines.
- The pharmacist provides appropriate HIV testing, or if the patient refuses testing, the pharmacist may provide PEP medication anyway, if the patient meets the other related requirements.
- The pharmacist counsels the patient on the use of PEP consistent with CDC guidelines.
- The pharmacist seeks consent to notify the patient's primary care provider. If the patient has no primary care provider, the pharmacist shall provide them with a list of providers.

ANALYSIS

According to the author's fact sheet:

"Senate Bill 339 increases the time that pharmacists are authorized to furnish preexposure prophylaxis (PrEP) – a highly effective HIV prevention medication from 60 days to 90 days. SB 339 allows pharmacists to furnish PrEP on an ongoing basis so long as the patient receives appropriate testing and follow up care consistent with CDC guidelines. Additionally, SB 339 requires health plans to reimburse pharmacies for pharmacist services in providing PrEP, including costs for the pharmacist's services and related testing.

SB 339 builds on California's groundbreaking law — SB 159 — that made California the first state to authorize pharmacists to provide PrEP and postexposure prophylaxis (PEP) without a physician's prescription. SB 159 was a major step, but the law needs refinement in order to be fully implemented. SB 339 provides that refinement by removing barriers that are preventing pharmacists from participating in this program. SB 339 will expand access to PrEP for Californians at risk of contracting HIV.

Despite significant progress, HIV remains a major public health challenge in California, with nearly 4,000 new HIV diagnoses each year. Black and Latino gay and bisexual men, Black cisgender women, transgender women, and youth continue to be the populations most impacted by HIV."

Provisions Related to Patient Care

This analysis will focus on the aspects related to patient care, not the requirements related to health insurers.

According to a Senate legislative analysis:

"Despite the incredible promise of PrEP and PEP to stop the HIV epidemic in its tracks, uptake of these medications has been slow. Preliminary data shows that in 2020 just 25% of the estimated 1.2 million people in the U.S. who have an

indication for PrEP were prescribed it and there are significant disparities in PrEP use along racial, ethnic, and gender lines. For example, in 2019, Black or African American people accounted for an estimated 42% of new HIV diagnoses but just 8% of PrEP prescriptions and Latinos accounted for an estimated 29% of new HIV diagnoses but just 14% of PrEP prescriptions.

The California Pharmacists Association states that a pharmacist's training consists of 3-4 years of professional graduate level study to earn a Doctor of Pharmacy (PharmD) degree. During these years, student pharmacists are also required to complete a minimum of 1,500 hours of clinical practice experience in conjunction with their formal didactic education. Once the didactic and clinical hours are completed, pharmacist candidates must successfully pass two board exams: North American Pharmacist Licensure Examination (NAPLEX) and California Practice Standards and Jurisprudence Exam (CPJE) to be duly licensed pharmacists with the California Board of Pharmacy. Licensed pharmacists are required to complete a minimum of 30 hours of continuing pharmacy education (CE) every two years to renew their pharmacist license within the state. It is within pharmacists' scope of practice to order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. They are qualified to provide appropriate care to patients on PrEP."

This bill expands access to HIV PrEP medication from qualified pharmacists to patients who are at risk for HIV exposure, as follows:

- Allows pharmacists to provide an initial 90-day course of PrEP.
- Clarifies that HIV testing must be conducted consistent with CDC guidelines.
- Deletes the requirement for the patient to be seen by a primary care provider to receive more than a 60-day course of medication once every two years.
- Requires the pharmacist to inform the patient that they may need to be seen to receive subsequent courses of PrEP, unless the pharmacist ensures the patient receives testing and follow-up care consistent with CDC guidelines.
- Allows the pharmacist to continue furnishing PrEP beyond a 90-day course if all the following conditions are met:
 - Patient receives testing and follow-up care consistent with CDC guidelines, which may include timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of childbearing capacity.
 - The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's record in the record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis furnished to each patient.
 - The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subdivision. If the patient does not have a primary care provider or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of primary care providers in the region.

Further, the bill requires the BOP to adopt emergency regulations on these protocols in accordance with CDC guidelines and in consultation with the Board by July 1, 2024.

Opponent's Arguments

Physician organizations express concerns with pharmacists continuously dispensing PrEP and PEP in perpetuity without a patient ever seeing a primary care provider and receiving a prescription. They state that pharmacists lack medical training to provide them with appropriate knowledge to interpret test results and if the patient does not receive appropriate follow-up care with a physician, a significant medical issue may arise.

Consideration of a Board Position

Unfortunately, HIV continues to spread in at-risk populations. Ideally, a patient would seek, and be able to receive, consistent care and treatment from a primary care provider, but that is not always practical. Pharmacists, under the bill, are required to encourage patients to see a primary care provider and to provide them with a list of providers and provide testing and medications consistent with CDC guidelines and regulations adopted by the BOP with input from the Board. If the patient does not ultimately obtain treatment from a primary care provider, for whatever reason, the patient may continue to receive this medication through their pharmacists.

This bill has the support of BOP, and the Board will be able to coordinate with the BOP on the updated regulations required by the bill. Accordingly, staff recommend the Board adopt a Support position.

- FISCAL: Minor and absorbable costs related to collaborating with the BOP to update required regulations.
- SUPPORT: ACLU California Action **Biocom California** California Board of Pharmacy California Community Pharmacy Coalition California Life Sciences Ca. Society of Health-System Pharmacists City and County of San Francisco City of West Hollywood County Health Executives Association of California County of Santa Clara **Desert AIDS Project** End the Epidemics National Association of Social Workers, California Chapter **Radiant Health Centers** San Francisco Community Health Center Somos Familia Valle

Western Center on Law & Poverty

<u>OPPOSITION:</u> Assn. of Ca. Life and Health Insurance Companies (unless amended) Amer. College of OB-GYNs District IX (unless amended) America's Health Insurance Plans California Association of Health Plans (unless amended) California Medical Association (unless amended)

<u>POSITION:</u> Staff Recommendation: Support.

ATTACHMENT: SB 339, Wiener - HIV Preexposure Prophylaxis and Postexposure Prophylaxis Version: 3/14/23 – Amended