

Key Findings

Analysis of California Senate Bill 339

HIV Preexposure Prophylaxis and Postexposure Prophylaxis

Summary to the 2023–2024 California State Legislature, April 20, 2023



SUMMARY

The version of California Senate Bill (SB) 339 analyzed by CHBRP would do the following:

- Update the definition of preexposure prophylaxis (PrEP) to include prescription drugs approved by the U.S. Food and Drug Administration (FDA) or recommended by the Centers for Disease Control and Prevention (CDC) to reduce a person's chance of contracting human immunodeficiency virus (HIV).
- Authorize a pharmacist to furnish up to a 90-day course of PrEP, and beyond a 90-day course under certain conditions.
- Require health plans regulated by the Department of Managed Health Care (DMHC) and health policies regulated by the California Department of Insurance (CDI) to reimburse for all pharmacist services and testing related to PrEP and postexposure prophylaxis (PEP) furnishment, equal to the rate of those delivered by physicians.

In 2024, all of the 22.8 million Californians enrolled in state-regulated health insurance, would have insurance subject to SB 339.

Benefit Coverage: At baseline, approximately 97% of commercial enrollees and Medi-Cal beneficiaries have insurance fully compliant with SB 339. Postmandate, 100% of enrollees would have coverage compliant with the mandate. SB 339 would not exceed essential health benefits (EHBs).

Medical Effectiveness: There is *clear and convincing evidence* that PrEP is effective in preventing HIV transmission and lowering the risk of HIV among users with moderate or high adherence. There is *limited evidence* that PEP is effective in preventing HIV transmission following nonoccupational exposures, and that pharmacists can safely and effectively furnish daily oral PrEP. There is *insufficient evidence* that pharmacists can

safely and effectively furnish PEP or injectable PrEP, and *insufficient evidence* that shows a difference in safety and effectiveness between a 60- and 90-day supply of pharmacist-furnished PrEP.

Cost and Health Impacts¹: CHBRP estimates SB 339 would increase total net annual expenditures by \$1,763,000 or 0.0011% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a \$1,638,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by an increase of \$125,000 in enrollee expenses for covered and/or noncovered benefits. In 2024, CHBRP estimates, as an upper bound, that SB 339 would result in an additional 134 enrollees who obtain PrEP and 63 enrollees who obtain PEP, which is equivalent to an estimated 3% increase. Given the estimated utilization postmandate, this would result in an increase in the number of the individuals screened for HIV and a small reduction in the number of new HIV cases and HIV transmissions.

CONTEXT

HIV attacks the body's CD4 and/or T-cells (a type of white blood cell), which are integral to the body's immune function. HIV spreads via direct contact with certain bodily fluids of an individual with a detectable viral load.² If undiagnosed and left untreated, HIV invades and effectively destroys CD4 cells during the virus replication process, leading to opportunistic infections, opportunistic cancers, and death. There is no cure for HIV/AIDS; however, with routine care and proper treatment, HIV-related morbidity and mortality can be prevented through the use of antiretroviral (ARV) drugs — known for inhibiting viral replication and allowing for immune reconstitution. Given the availability of ARVs, it is possible for people living with HIV to achieve a life expectancy similar to that of the general population.

PrEP is a long-term regimen recommended for the population that has repeated, intimate exposure to HIV-positive individuals or other high-risk individuals of

¹ Similar cost and health impacts could be expected for the following year, though possible changes in medical science

and other aspects of health make stability of impacts less certain as time goes by.

² Refer to CHBRP's full report for full citations and references.

unknown HIV status. PEP is a short-term, daily therapy similar to PrEP. The CDC recommends using PEP only in emergency situations if HIV exposure is suspected. Examples of events meeting this standard include sexual intercourse or shared use of drug equipment with a (suspected) HIV-positive person, newborns born to HIV-positive mothers, cases of sexual assault, condom failure, or occupational transmission to health care workers.

The FDA has approved two oral medications and one injectable treatment for PrEP; the CDC recommends the same medications for PrEP to reduce the risk of contracting HIV. The CDC and U.S. Department of Health and Human Services recommend one PEP regimen specific to adults and one specific to newborns.

Under existing California law, pharmacists are authorized to provide specific regimens of PrEP (for up to 60 days, and beyond under certain conditions) and PEP, and practice under collaborative practice agreements. They are also authorized to order a medication-related laboratory test that is waived under the Clinical Laboratory Improvement Amendments (CLIA) of 1988. However, reimbursement for PrEP- and PEP-related testing and services are limited to those related to testing for HIV and sexually transmitted infections.

In a recent study conducted by the California HIV/AIDS Policy Research Centers (CHAPRC) assessing the adoption of SB 159 (2019) — the legislation that authorized pharmacists to furnish PrEP and PEP — researchers found that of the more than 900 Californian pharmacists surveyed, only 11% and 13% had initiated PrEP and PEP, respectively, as authorized by SB 159. CHAPRC found that barriers to implementation varied by pharmacy type. For example, 53% of respondents affiliated with chain community pharmacies cited insufficient staff/time as the main barrier to furnishing PrEP compared to 18% affiliated with independent pharmacies. Independent pharmacies, however, cited lack of insurance coverage as the main barrier to furnishing PrEP (33%) as well as low demand among patients (24%). Among all respondents, 42% believed that the current 60-day limit on PrEP — as stipulated by SB 159 (2019) — did not allow enough time to ensure successful referral to a primary care provider for PrEP continuation.

It is important to note that pharmacies are currently set up to bill health plans and insurers for drugs; their billing systems are not structured to bill for services typically seen under the medical benefit, including cognitive or clinical services, such as those related to SB 339.

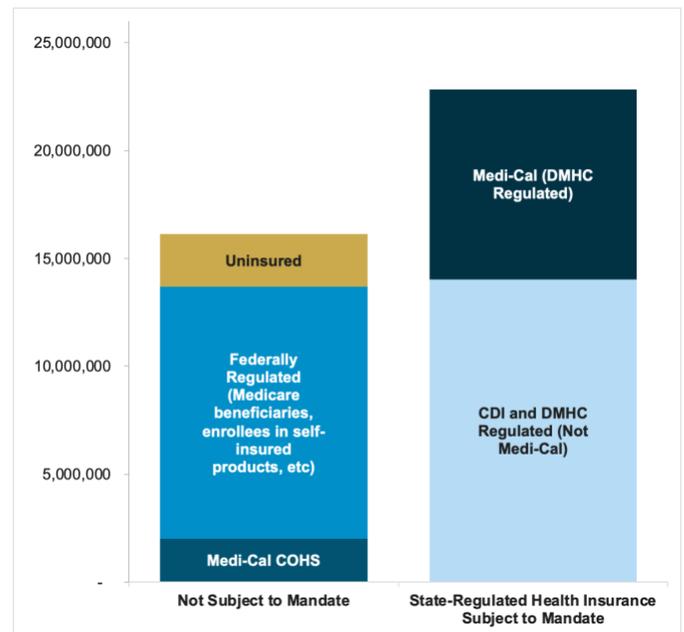
BILL SUMMARY

SB 339 would do the following:

- Update the current definition of PrEP in law to include prescription drugs approved by the FDA or recommended by the CDC to reduce a person’s chance of contracting HIV.
- Authorize a pharmacist to furnish up to a 90-day course of PrEP, and beyond a 90-day course under certain conditions.
- Require health plans regulated by DMHC and health policies regulated by CDI to reimburse for all pharmacist services and testing related to the furnishing of PrEP and PEP at 100% the rate of those delivered by physicians.

Figure A notes how many Californians have health insurance that would be subject to SB 339.

Figure A. Health Insurance in CA and SB 339



Source: California Health Benefits Review Program, 2023.

Key: CDI = California Department of Insurance; COHS = County Organized Health System; DMHC = Department of Managed Health Care.

IMPACTS

Benefit Coverage, Utilization, and Cost

CHBRP assumes the following:

- If enacted, SB 339 would encourage pharmacists to begin newly offering PrEP and PEP services and testing.
- Pharmacists would be limited in newly offering PrEP and PEP due to constraints in pharmacy billing systems (i.e., an inability to bill for services on the medical benefit).
- Any increase in cabotegravir injection PrEP medication (also known as CAB-LA) furnishing by pharmacists would be limited by pharmacists' ability to provide private consultation and administration of the intramuscular injection.

In addition to the results of the aforementioned CHAPRC study, another study on SB 159 implementation found that 2.9% of 209 pharmacies in a San Francisco Bay Area community had begun furnishing PrEP/PEP under the new law. Based on the results of these studies, CHBRP further assumes that:

- SB 339 would encounter similar take-up issues faced by SB 159 (2019) postmandate, which would provide an initial boost to supply before stabilizing at this higher level.
- Postmandate, there would be an upper boundary of a 3% increase in overall utilization of PrEP/PEP furnished by a pharmacist based on the limited increase seen following SB 159.
- The increase in utilization postmandate would be due to the reasons listed below.
 - A shift transferring PrEP/PEP prescriptions currently issued by primary care providers to being furnished by a pharmacist.
 - New uptake of PrEP/PEP by enrollees due to the expansion of scope to 90 days from the baseline of 60 days in current law; note, this is not a measurable impact.

Benefit Coverage

At baseline, 97% (or 22.1 million) of the 22.8 million enrollees with state-regulated insurance have coverage fully compliant with SB 339; the 3% of enrollees who do not are concentrated in DMHC-regulated individual plans. Postmandate, approximately an additional 786,000 enrollees would gain coverage for pharmacist-furnished PrEP, PEP, and related services and testing.

Utilization

At baseline, 4,462 enrollees use 14,216 oral PrEP prescriptions, 80 CAB-LA injection prescriptions, and a total of 1,470 PrEP-related associated services per year. There are 2,111 enrollees who use 5,592 oral PEP prescriptions and 832 PEP-associated services per year.

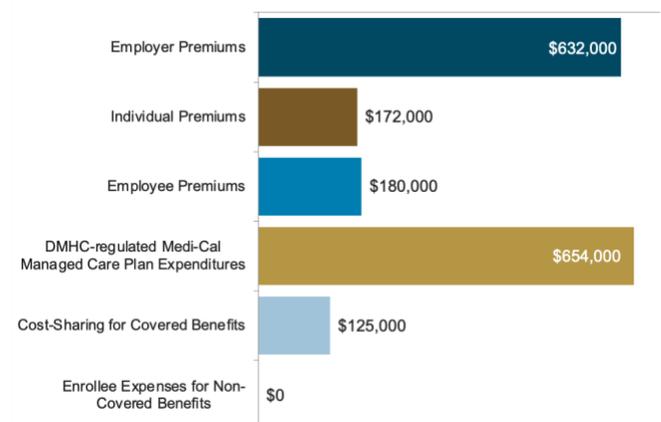
Postmandate, an additional 134 enrollees would use PrEP and PrEP-associated services, with an increase of 426 (or 3%) in oral PrEP prescriptions, 48 (or 60%) in CAB-LA prescriptions, and 1,481 (or 101%) in PrEP-associated services per year due to expanded coverage for associated testing and services. An additional 63 enrollees would use PEP and PEP-associated services, with an increase of 168 (or 3%) oral PEP prescriptions, and 1,026 (or 123%) in PEP-associated services each year.

Expenditures

CHBRP estimates SB 339 would increase total net annual expenditures by \$1,763,000 or 0.0011% for enrollees with state-regulated insurance.

No offsets are projected in the first year postmandate. There is the potential of some offset to cost increases due to the potential avoidance of HIV infection or AIDS-related conditions in the long term (i.e., beyond the first 12 months after implementation).

Figure B. Expenditure Impacts of SB 339



Source: California Health Benefits Review Program, 2023.

Medi-Cal

For this analysis, CHBRP has included potential impacts related to Medi-Cal beneficiaries. In addition to the expected increase of \$654,000 in premiums CHBRP is estimating for the 8.8 million Medi-Cal beneficiaries enrolled in DMHC-regulated plans (a figure that

represents a 0.0022% increase in premiums), it seems reasonable to assume that a population proportional increase of \$149,000 would occur for the 2.0 million beneficiaries enrolled in county organized health systems (COHS) managed care.

CalPERS

For enrollees associated with CalPERS in DMHC-regulated plans, premiums are expected to increase by 0.0009% (\$0.0061 per member per month, \$54,000 total increase in expenditures).

Covered California – Individually Purchased

Premium increases among Covered California plans and policies are expected to increase, ranging from \$0.0042 per member per month for CDI-regulated individual policies, to \$0.0055 per member per month for DMHC-regulated small-group plans.

Number of Uninsured in California

Because the change in average premiums does not exceed 1% for any market segment, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 339.

Medical Effectiveness

The medical effectiveness review summarizes findings from evidence on the effectiveness of PrEP/PEP in preventing HIV/AIDS, the ability of pharmacists to prescribe PrEP/PEP safely and effectively, as well as any harms or adverse events associated with PrEP/PEP.

CHBRP's literature review for PrEP focused on the three FDA-approved medications for PrEP in the United States. Health outcomes such as HIV incidence, risk of contracting HIV, and HIV transmission were explored specifically in relation to PrEP/PEP. The literature search did not focus on investigating these outcomes in comparison to other means of HIV/AIDS prevention (e.g., safe sexual practices, sexually transmitted infections testing).

CHBRP found the following:

³ *Clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

⁴ *Limited evidence* indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

- There is *clear and convincing evidence*³ that PrEP is effective in preventing HIV transmission and lowering the risk of HIV among users with moderate or high adherence — as both are associated with high protection from PrEP.
- There is *limited evidence*⁴ that PEP is effective in preventing HIV transmission following occupational and nonoccupational exposures.
- There is *limited evidence* that pharmacists can safely and effectively furnish daily oral PrEP. There is *insufficient evidence*⁵ that pharmacists can safely and effectively furnish CAB-LA (PrEP)
- There is *insufficient evidence* that pharmacists can safely and effectively furnish PEP.
- There is *insufficient evidence* that shows a difference in safety and effectiveness between a 60-day and 90-day supply of pharmacist-furnished PrEP and PEP.

There are adverse events associated with PrEP and PEP. Despite these, the CDC asserts that the benefits of PrEP and PEP medication use outweigh their reported risks and that the schedule of follow-up monitoring visits is designed to address any potential medication-related harm in a timely manner.

Public Health

The public health impact analysis estimates the short-term impact⁶ of SB 339 on utilization of PrEP and PEP; HIV risk reduction; HIV incidence and transmission; quality of life; and racial/ethnic, sexual orientation/gender identity, and geographic disparities.

Given the anticipated increase in utilization postmandate, this would result in an increase in the number of the individuals screened for HIV, a small reduction in the number of new HIV infections, as well as a small reduction in the number of future HIV transmissions (i.e., a reduction in HIV transmission from an HIV-positive individual to an HIV-negative individual).

CHBRP is unable to estimate short-term impacts of SB 339 on the impact of disparities for utilization of PrEP due to lack of data.

⁵ *Insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

⁶ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

Long-Term Impacts

CHBRP estimates utilization of PrEP and PEP would continue to increase after the first year postmandate as (1) pharmacists obtain the required certification to initiate and furnish PrEP and PEP for prevention, (2) pharmacist awareness of PrEP and PEP continues to grow, and (3) pharmacies develop and implement the billing mechanism to bill for associated medical services, eventually leveling out; therefore, the number of enrollees who would avoid contracting HIV would increase over time and subsequently, the number of future HIV transmissions would decrease over time.

Expected increases in costs would be proportional to any further increases in utilization. If those potential

utilization increases do not materialize in the long term due to the limiting factor of enrollees who are eligible for and interested in taking PrEP or PEP, then the costs would also remain constant postmandate.

Essential Health Benefits and the Affordable Care Act

SB 339 would not require coverage for a new state benefit mandate that appears to exceed the definition of essential health benefits (EHBs) in California.