

MEDICAL BOARD OF CALIFORNIA
LEGISLATIVE ANALYSIS

BILL NUMBER: SB 159
AUTHOR: Wiener
BILL DATE: July 1, 2019, Amended
SUBJECT: HIV: Preexposure and Postexposure Prophylaxis
SPONSOR: California Pharmacists Association; California Society
of Health-System Pharmacists; Equality California;
and San Francisco AIDS Foundation
POSITION: Support if Amended

DESCRIPTION OF CURRENT LEGISLATION:

This bill would allow a pharmacist, exercising appropriate professional judgement, to furnish a 60-day supply of preexposure prophylaxis (PrEP) or postexposure prophylaxis (PEP), if specified conditions are met. This bill would prohibit a health plan or insurer from subjecting combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, including PrEP and PEP, to prior authorization or step therapy. This bill would prohibit plans and insurers from prohibiting, or allowing a pharmacy benefit manager to prohibit, a pharmacy provider from providing PrEP or PEP. This bill would prohibit a health plan or insurer from covering PrEP, as authorized, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber. This bill would require Medi-Cal to reimburse pharmacies for initiating and furnishing PrEP and PEP.

BACKGROUND:

According to the committee analysis:

In 2012, the U.S. Food and Drug Administration (FDA) approved Truvada, a name brand daily-use drug for PrEP that can reduce the risk of sexually acquired HIV-infection in adults at high risk. According to the CDC, PrEP is “highly effective for preventing HIV if used as prescribed, but it is much less effective when not taken consistently. Daily PrEP reduces the risk of getting HIV from sex by more than 90%. Among people who inject drugs, it reduces the risk by more than 70%.” For over 20 years, CDC has recommended PEP to protect healthcare workers who have been accidentally exposed to HIV in the workplace.

PEP involves taking certain HIV medicines within 72 hours after a possible exposure to HIV to prevent infection. PEP involves taking HIV medications every day for 28 days, and the CDC indicates that it should be used only in emergency situations, and is not intended to replace regular use of other HIV prevention methods, such as PrEP.

In 2017, the CDC published Preexposure Prophylaxis for HIV Prevention in the United States – 2017 Update: A Clinical Practice Guideline, which provided comprehensive information for the use of daily oral antiretroviral PrEP to reduce the risk of acquiring HIV infection in adults. The CDC Guidelines indicate that “Daily oral PrEP ... has been shown to be safe and effective in reducing the risk of sexual HIV acquisition in adults; therefore, PrEP is recommended as one prevention option for sexually-active adult men who have sex with men, ...adult heterosexually active men and women, ...and injection drugs users at substantial risk of HIV acquisition.”

In assessing an individual’s clinical eligibility prior to prescribing PrEP, CDC recommends the person have a documented negative HIV test, no signs or symptoms of acute HIV infection, normal renal function, no use of contraindicated medications, no documented hepatitis B virus infection, and a hepatitis B vaccination.

The CDC further recommends that HIV infection should be assessed at least every 3 months while patients are taking PrEP, renal function should be assessed at baseline and monitored at least every 6 months, and follow-up visits at least every 3 months should provide the following: HIV testing, medication adherence counseling, behavioral risk reduction support, side effect assessment, and STI symptom assessment.

The most recent CDC guidelines for PEP, Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Non-occupational Exposure to HIV— United States, 2016, encourage health care providers to evaluate individuals for PEP when care is sought within 72 hours after a potential non-occupational exposure that presents a substantial risk for HIV acquisition.

CDC recommends individuals considering PEP take an HIV test, but if one is unavailable and PEP is otherwise indicated, PEP “should be initiated without delay and can be discontinued if the patient is later determined to have HIV infection already or the source is determined not to have HIV infection.” A complete course of PEP is 28 days of a 3-drug antiretroviral regimen. The guidelines further indicate, “All persons evaluated for possible PEP should be provided any indicated prevention, treatment, or supportive care for other exposure-associated health risks and conditions (e.g., bacterial sexually transmitted infections, traumatic injuries, hepatitis B virus and hepatitis C virus infection, or pregnancy). All persons who report behaviors or situations that place them at risk for frequently recurring HIV exposures (e.g., injection drug use, or sex without condoms) or who report receipt of [more than one] course of PEP in the past year should be provided risk-reduction counseling and intervention services, including consideration of PrEP.”

ANALYSIS:

This bill would allow a pharmacist to initiate and furnish HIV PrEP and PEP in accordance with this bill.

This bill would define PrEP to mean a fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another drug or drug combination that meets the same clinical eligibility recommendations provided in CDC guidelines. This bill would define the CDC Guidelines for PrEP as the “2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline,” published by the CDC.

This bill would require, before furnishing PrEP to a patient, a pharmacist to complete a training program approved by the Board of Pharmacy (BOP), in consultation with the Medical Board of California (Board), on the use of PrEP and PEP. This bill would require the training to include information about financial assistance programs for PrEP and PEP, including the HIV prevention program described in existing law. This bill would require BOP to consult with the Board, as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the California Department of Public Health (CDPH), on training programs that are appropriate to meet the requirements of this bill.

This bill would allow a pharmacist exercising appropriate professional judgment, to furnish a 60-day supply of PrEP if all of the following conditions are met:

- The patient is HIV negative, as documented by a negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care finger stick blood test approved by the federal FDA. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist would be required to order an HIV test. If the test results are not transmitted directly to the pharmacist, this bill would require the pharmacist to verify the test results to the pharmacist’s satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test would be required to direct the patient to a primary care provider and provide a list of providers and clinics in the region.
- The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.
- The patient does not report taking any contraindicated medications.
- The pharmacist provides counseling to the patient on the ongoing use of PrEP, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of child-bearing capacity. The pharmacist would be required to notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for PrEP and that a pharmacist may not furnish a 60-day supply of PrEP to a single patient more than once every two years.
- The patient reports having normal kidney function, and the pharmacist orders a test to measure kidney function. This bill would require the patient to provide contact information and sign an agreement to stop taking PrEP if laboratory results indicate that the patient should not take PrEP. This bill would require the pharmacist to contact the patient if laboratory results indicate that the patient should not take PrEP.

- The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's health record. This bill would require the pharmacist to maintain records of PrEP furnished to each patient.
- The pharmacist does not furnish a 60-day supply of PrEP to a single patient more than once every two years, unless directed otherwise by a prescriber.
- 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, this bill would require the pharmacist to provide the patient a list of physicians, clinics, or other health care service providers to contact regarding ongoing care for PrEP.

This bill would define PEP as any of the following: “

- Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily.
- Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily.
- Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

This bill would define “CDC guidelines” for PEP as the “Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016,” published by CDC.

This bill would allow a pharmacist exercising appropriate professional judgment, to furnish a complete course of PEP if all of the following conditions are met:

- The pharmacist screens the patient and determines the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for PEP consistent with CDC guidelines.
- The pharmacist provides HIV testing or determines the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for PEP under this section, the pharmacist may furnish PEP.
- The pharmacist provides counseling to the patient on the use of PEP consistent with CDC guidelines, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV and sexually transmitted diseases. The pharmacist shall also inform the patient of the availability of PrEP for persons who are at substantial risk of acquiring HIV.
- The pharmacist notifies the patient's primary care provider of the PEP treatment. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist would be required to provide the patient a list of physicians, clinics, or other health care service providers to contact regarding follow-up care for PEP.

This bill would specify that a pharmacist initiating or furnishing PrEP or PEP shall not allow the person to whom the drug is furnished to waive the consultation required by BOP.

This bill would require BOP, by July 1, 2020, to adopt emergency regulations to implement this bill in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. This bill would require BOP to consult with the Board in developing these regulations.

This bill would specify that a health care service plan or health insurer must not subject combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, PrEP or PEP, to prior authorization or step therapy. This bill would specify that a health care service plan or health insurer shall not prohibit, or permit a delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing PrEP or PEP. This bill would specify that a health care service plan or health insurer shall not cover PrEP that has been furnished by a pharmacist in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

This bill would specify that it does not require a health care service plan or health insurer to cover PrEP or PEP by a pharmacist at an out-of-network pharmacy, unless the health care service plan has an out-of-network pharmacy benefit. This bill would require Medi-Cal to reimburse pharmacies for initiating and furnishing PrEP and PEP.

According to the author's office, "Currently, PrEP and PEP both require a physician's prescription, which delays or prevents some people from accessing it. Some people are not comfortable going to see a doctor. Others struggle to access a doctor or are confronted with long delays to obtain an appointment. And, sadly, although many doctors understand the need for PrEP, too many doctors don't know much about it, judge people for requesting it, try to persuade them not to request it, and, generally, don't know enough about sexual health, particularly LGBTQ sexual health. To be clear, many doctors 'get it' and do a great job in this area. Significant work remains to educate the profession. Another barrier to PrEP and PEP uptake is the requirement by some insurance companies for prior authorization. Notably, Medi-Cal does not require a prior authorization. Prior authorizations can lead to delays of weeks or months in accessing PrEP and can lead to someone becoming HIV positive."

The Board supports the use of PrEP and PEP and believes they are both important medications to use to help prevent HIV infections. The Board supports pharmacists being able to dispense a complete course of PEP, as it will increase access to PEP, which is important as it must be initiated 72 hours after exposure and PEP only requires a 28-day course. However, the Board believes that because PrEP requires regular monitoring, testing, and adherence, that it is not appropriate for pharmacists to initiate PrEP, as they do not have the ability to provide the monitoring and testing on an on-

going basis. The Board has taken a support if amended position on this bill, and is requesting that the provisions that allow pharmacists to initiate PrEP be deleted.

FISCAL: None

SUPPORT: California Pharmacists Association (co-sponsor); California Society of Health System Pharmacists (co-sponsor); Equality California (co-sponsor); San Francisco AIDS Foundation (co-sponsor); Alameda County; American Civil Liberties Union of California; APLA Health; California Health+ Advocates California LGBTQ Health and Human Services Network; California Life Sciences Association; California Retailers Association; City of West Hollywood; City and County of San Francisco; County Health Executives Association of California; County of Los Angeles; County of Santa Clara; Health Officers Association of California; Human Rights Campaign; Los Angeles LGBT Center; Lutheran Social Services of Northern California; NARAL Pro-Choice California; National Association of Chain Drug Stores; National Association of Social Workers, California Chapter; San Francisco Department of Public Health; San Francisco Hepatitis C Task Force; San Francisco Lesbian Gay Bisexual Transgender Community Center; Shanti; St. Anthony's Medical Clinic; St. James Infirmary; and United Nurses Associations of California/Union of Health Care Professionals

OPPOSITION: AIDS Healthcare Foundation (unless amended); American College of Obstetricians and Gynecology District IX; California Academy of Preventive Medicine; California Chapter of the American College of Cardiology; California Medical Association (unless amended); California Urological Association; and Infectious Diseases Association of California