

California Health Benefits Review Program

Analysis of California Senate Bill 339 HIV Preexposure Prophylaxis and Postexposure Prophylaxis

A Report to the 2023–2024 California State Legislature

April 20, 2023



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.

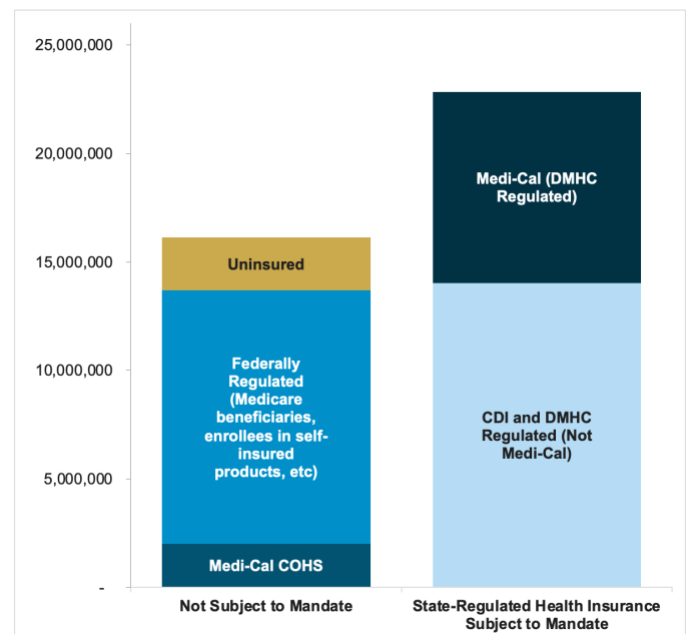
BILL SUMMARY

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.

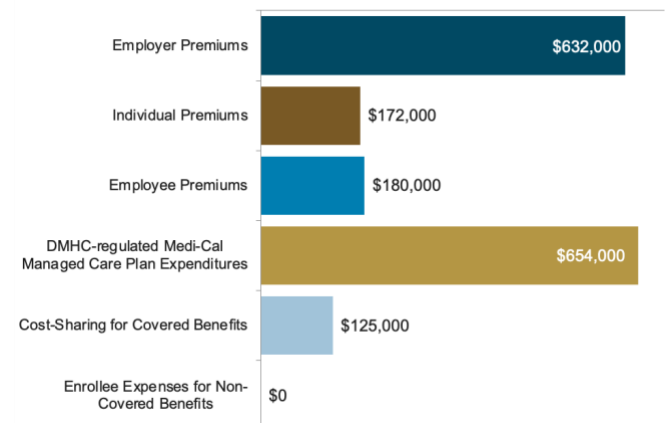
Postmandate, an additional 134 enrollees would use PrEP and PrEP-associated services, with an increase of 426 (or 3%) in oral PrEP prescriptions, 48 (or 60%) in CAB-LA prescriptions, and 1,481 (or 101%) in PrEP-associated services per year due to expanded coverage for associated testing and services.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

- 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.

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.

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.

A Report to the California State Legislature

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HIV Preexposure Prophylaxis and Postexposure
Prophylaxis

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California Health Benefits Review Program
MC 3116; Berkeley, CA 94720-3116
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The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact. Content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications, are available at www.chbrp.org.

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Table 1. Impacts of SB 339 on Benefit Coverage, Utilization, and Cost, 2024

	Baseline (2024)	Postmandate Year 1 (2024)	Increase/ Decrease	Change Postmandate
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	22,842,000	22,842,000	0	0.00%
Total enrollees with health insurance subject to SB 339	22,842,000	22,842,000	0	0.00%
Percentage of enrollees with coverage for mandated benefit	97%	100%	3%	3.57%
Number of enrollees with fully compliant coverage for mandated benefit	22,055,552	22,842,000	786,448	3.57%
Utilization and cost				
Pharmacist-furnished pre-exposure prophylaxis (PrEP)				
Number of enrollees using PrEP	4,462	4,595	134	3.00%
Annual prescriptions				
Oral PrEP	14,216	14,643	426	3.00%
Cabotegravir (CAB-LA)	80	128	48	60.00%
Annual PrEP-associated services (b)	1,470	2,951	1,481	100.81%
Average annual cost per enrollee using PrEP				
Oral PrEP prescriptions	\$6,477.57	\$6,477.57	\$0.00	0.00%
CAB-LA prescriptions	\$12,938.02	\$12,938.02	\$0.00	0.00%
Annual PrEP-associated services (b)	\$1,048.57	\$1,048.57	\$0.00	0.00%
Average annual enrollee cost sharing				
Oral PrEP	\$473.11	\$473.11	\$0.00	0.00%
CAB-LA	\$124.16	\$124.16	\$0.00	0.00%
Annual PrEP-associated services (b)	\$76.41	\$76.41	\$0.00	0.00%
Pharmacist-furnished post-exposure prophylaxis (PEP)				
Number of enrollees using PEP	2,111	2,174	63	3.00%
Annual prescriptions				
Oral PEP prescriptions	5,592	5,760	168	3.00%
Annual PEP-associated services (b)	832	1,859	1,026	123.29%
Average annual cost per enrollee using PEP				
Oral PEP prescription	\$4,719.64	\$4,719.64	\$0.00	0.00%
Annual PEP-associated services (b)	\$459.13	\$1,175.56	\$716.42	156.04%
Average annual enrollee cost sharing				
Oral PEP prescription	\$444.59	\$444.59	\$0.00	0.00%
Annual PEP-associated services (b)	\$86.40	\$93.62	\$7.23	8.36%
Expenditures				
Premiums				
Employer-sponsored (c)	\$62,843,134,000	\$62,843,712,000	\$578,000	0.0009%

CalPERS employer (d)	\$6,158,262,000	\$6,158,316,000	\$54,000	0.0009%
Medi-Cal (excludes COHS) (e)	\$29,618,383,000	\$29,619,037,000	\$654,000	0.0022%
Enrollee Premiums (expenditures)				
Enrollees, individually purchased insurance	\$22,774,757,000	\$22,774,929,000	\$172,000	0.0008%
Outside Covered California	\$5,222,350,000	\$5,222,390,000	\$40,000	0.0008%
Through Covered California	\$17,552,407,000	\$17,552,539,000	\$132,000	0.0008%
Enrollees, group insurance (f)	\$19,805,668,000	\$19,805,848,000	\$180,000	0.0009%
Enrollee out-of-pocket expenses				
Cost-sharing for covered benefits (deductibles, copayments, etc.)	\$14,964,510,000	\$14,964,635,000	\$125,000	0.0008%
Expenses for noncovered benefits (g) (h)	\$0	\$0	\$0	0.00%
Total expenditures	\$156,164,714,000	\$156,166,477,000	\$1,763,000	0.0011%

Source: California Health Benefits Review Program, 2023.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.⁷

(b) PrEP- and PEP-associated services include consultations, HIV screenings, other health condition screenings, and certain vaccinations.

(c) In some cases, a union or other organization. Excludes CalPERS.

(d) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.1% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.⁸ CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(e) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. In addition, CHBRP is estimating it seems likely that there would also be a proportional increase of \$0.59 million for Medi-Cal beneficiaries enrolled in COHS managed care.

(f) Enrollee premium expenditures include contributions by enrollees to employer (or union or other organization)-sponsored health insurance, health insurance purchased through Covered California, and any contributions to enrollment through Medi-Cal to a DMHC-regulated plan.

(g) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that would be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(h) For covered benefits, such expenses would be eliminated, although enrollees with newly compliant benefit coverage might pay some expenses if benefit coverage is denied (through utilization management review).

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; PEP = postexposure prophylaxis; PrEP = preexposure prophylaxis.

⁷ For more detail, see CHBRP's resource *Sources of Health Insurance in California*, available at http://chbrp.org/other_publications/index.php.

⁸ For more detail, see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at http://chbrp.org/other_publications/index.php.

POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)⁹ conduct an evidence-based assessment of the medical, financial, and public health impacts of Senate Bill (SB) 339, HIV Preexposure Prophylaxis and Postexposure Prophylaxis, as amended on March 14, 2023.

Bill-Specific Analysis of SB 339, HIV Preexposure Prophylaxis and Postexposure Prophylaxis

Bill Language

SB 339 would do the following:

- Update the current definition of preexposure prophylaxis (PrEP) in law 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 the furnishing of PrEP and postexposure prophylaxis (PEP) at 100% the rate of those delivered by physicians.

The full text of SB 339 can be found in Appendix A.

Relevant Populations

If enacted, SB 339 would apply to the health insurance of approximately 22.8 million enrollees (58.6% of all Californians). This represents 100% of the 22.8 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law, which includes health insurance regulated by DMHC or CDI. If enacted, the law would apply to the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies, including Medi-Cal plans regulated by DMHC.

As of January 1, 2022, outpatient prescription drugs are covered on a fee-for-service basis by the California Department of Health Care Services (DHCS) for all Medi-Cal beneficiaries under a program called Medi-Cal Rx.¹⁰ Their pharmacy benefit is “carved out” of the coverage provided by DMHC-regulated Medi-Cal plans. HIV/AIDS drugs are included in the carve out for all DMHC-regulated Medi-Cal plans and are instead covered under Medi-Cal Rx. SB 339 would not be expected to impact benefit coverage of PrEP and PEP drugs. However, pharmacists’ services and laboratory tests ordered by pharmacists, including those related to PrEP and PEP counseling and testing, are not carved out and remain a medical benefit. Thus, DMHC-regulated Medi-Cal plans would be responsible for pharmacist services and testing related to PrEP and PEP if SB 339 were enacted.

⁹ CHBRP’s authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.

¹⁰ For more on outpatient prescription drug coverage among Californians with state-regulated health insurance, see CHBRP’s resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance for 2023*, available at https://chbrp.org/other_publications/index.php.

Analytic Approach and Key Assumptions

CHBRP previously analyzed similar bill language, SB 159 in 2019. Where applicable, this analysis builds off that previous analysis.

FDA-Approved and CDC-Recommended PrEP and PEP

The FDA has approved two oral medications (emtricitabine and tenofovir disoproxil fumarate [F/TDF], brand name Truvada®, and emtricitabine and tenofovir alafenamide [F/TAF], brand name Descovy®) and one injectable treatment (cabotegravir extended-release injectable suspension [CAB-LA], brand name Apretude®) for PrEP; the CDC recommends the same medications for PrEP to reduce the risk of contracting HIV.

PrEP Medication Name	Acronym	Brand Name
Emtricitabine and tenofovir disoproxil fumarate	F/TDF	Truvada®
Emtricitabine and tenofovir alafenamide	F/TAF	Descovy®
Cabotegravir extended-release injectable suspension	CAB-LA	Apretude®

The CDC and US Department of Health and Human Services recommend PEP regimens of F/TDF with raltegravir (RAL) twice daily or dolutegravir (DTG) for adults, and zidovudine (AZT) or AZT and lamivudine (3TC) for newborns.

See the *Background on Antiretrovirals for the Prevention of HIV/AIDS* section for more information. CHBRP has included only these medications, and any available generics, throughout the analysis.

Assumptions

CHBRP made the following assumptions for analysis of SB 339:

- CHBRP used the *CDC U.S. Public Health Service Clinical Practice Guideline for PrEP, 2021 Update* (CDC/USPHS, 2021) and the *CDC Updated Guidelines for Antiretroviral Postexposure Prophylaxis* (CDC, 2016) to determine the appropriate services and testing required for furnishing of PrEP and PEP. These guidelines focus on early tests for related diseases. CHBRP assumed that SB 339 would not affect coverage for services that may be relevant later in a disease progression (such as hospitalization for hepatitis).
- The CDC guidelines on PEP include recommendations for nonoccupational postexposure prophylaxis (nPEP) and occupational postexposure prophylaxis (oPEP). CHBRP has assumed that oPEP is processed under workers' compensation, and therefore would be outside the pharmacy or medical benefit coverage required under SB 339.
- CHBRP has assumed that all PrEP and PEP drugs are covered under the pharmacy benefit, and that administration of drugs (i.e., in the case of SB 339, CAB-LA), would be covered under the medical benefit.

DHCS began implementation of the California Advancing and Innovating Medi-Cal (CalAIM) initiative in 2022. To the extent possible for this analysis, CHBRP has incorporated known CalAIM changes into its methods and approach.

Interaction With Existing State and Federal Requirements

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

California Policy Landscape

California law and regulations

Existing law authorizes pharmacists to furnish certain regimens of PrEP to patients for a regimen that is a minimum of 30 days, and up to 60 days. Pharmacists must meet certain criteria in order to furnish a regimen beyond 60 days.¹¹ Existing law also authorizes pharmacists to furnish certain regimens of PEP.¹² DMHC-regulated health plans and CDI-regulated health policies are prohibited from requiring prior authorization or step therapy for these PrEP and PEP formulations, unless the FDA has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of HIV/AIDS and the health plan or policy covers at least one without such requirements. Current law also prohibits coverage under DMHC-regulated plans and CDI-regulated policies for PrEP furnished by a pharmacist in excess of a 60-day supply to a single patient more than once every two years, unless directed by a prescriber.¹³

SB 339 would amend existing law to allow for pharmacists to furnish a longer regimen of PrEP and require coverage of services and testing related to PrEP and PEP furnishing. Table 2 outlines how SB 339 differs from existing law.

Table 2. Comparison of Existing Law to SB 339 Provisions

Provision	Existing Law	SB 339
Definition of PrEP	Fixed dose combination of TDF (300 mg) with FTC (200 mg) or another drug or drug combination determined by BOP to meet same clinical eligibility recommendations in CDC guidelines	A prescription drug approved by the FDA or recommended by the CDC to reduce a person's chance of contracting HIV
Definition of PEP	(1) Fixed dose combination of TDF (300 mg) with FTC (200 mg) with either raltegravir (400 mg) or dolutegravir (50 mg) (2) TDF (300 mg) and FTC (200 mg) with darunavir (800 mg) and ritonavir (100 mg) (3) Other drug(s) determined by BOP to meet same clinical eligibility recommendations in CDC guidelines	No change
Coverage for all PrEP when furnished by pharmacist	Only for F/TDF	Yes
Coverage for PEP when furnished by pharmacist	Yes	Yes
Number of days pharmacists authorized to furnish PrEP regimen	DMHC/CDI: Minimum of 30 days, maximum of 60 days, >60 days under certain conditions (a) Medi-Cal: up to 60 days	DMHC/CDI: Up to 90 days (b), if certain conditions are met (c) Medi-Cal: no limit
Reimbursement to pharmacist for PrEP or PEP-related services and testing	DMHC/CDI: No Medi-Cal: 85% of physician fee schedule	DMHC/CDI: 100% physician fee schedule Medi-Cal: no change

Source: California Health Benefits Review Program, 2023; BPC 4052.02 and 4052.03.

Note: (a) Pharmacist must ensure the following in order to furnish a regimen longer than 60 days: (1) patient is HIV negative; (2) patient does not report signs or symptoms of acute HIV infection; (3) patient does not report taking contraindicated medications; (4) pharmacist must provide PrEP counseling.

¹¹ Business and Professions Code (BPC) 4052.02.

¹² BPC 4052.03.

¹³ Health and Safety Code (HSC) 1342.74; Insurance Code (INS) 10123.1933.

(b) In addition to the requirements under (a), pharmacist must notify the patient that they may need to be seen by a primary care provider to receive subsequent PrEP prescriptions and that pharmacists may not furnish a 90-day course to a single patient more than once every 2 years unless the pharmacist ensures the patient receives testing and follow-up care consistent with CDC guidelines.

(c) Pharmacist must ensure the following in order to furnish a regimen longer than 90 days: (1) patient receives testing and follow-up care consistent with CDC guidelines; (2) documentation of services provided by pharmacist in the patient's record; (3) notification to patient's primary care provider that pharmacist completed the previous requirements. If no primary care provider or patient refuses to consent, pharmacist must provide a list of primary care providers in region.

Key: BOP = Board of Pharmacy; CDC = Centers for Disease Control and Prevention; CDI = California Department of Insurance; DMHC = Department of Managed Health Care; FDA = Food and Drug Administration; F/TDF = emtricitabine and tenofovir disoproxil fumarate; FTC = emtricitabine; HIV = human immunodeficiency virus; PEP = postexposure prophylaxis; PrEP = preexposure prophylaxis; TDF = tenofovir disoproxil fumarate.

Pharmacist scope of practice

Existing law authorizes pharmacists to do the following:

- Furnish naloxone, oral contraceptives, smoking cessation products, vaccines (e.g., influenza, COVID-19)¹⁴ via formalized guidelines;¹⁵
- Per SB 159 (2019), furnish specific regimens of PrEP and PEP.¹⁶ See the *Background on Antiretrovirals for the Prevention of HIV/AIDS* section for more information;
- Provide patients with consultation, training, and education about medications, disease management, and disease prevention;¹⁷
- Order and interpret tests for the specific purpose of monitoring and managing efficacy and toxicity of medications. Any tests orders or interpreted by a pharmacist must be done in coordination with the patient's primary care provider or diagnosing prescriber;¹⁸
- To practice under collaborative practice agreements;¹⁹ this is another manner in which PrEP has been furnished in the past; and
- Per SB 409 (2021), order a medication-related laboratory test that is waived under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 (FDA, 2023).²⁰ Prior to the passage of SB 409 (2021), only Advanced Practice Pharmacists (APPs)²¹ were authorized to order laboratory tests.

Pharmacists may order a CLIA-waived test that detects any of the following illnesses, conditions, or diseases, if it does not require the use of specimens collected by vaginal swab, venipuncture, or the collection of seminal fluid: SARS-CoV-2 or other respiratory illness, condition, or disease; mononucleosis; sexually transmitted infection, including HIV; strep throat; anemia; cardiovascular health; conjunctivitis;

¹⁴ In general, pharmacists are currently not reimbursed for administration of vaccines by commercial health plans/insurers. Medi-Cal provides reimbursement to pharmacists who are registered as ordering, referring, and prescribing (ORP) providers for the initiation and administration of vaccines at a rate of 85% of the fee schedule for physician services. WIC 14132.968(a)(3).

¹⁵ BPC 4052.01; BPC 4052.3; BPC 4052.9; BPC 4052.8; BPC 4052.03; BPC 4052.02.

¹⁶ BPC 4052.02 and 4052.03.

¹⁷ BPC 4052(a)(8).

¹⁸ BPC 4052(a)(12).

¹⁹ Collaborative practice agreements are a formal agreement in which a licensed health care professional makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions (CDC, 2013). Under California law, pharmacists may initiate, adjust, or discontinue medications for a patient under a CPA with any health care professional with prescriptive authority per BPC 4052(a)(13).

²⁰ The Clinical Laboratory Improvement Amendments (CLIA) law regulates laboratory testing and require clinical laboratories to be certified by the Center for Medicare and Medicaid Services (CMS) before they can accept human samples for diagnostic testing. Laboratories may obtain multiple types of CLIA certificates, based on the kinds of diagnostic tests they conduct (CMS, 2021). CLIA-waived tests are those tests that are determined by CDC or FDA to be so simple that there is little risk of error (CMS, n.d.).

²¹ APPs are licensed pharmacists recognized by the California Board of Pharmacy, pursuant to BPC 4210. A board-recognized APP is entitled to practice advanced practice pharmacy, as described in BPC 4052.6, within or outside of a licensed pharmacy.

urinary tract infection; liver and kidney function or infection; thyroid function; substance use disorder; or diabetes.²² It should be noted that tests for HIV, liver and kidney function, and sexually transmitted infections are relevant to SB 339. See the *Background on Antiretrovirals for the Prevention of HIV/AIDS* section for more information.

Although SB 409 (2021) granted pharmacists the authority to order certain laboratory tests and services, it did not provide a reimbursement mechanism for pharmacists to bill for the CLIA-waived tests or their administration. SB 306 (2021) provides an avenue for reimbursement for the STI-related laboratory tests by requiring DMHC-regulated health plans and CDI-regulated health policies to provide coverage for clinician-ordered home test kits for sexually transmitted infections, including HIV, and the laboratory costs for processing the kits. Pharmacists may only obtain reimbursement for administration of these laboratory tests, and for the cost and administration of the other SB 339-related laboratory tests, through direct patient payment or contracts with third-party payers. The process of getting credentialed through third-party payers can take 120 and 180 days with each payer.

It should be noted that pharmacies are 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 the administration of injectable drugs or the extensive counseling related to SB 339.

Preventive services

Existing California law requires coverage of the following preventive services without cost sharing or prior authorization:²³

- The United States Preventive Services Task Force (USPSTF) A and B recommendations;
- The Health Resources and Services Administration (HRSA)-supported health plan coverage guidelines for women's preventive services;
- The HRSA-supported comprehensive guidelines for infants, children, and adolescents, which include:
 - The Bright Futures Recommendations for Pediatric Preventive Health Care; and
 - The recommendations of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; and
- The Advisory Committee on Immunization Practices (ACIP) recommendations that have been adopted by the Director of the CDC.

These requirements align with the federal preventive services listed under the Affordable Care Act.²⁴

The USPSTF currently recommends that clinicians offer PrEP with effective antiretroviral therapy to those who are at high risk of acquiring HIV (Grade A).²⁵

²² BPC 1206.5.

²³ HSC 1367.002; INS 10112.2.

²⁴ As of the published date of this report, the federal preventive services mandate was being challenged in court. Due to the alignment between California and federal law regarding coverage, cost sharing, and utilization management of certain preventive services, the court case will not impact DMHC-regulated health plans or CDI-regulated health policies.

²⁵ As of the published date of this report, this topic is being updated by the USPSTF. The draft recommendation is consistent with the current one.

Similar requirements in other states

Nine other states, including Colorado, Oregon, Virginia, Kentucky, Maine, Missouri, Nevada, New York, and Utah currently allow registered pharmacists to prescribe PrEP.²⁶ Colorado, Nevada, Oregon, and Virginia all require reimbursement for pharmacist provided services.

Six states, including Arkansas, Florida, Maryland, Minnesota, New Jersey, and Rhode Island have introduced legislation similar to SB 159 of 2019 and SB 339. All six states' legislation would authorize pharmacists to prescribe, dispense, and/or administer PrEP and PEP.²⁷ Maryland and Florida's bills would also prohibit step therapy and prior authorization for PrEP and PEP; Maryland's would also prohibit cost sharing. Minnesota's legislation would authorize pharmacists to order, conduct, and interpret laboratory tests necessary for medications to prevention acquisition of HIV.

Federal Policy Landscape

Federal programs

The federal government offers several funding opportunities through federal agencies for HIV/AIDS prevention, testing, care, treatment, and research. The Health Resources and Services Administration (HRSA)'s Ryan White HIV/AIDS program offers grants specifically to improve and expand health care services for underserved populations. The program works with cities, states, and local community-based organizations to provide primary medical care and support services for the uninsured and underinsured. It serves approximately half a million people each year (HHS, 2022a).

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how SB 339 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).^{28,29}

²⁶ Colorado House Bill (HB) 20-1061 (2020); 201 Kentucky Administration Regulations 2:380; Maine SB 1115 (2021); Missouri HB 370 (2021); New York Assembly Bill (AB) 2198 (2021) and SB 728 (2021); Oregon HB 2958 (2021); Utah 58-17b-627; Virginia HB 2079 (2021).

²⁷ Arkansas HB 1007; Florida SB 416; Maryland SB 64; Minnesota SB 2320 and HB 2466; New Jersey SB 3030; Rhode Island HB 5876.

²⁸ The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to qualified health plans sold in Covered California — to cover 10 specified categories of EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.

²⁹ Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.

Essential health benefits

In California, nongrandfathered³⁰ individual and small-group health insurance is generally required to cover EHBs.³¹ In 2024, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs.³²

States may require state-regulated health insurance to offer benefits that exceed EHBs.^{33,34,35} Should California do so, the state could be required to defray the cost of additionally mandated benefits for enrollees in health plans or policies purchased through Covered California, the state's health insurance marketplace. However, state benefit mandates specifying provider types, cost sharing, or other details of existing benefit coverage would not meet the definition of state benefit mandates that could exceed EHBs.³⁶ Both Massachusetts and Utah currently pay defrayment costs for exceeding EHBs.

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

³⁰ A grandfathered health plan is “a group health plan that was created – or an individual health insurance policy that was purchased – on or before March 23, 2010. Plans or policies may lose their ‘grandfathered’ status if they make certain significant changes that reduce benefits or increase costs to consumers.” Available at: www.healthcare.gov/glossary/grandfathered-health-plan.

³¹ For more detail, see CHBRP's issue brief *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits*, available at https://chbrp.org/other_publications/index.php.

³² See CHBRP's resource *Sources of Health Insurance in California for 2024* and CHBRP's issue brief *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits*, both available at https://chbrp.org/other_publications/index.php.

³³ ACA Section 1311(d)(3).

³⁴ State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

³⁵ However, as laid out in the Final Rule on EHBs the U.S. Department of Health and Human Services (HHS) released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs, and there would be no requirement that the state defray the costs of those state-mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.

³⁶ Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and qualified health plan issuers would be responsible for calculating the cost that must be defrayed. Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

BACKGROUND ON ANTIRETROVIRALS FOR THE PREVENTION OF HIV/AIDS

As noted in the *Policy Context* section, SB 339 would also authorize a pharmacist to furnish up to a 90-day course of preexposure prophylaxis (PrEP) (and beyond a 90-day course under certain conditions). SB 339 would also require DMHC-regulated health plans and CDI-regulated health policies 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. This background section provides information related to antiretrovirals for the prevention of HIV/AIDS as well as pharmacist awareness and implementation of SB 159 (2019) for the consideration of the medical effectiveness, cost and utilization, and public health impacts.

Human Immunodeficiency Virus (HIV)

Human immunodeficiency virus (HIV) attacks the body's CD4 and/or T-cells (i.e., 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.³⁷ 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. Without initial treatment and routine adherence to treatment, HIV typically progresses through three stages of disease: (1) acute HIV infection, (2) chronic HIV infection, and (3) acquired immunodeficiency syndrome (AIDS) (CDC, 2022a). 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) drugs³⁸ — known for inhibiting viral replication and allowing for immune reconstitution (CDC, 2023). 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 (Antiretroviral Therapy Cohort Collaboration, 2017).

Population at Risk for HIV in California

The population of highest interest for this provision is the pool of Californians that meet the CDC's indications for PrEP (CDC/USPHS, 2021). More specifically, men who have sex with men (MSM), high-risk heterosexuals (i.e., individuals who engage in sex with two or more opposite sex partners in the past six months and engage in sex with an HIV-infected partner or condomless sex in the past four weeks or sex with a high-risk partner), and persons who inject drugs (PWID). Black and Latino persons have the highest prevalence of HIV and continue to be at highest risk for contracting HIV (CDPH, 2016).

PrEP population

The California Department of Public Health, Office of AIDS estimates that approximately 220,000 to 240,000 Californians would meet the criteria for PrEP (CDPH, 2016), which is approximately 1.5 to 1.7 times the prevalence of people living with HIV in California (139,703 in 2020) (CDPH, 2020).³⁹ From 2016 through 2020, the number of HIV diagnoses in California declined by approximately 23%, from 5,140 in 2016 to 3,965 in 2020. Of the 3,965 newly diagnosed with HIV, approximately 85% are male (CDPH, 2020). See Table 3 for estimates of Californians with high risk of HIV infection who would be candidates for PrEP.

³⁷ Common methods of HIV transmission include engaging in unprotected sex (e.g., sex without a condom) or through the sharing of needles, syringes, or other drug injection equipment (CDC, 2020).

³⁸ ARV treatment involves highly effective antiretroviral drugs to suppress HIV replication, and is comprised of more than 30 antiretroviral drugs from eight FDA-approved HIV drug classes that may be used to prevent HIV infection (i.e., PrEP or PEP) or treat HIV infection (HHS, 2022b).

³⁹ Since the release of these CDPH estimates in 2016, the CDC released expanded criteria for PrEP eligibility in 2021 (CDC/USPHS, 2021). CHBRP is unable to estimate how many Californians would meet the criteria for PrEP per the 2021 CDC expanded criteria for PrEP eligibility.

Table 3. Estimated Number of Californians at High Risk for HIV Infection in California, 2016

Population	Estimated Number of Californians with Indication for PrEP
Men who have sex with men (MSM)	103,779-120,879
High-risk heterosexuals	105,541
Persons who inject drugs (PWID)	12,208
Total	221,528 – 238,628

Source: California Health Benefits Review Program, 2023, based on CDPH, 2016.

Note: Insurance status of this population is unknown; it may include Medi-Cal, privately insured, uninsured, Medicare, and other forms of insurance.

Key: PrEP = preexposure prophylaxis.

PEP population

CHBRP was unable to find an estimate of the California population at risk of requiring PEP. Identifying the population that meets the PEP criteria is challenging to the public health community because, by definition, the exposures are periodic, emergency-based, and dispersed among a disparate population. Additionally, determining patient PEP uptake and adherence is challenging due to PEP initiation potentially occurring in different settings than follow-up visits (e.g., emergency department, or free clinic followed by a private physician visit). Frequently, there is a lack of patient follow-up to confirm PEP adherence or for confirmatory HIV testing (Ford et al., 2015).

Antiretrovirals for Prevention of HIV/AIDS

Preventing the transmission of HIV to the HIV-negative population has been the focus of a concerted U.S. public health effort for more than 30 years. PrEP and PEP are an essential part of the HIV prevention toolbox, which also includes education, needle exchanges, and condom programs. Both strategies involve using ARVs to abort the establishment of chronic HIV infection. By protecting the cells, these medications eliminate the ability of HIV to replicate and destroy the immune system. The drug compounds used in PrEP and PEP regimens also may be used as part of a larger HIV treatment regimen. See Table 4 for a list of PrEP medications and Table 5 for a summary comparison of PrEP and PEP.

PrEP

PrEP is a long-term regimen⁴⁰ recommended for the population that has repeated, intimate exposure to HIV-positive individuals or other high-risk individuals of unknown HIV status. Per the CDC/US Public Health Service's *Preexposure Prophylaxis or the Prevention of HIV Infection in the United States—2021 Update*, it is recommended that all health care providers perform an HIV risk-behavior assessment using approved questions and baseline HIV test, and prescribe a PrEP regimen for those patients at high risk for HIV (CDC/USPHS, 2021). PrEP is indicated for all routes of sexual exposure (CDC/USPHS, 2021). PrEP can be administered in oral (i.e., pill) or injection form. At present, there are two FDA-approved oral medications for use as PrEP (F/TDF, F/TAF) and one FDA-approved injection for use as PrEP (CAB-LA) (see Table 4) (CDC, 2022b).

⁴⁰ For individuals not at ongoing risk for getting HIV, those individuals may opt for on-demand PrEP (also known as intermittent, non-daily, event-driven, or off-label PrEP use). Per the CDC, on-demand PrEP may be taken on a 2-1-1 schedule (i.e., 2 pills, 2 to 24 hours prior to sex; 1 pill 24 hours after the first dose; and 1 pill 24 hours after the second dose) (CDC/USPHS, 2021).

Oral PrEP medications

Two oral medications have been approved by the FDA for PrEP use. For both medications, PrEP users are instructed to take a single tablet once per day as long as they remain in circumstances where HIV exposure is likely to occur (CDC/USPHS, 2021). FDA-approved in 2012, emtricitabine and tenofovir disoproxil fumarate (F/TDF), the generic medication equivalent to Truvada, is the most commonly prescribed medication for PrEP, including among women and PWID on medication-assisted therapy (CDC/USPHS, 2021). Emtricitabine and tenofovir alafenamide (F/TAF) (brand name Descovy) was approved by the FDA in 2019 for daily PrEP use by men and transgender women at sexual risk (CDC/USPHS, 2021).⁴¹

Cabotegravir PrEP injection medication

In December 2021, cabotegravir (also known as CAB-LA) was approved by the FDA for PrEP use via intramuscular injection, currently available as Apretude (FDA, 2021). Unlike oral PrEP medications, which require daily adherence, 600 mg of CAB-LA can be injected in the gluteal muscle every two months for individuals at high risk for HIV (CDC/USPHS, 2021).⁴² Per the CDC, CAB-LA may be preferred among patients at high risk for HIV who may also be experiencing issues with adherence to a daily PrEP dosing schedule and/or experiencing serious kidney disease (CDC/USPHS, 2021).

Table 4. Preexposure Prophylaxis (PrEP) Medications

Generic	Brand Name	Common Dosage	Frequency	Potential Side Effects
F/TDF	Truvada	200 mg/300 mg 167 mg/250 mg	Once per day	Rash, headache, nausea, abdominal pain, weight loss, loss of bone mineral density (b)
F/TAF	Descovy	200 mg/25 mg 120 mg/15 mg	Once per day	Diarrhea, nausea, headache, fatigue, weight gain, loss of bone mineral density (b)
CAB-LA	Apretude	600 mg	Intramuscular injection every 2 months (a)	Pain, tenderness, and skin induration at the injection site

Source: California Health Benefits Review Program, 2023, based on CDC/USPHS, 2021.

Note: (a) CAB-LA is administered via injection into the gluteal muscle.

(b) Rare but serious side effects include kidney and liver problems, and potentially fatal lactic acidosis (i.e., lactic acid build-up in the bloodstream).

Key: CAB-LA = cabotegravir extended-release injectable suspension; F/TAF = emtricitabine and tenofovir alafenamide; F/TDF = emtricitabine and tenofovir disoproxil fumarate.

PEP

PEP is a short-term, daily therapy similar to PrEP. Per the CDC's *Updated Guidelines for Antiretroviral Postexposure Prophylaxis*, this regimen must be started within 72 hours of (suspected) HIV exposure and is only taken for 28 days (CDC, 2016). In combination with the single tablet, F/TDF, adult patients also take another drug such as raltegravir (twice) or dolutegravir (once) daily. PEP is considered an emergency treatment and recommended for those with episodic suspected or confirmed exposure such as sexual assault survivors, workers with occupational exposure, MSM, PWID, as well as for the prevention of perinatal HIV transmission.⁴³

⁴¹ It's important to note that F/TAF is not recommended for people assigned female sex at birth who could get HIV through receptive vaginal intercourse (CDC/USPHS, 2021).

⁴² An optional 30 mg of daily oral CAB may also be taken for a 4-week lead-in prior to injections among individuals who may be concerned about potential side effects associated with CAB-LA.

⁴³ It's important to note that the prevention of perinatal HIV transmission is comprised of three components: (1) fully suppressive ARV drugs among pregnant persons throughout pregnancy, (2) intrapartum ARV (intravenous

Table 5. Summary of Preexposure Prophylaxis (PrEP) and Postexposure Prophylaxis (PEP) Regimen for the Prevention of HIV Infection

HIV Preexposure Prophylaxis		HIV Postexposure Prophylaxis
Reasons for initiation	PrEP is recommended for seronegative persons, before possible exposure, who think they may have repeated exposure to HIV. Individuals at high-risk for HIV include HIV-negative partner in serodiscordant* couples; MSM with multiple partners; sex workers, and PWID who share needles, syringes, or other drug injection equipment	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
Oral Medications		
Regimen	Combination therapy taken in a single tablet form (F/TDF or F/TAF) taken once daily for as long as the patient has intimate exposure to HIV-positive individuals	For adults: F/TDF (once daily) with raltegravir (RAL) (twice daily) or dolutegravir (DTG) (once daily) as initiated within 72 hours of suspected exposure and continued for 28 days For Newborns: zidovudine (AZT) for 4 weeks (low risk) or AZT and lamivudine (3TC) for 6 weeks (high risk with untreated HIV-positive mother) initiated as close to birth as possible (6–12 hours)
Recommended concurrent care	Baseline HIV & STI tests; quarterly blood panels for refill authorization, pregnancy test, HIV test or risk assessment, and adherence; blood tests every three months for kidney/liver effects and STI tests; annual appointments to evaluate effectiveness and adherence to therapy protocol and desire to continue oral medications for PrEP	Baseline HIV test; follow-up appointment with HIV test; counseling on risk behavior reduction
Injections		
Regimen	Intramuscular CAB-LA injection, received every two months for as long as the patient has intimate exposure to HIV-positive individuals	
Recommended concurrent care	Baseline HIV and STI tests; provider visit one-month after initial injection to receive second CAB-LA injection and HIV test; bi-monthly provider visits after second injection to receive third CAB-LA injection and HIV test; STI screenings every four months among MSM and transgender women; STI screenings every 6 months for heterosexually active women and men; annual appointments to evaluate effectiveness and desire to continue CAB-LA injection for PrEP	

Source: California Health Benefits Review Program, 2023, based on CDC/USPHS, 2021, and PTHDPPT, 2023

Note: *A serodiscordant couple is a romantic or sexual relationship where one person within the couple is living with HIV and the other person is not.

Key: CAB-LA = cabotegravir extended-release injectable suspension; F/TAF = emtricitabine and tenofovir alafenamide; F/TDF = emtricitabine and tenofovir disoproxil fumarate; HIV = human immunodeficiency virus; MSM = men who have sex with men; PEP = postexposure prophylaxis; PrEP = preexposure prophylaxis; PWID = persons who inject drugs; STI = sexually transmitted infection.

zidovudine [ZDV] prophylaxis) among pregnant persons near the time of delivery, and (3) a postexposure prophylaxis to prevent transmission from mother to newborn baby (NIH, 2023).

Initiating and Furnishing PrEP and PEP in a Pharmacy

As mentioned in the *Policy Context* section, with the passage of SB 159 in 2019, California authorized pharmacists to initiate and furnish up to a 60-day supply of PrEP in addition to a 30-day course of PEP — pending the successful completion of HIV preventative care training⁴⁴ — effective January 2020. Adapted from the CDC’s *U.S. Public Health Service Clinical Practice Guideline for PrEP, 2021 Update* (CDC/USPHS, 2021), the process for pharmacist-initiated PrEP and PEP includes:

1. Obtaining sexual, medical, and substance history using the 5 P’s (partners, practices, prevention of pregnancy, protection from STDs, and past history of STDs).
2. Screening for acute HIV infection.
3. If the individual passes the screening, obtaining a negative HIV test within 7 days before starting PrEP.
 - Under SB 409 — passed in 2021 — pharmacists may conduct CLIA-waived tests, including HIV testing.⁴⁵
4. Ordering other baseline testing for sexually transmitted infections (STIs), including syphilis, gonorrhea, and chlamydia; hepatitis B virus (HBV); kidney function; pregnancy, post-confirmation of negative HIV test result; and lipid profile levels (specific to F/TAF).
 - Under SB 409, pharmacists may conduct CLIA-waived tests, including HIV testing and STI testing.
 - Under SB 306 — passed in 2021 — pharmacists may furnish STI home test kits, inclusive of HIV and other STIs, and receive reimbursement for related tests.
5. Providing PrEP or PEP, educating the patient about the medications and the regimen to maximize their safe use, and counseling on medication adherence and HIV-risk reduction support and prevention services or service referrals to minimize exposure to HIV and other STIs.
6. Arranging for 60-to-90-day follow-up.
7. Completing referrals to a primary care provider and/or other prevention services.

Implementation of SB 159 and Related Knowledge and Awareness

Few studies have assessed the implementation of SB 159 (2019) or knowledge and awareness surrounding HIV prevention services within a pharmacy setting. At present, CHBRP is aware of two studies evaluating the implementation of HIV prevention services within California pharmacies (Bellman et al., 2022; CHAPRC, 2023).

In one observational study conducted in the San Francisco Bay Area community after implementation of SB 159, Bellman et al. (2022) found that of 209 pharmacies contacted, only six (2.9%) reported furnishing PrEP and PEP under SB 159, two reported preparing to furnish under SB 159, and one reported furnishing via Collaborative Practice Agreement.⁴⁶ Of the subset of pharmacies interviewed for follow-up (i.e., 2.9%), barriers to SB 159 implementation included:

- The unintended impact of the COVID-19 pandemic, issues related to laboratory tests (i.e., lack of recognition of pharmacists as authorized providers of laboratory tests, patient hesitancy in using at-home test kits, and lack of patient understanding of how to obtain laboratory tests);
- Lack of staff bandwidth and resources;

⁴⁴ Per the California State Board of Pharmacy (CSBP), before initiating and furnishing HIV PrEP and PEP, pharmacists must complete a 90-minute training (followed by a 10-question multiple choice assessment), as stipulated by SB 159. Upon obtaining a passing score, pharmacists receive a certification of successful completion and 1.5 hours of continuing education (CE) credit (CSBP, 2023).

⁴⁵ Within a pharmacy setting, the CDC permits a rapid fingerstick HIV Ag/Ab test (i.e., a CLIA-waived test) (CDC/USPHS, 2021).

⁴⁶ It’s important to note that prior to the passage of SB 159, pharmacists were permitted to furnish PrEP/PEP under a Collaborative Practice Agreement (i.e., a formal practice agreement between a licensed primary care provider and pharmacist) (Communication with M. Stebbins, March 2023). In addition, prior to the passage of SB 409, pharmacists were permitted to order lab tests (inclusive of STI tests) through a CPA or as a certified Advanced Practice Pharmacist. (Communication with M. Stebbins, March 2023).

- Lack of reimbursement for STI home-test kits;
- Refill limitation;
- Lack of patient awareness;
- Difficulty in arranging patient follow-up care; and
- Vague wording surrounding the policy (Bellman et al., 2022).

In contrast, facilitators to SB 159 implementation included:

- Partnerships with clinics and health centers;
- The ability to address patient privacy; and
- Pharmacists' motivation to address an unmet need in their patient population (Bellman et al., 2022).

In a recent study conducted by the California HIV/AIDS Policy Research Centers⁴⁷ (CHAPRC) assessing the adoption of SB 159, 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, 2023). In other words, a supermajority had never furnished PrEP or PEP, and only 72% were aware of SB 159 (CHAPRC, 2023). Furthermore, even fewer (62%) were aware of SB 409, which permits pharmacists to conduct HIV and STI testing. Despite most respondents (96%) indicating the importance of pharmacy-based PrEP and PEP, only half (50%) indicated feeling confident in their knowledge of PrEP, and even fewer (41%) reported feeling confident in prescribing PrEP. Moreover, less than a third (29%) of currently practicing licensed pharmacists reported receiving training on furnishing PrEP and PEP, as required under SB 159 (CHAPRC, 2023). CHAPRC (2023) 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%) (CHAPRC, 2023). Among all respondents, 42% believed that the current 60-day limit on PrEP — as stipulated by SB 159 — did not allow enough time to ensure successful referral to a primary care provider for PrEP continuation (CHAPRC, 2023).

Disparities⁴⁸ and Social Determinants of Health in Prevention of HIV/AIDS

Disparities are noticeable and preventable or modifiable differences between groups of people. Health insurance benefit mandates or related legislation may impact disparities. Where intersections between health insurance benefit mandates and social determinants or systemic factors exist, CHBRP describes relevant literature. CHBRP found literature identifying disparities and social determinants of health in prevention of HIV/AIDS by race/ethnicity, gender identity/sexual orientation, and geographic location.

Race or Ethnicity

Similar to those reported at the national level, racial/ethnic disparities in PrEP uptake among Californians have been identified, especially among Black and Latino persons (CDC, 2018a). Two studies identified disparities among Californians with public coverage (i.e., Medi-Cal) (Harawa et al., 2018; Harawa et al., 2022). Harawa et al. (2018) found that although PrEP uptake by Medi-Cal users was 25 times greater in 2016 than in 2012 (from 9 per million Medi-Cal enrollees in 2012 to 228 per million in 2016), the uptake rate among races varied, with some groups at higher risk for having lower uptake rates. For example, the

⁴⁷ This study was conducted in collaboration with the UCLA Center on Reproductive, Health, Law, and Policy; Birth Control Pharmacist; and the California Society of Health-System Pharmacists (CHAPRC, 2023).

⁴⁸ Several competing definitions of “health disparities” exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population. (Wyatt et al., 2016).

disparity between Black and White Medi-Cal enrollees' uptake widened between 2013 and 2016; uptake among Black persons increased from 14.6 per million to 282 per million while uptake among White persons increased from 16.6 per million to 447 per million. The greatest rate increase occurred among Latino persons — who also experience a disproportionate share of HIV infection — but they still had the lowest utilization rate (106 per million) in 2016. Harawa et al (2022) found that racial/ethnicity disparities in PrEP uptake continued to persist, with Black and Latino Medi-Cal enrollees having far lower PrEP uptake rates relative to their risk in comparison to White male Medi-Cal enrollees in 2019. Tuller (2018) found that racial/ethnic disparities were present in the general population as well as with Black persons who represented 44% of new HIV infections and only 13% of PrEP users. Similarly, Latino persons represented 24% of new infections and only 18% of PrEP users while White persons accounted for 25% of new HIV diagnoses, yet 62% of PrEP users (Tuller, 2018). CHBRP found no studies identifying racial/ethnic disparities in PEP use across the population.

Gender Identity or Sexual Orientation⁴⁹

Of the subpopulations at highest risk for HIV, MSM and transgender women (male-to-female) experience high rates of HIV. CDC reports that 22% to 28% of transgender women in the United States are living with HIV (CDC, 2018b). MSM represent about 2% of the U.S. population but accounted for 67% of new HIV infections in 2016 (CDC, 2018c). Both groups also have been found to have among the lowest rates of PrEP initiation and continuation. For example, 761 young California MSM (aged 18 to 29 years) using geosocial apps were surveyed about their use of PrEP. Fewer than 10% reported ever taking PrEP, and of those who reported ever taking PrEP, 72% reported currently taking PrEP (Holloway et al., 2017). CHBRP found no studies identifying disparities in PEP use by sexual orientation.

Geographic Location

A small qualitative study sponsored by the California HIV/AIDS Research Centers reported interview results from rural county PrEP navigators and AIDS Drug Assistance Program (ADAP) enrollment workers. These frontline workers reported that very few providers are educated about or willing to provide PrEP in their locales, thus PrEP users have to travel longer distances to receive care. Informants believed this barrier reduced PrEP initiation and continuation (Fuller et al., 2018). Harawa et al. (2018) found a similar disparity in uptake between rural and urban Medi-Cal beneficiaries; rural uptake was 104 per million beneficiaries and urban uptake was 2.5 times greater (253 per million) in 2016. CHBRP found no studies identifying disparities in PEP use by geographic location.

Barriers to Access and Use of Antiretrovirals to Prevent HIV/AIDS

Barriers to Accessing PrEP

Despite the effectiveness of PrEP in the prevention of HIV, numerous barriers to PrEP access and utilization among those at high risk for HIV have been identified. In a narrative review conducted by Mayer et al. (2020), seven key barriers to PrEP uptake were identified:

- Poor awareness and/or knowledge of PrEP;
- Low perception of HIV risk;
- Social stigma from primary care providers and/or family/partner/friends;⁵⁰

⁴⁹ CHBRP defines gender identity as one's internal sense of one's own gender, or the gender in which a person identifies, whether it be male, female, or nonbinary. Gender identity and sexual orientation are different facets of one's identity; an individual's gender does not determine a person's sexual orientation (i.e., a person's emotional, romantic, or sexual attraction to other people) (ACOG, 2022; CDC, 2022c).

⁵⁰ Stigma can play a large role in preventing patient initiation of PrEP/PEP, in which both the patient and/or provider may contribute to a lack of discussion. Physicians may be reluctant to ask about sexual history and habits. Similarly, patients may be reluctant to share information for fear of being stigmatized or labeled (Miller, 2019).

- Distrust of providers and/or the healthcare system;
- Lack of access to medical care (e.g., transportation barriers, time constraints);
- Lack of access to financial assistance; and
- Concerns about potential side effects associated with PrEP use.

In addition, Patel et al. (2017) cited lack of insurance coverage as a barrier to access and use of PrEP. In a multicity (Jackson, MS; St. Louis, MO; Providence, RI) evaluation of the impact of insurance coverage on utilization of PrEP within three clinics, Patel et al. (2017) found that insurance coverage was significantly associated with PrEP utilization. Of the 201 PrEP patients included in the evaluation, researchers found that insured patients were four times as likely to use PrEP services compared to the uninsured.

Barriers to Accessing PEP

Similar to PrEP, a number of barriers to PEP use have been identified by the San Francisco AIDS Foundation (Holtz, 2020), including:

- Inequities in health care access (e.g., lack of insurance coverage, time constraints);
- Affordability/financial constraints—particularly among youth and adolescents and individuals on fixed incomes;
- Lack of widespread awareness surrounding PEP; and
- Stigma.

SB 159 allowed patients to bypass steps involving consultation with a medical provider and obtaining prior authorization; however, social stigma continues to play an outsized role in deterring patient initiation (Holtz, 2020).⁵¹

⁵¹ Communication with Content Expert, Dr. R. Landovitz, in March 2023.

MEDICAL EFFECTIVENESS

As noted in the *Policy Context* section, SB 339 would also authorize a pharmacist to furnish up to a 90-day course of preexposure prophylaxis (PrEP) (and beyond a 90-day course under certain conditions). SB 339 would also require DMHC-regulated health plans and CDI-regulated health policies 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. Additional information on HIV/AIDS and PrEP/PEP is included in the *Background on Antiretrovirals for the Prevention of HIV/AIDS* section. The medical effectiveness review summarizes findings from evidence⁵² 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.

Research Approach and Methods

Studies of the effectiveness of PrEP in preventing HIV/AIDS were identified through searches of PubMed, the Cochrane Library, Web of Science, the Cumulative Index of Nursing and Allied Health Literature (CINAHL), and PsycINFO. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English. The search was limited to studies published from 2019 to present because CHBRP previously conducted thorough literature searches on these topics in 2019 for SB 159 and in 2018 for SB 1021. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B.

Of the 474 articles found in the literature search, 77 were reviewed for potential inclusion, and 11 were included in the review of medical effectiveness for SB 339. The other articles were eliminated because they did not focus on medications for HIV prevention, were of poor quality, or did not report findings from clinical research studies. While reviewing the articles for potential inclusion, three articles cited by these articles were identified for potential inclusion, and one was included in this report.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.⁵³ Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Key Questions

1. For persons at risk of HIV transmission⁵⁴, what is the effectiveness of HIV prevention therapies (i.e., PrEP), in preventing HIV transmission?
 - What are the associated harms of these medications?

⁵² Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence in the *Medical Effectiveness Analysis and Research Approach* document (posted at http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php), in the absence of fully applicable to the analysis peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

⁵³ Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. For more information on CHBRP's use of grey literature, visit http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

⁵⁴ This includes specific groups with high-risk behaviors, including a subset of all groups identified: men who have sex with men (MSM), heterosexual men and women, and persons who inject drugs

2. What is the effectiveness of HIV prevention medications (i.e., PEP), in preventing HIV transmission, as well as the associated harms, as compared to persons not using HIV prevention medications?
3. For persons at risk of HIV transmission, what is the effectiveness of pharmacy access on uptake and adherence of HIV prevention medications, as compared to uptake and adherence of HIV prevention medications in primary care offices or HIV primary care clinics?
4. Can pharmacists safely and effectively furnish PrEP and PEP for HIV?
5. Is there any research that shows a difference between a 60- and 90-day supply furnished by a pharmacist for HIV prevention medications?

Methodological Considerations

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. In other words, the literature search did not focus on investigating these outcomes in comparison to other means of HIV/AIDS prevention (e.g., safe sexual practices or sexually transmitted infections testing).

Outcomes Assessed

The effectiveness of PrEP and PEP for HIV prevention is assessed using the following outcomes:

1. HIV incidence;
2. HIV risk reduction;
3. HIV transmission; and
4. Quality of life.

Adverse outcomes associated with PrEP and PEP, as measured in the literature, included adverse health outcomes (e.g., decreased kidney and liver function, loss of bone mass), reproductive outcomes, antiretroviral drug resistance, and sexual risk compensation.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of HIV prevention medications (i.e., PrEP and PEP) addressed by SB 339, including PrEP and PEP therapy furnished by a pharmacist. Each section is accompanied by a corresponding figure. The title of the figure indicates the test, treatment, or service for which evidence is summarized. The statement in the box above the figure presents CHBRP's conclusion regarding the strength of evidence about the effect of a particular test, treatment, or service based on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. Definitions of CHBRP's grading scale terms is included in the box below, and more information is included in Appendix B.

The following terms are used to characterize the body of evidence regarding an outcome:

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.

Preponderance of evidence indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

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.

Inconclusive evidence indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

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.

More information is available in Appendix B.

Effectiveness of Medications that Prevent HIV/AIDS

PrEP

This report builds off analyses completed for SB 159 (2019) and SB 1021 (2018) on the use of daily tenofovir-based oral PrEP. The report for SB 159 found that evidence from 13 fair- and high-quality randomized control trials (RCTs) and three observational studies shows that daily tenofovir-based oral PrEP is effective in preventing HIV transmission and lowering the risk of HIV among users with moderate or high adherence (CHBRP, 2019).

Since the SB 159 report was completed, the FDA has approved additional antiretroviral medications for PrEP regimens — emtricitabine and tenofovir alafenamide (F/TAF) which is an additional daily tenofovir-based oral PrEP, and cabotegravir extended-release injectable suspension (CAB-LA) — and several new RCTs have been conducted.

In a systematic review and meta-analysis to inform the U.S. Preventive Services Task Force (USPSTF) (Chou et al., 2019; 12 RCTs; 18,244 subjects), a meta-analysis (11 trials included) was conducted to calculate pooled relative risks (RRs) for effects of PrEP (F/TDF) vs. placebo or no PrEP on HIV infection in persons at increased risk for HIV infection. Six trials enrolled persons at increased risk because of heterosexual contact, three trials included men who have sex with men or transgender women, 1 trial included high-risk women and men who have sex with men, and one trial included people who inject drugs (PWID). Eight trials (10,626 subjects) reported that F/TDF was associated with a significantly reduced risk of HIV infection vs. placebo or no PrEP (RR = 0.44, 95% CI: 0.27–0.72; $I^2 = 74\%$).

The DISCOVER RCT reported that F/TAF was noninferior to F/TDF in reducing the risk of acquiring HIV among men and transgender women who have sex with men at 48 weeks follow-up (Mayer et al, 2020). In this RCT, Mayer et al. (2020; 5,857 subjects) reported that daily F/TAF showed noninferior efficacy to daily F/TDF for HIV prevention (0.47 incidence rate ratio [IRR]; 95% CI: 0.19–1.15). Additionally, there were no differences in adherence between the two groups (self-report, pill count, and blood spot

analysis⁵⁵), with 96% to 98% of participants reported taking the study drug more than 80% of the time across all study visits. An additional follow-up at 96 weeks (Ogbuagu et al., 2021) reported that F/TAF continued noninferiority to F/TDF (IRR 0.54; 95% CI: 0.23–1.26) when the last participant had completed 96 weeks of follow-up.

Two concurrently conducted double-blind multinational RCTs (HIV Prevention Trials Network [HPTN] 083 and HPTN 084) comparing CAB-LA to oral daily F/TDF reported that CAB-LA provided greater protection against HIV infection than an oral daily F/TDF (Delany-Moretlwe et al., 2022; Landovitz et al., 2021). Both trials were stopped early due to efficacy of CAB-LA.

The HPTN 083 (Landovitz et al., 2021; 4,566 participants) compared CAB-LA to F/TDF in high-risk men who have sex with men and transgender women. Individuals were followed for 153 weeks and were randomly assigned to either CAB-LA or F/TDF. This trial reported a significantly lower HIV infection rate in the CAB-LA group compared to F/TDF (13 versus 39, respectively), demonstrating a 66% (95% CI: 38%–82%) lower risk of HIV acquisition for the CAB-LA compared to F/TDF. CAB-LA final analysis reported a 68% (95% CI: 35%–81%) reduction in the risk of HIV acquisition in the CAB-LA group.

The HPTN 084 trial (Delany-Moretlwe et al., 2022; 3,223 participants) compared CAB-LA to F/TDF in high-risk adult women in sub-Saharan South Africa. This trial reported a significantly lower HIV infection rate in the CAB-LA group compared to F/TDF (4 versus 34, respectively; $p < 0.0001$). Primary analysis showed an 88% (HR 0.12, 0.05–0.31; $p < 0.0001$) reduction in the risk of acquiring HIV-1 infection with CAB-LA.

Adherence to PrEP

Adherence to PrEP is a key factor in the incidence of HIV infection (Golub et al., 2018). Maximizing adherence is important because higher adherence to PrEP is associated with a lower risk of contracting HIV. The previous CHBRP analyses (CHBRP, 2018; CHBRP, 2019) included a meta-regression of seven RCTs reporting that adherence to daily tenofovir-based oral PrEP was a significant moderator of effectiveness (regression coefficient = -0.02, $p < 0.0001$). High-adherence to daily tenofovir-based oral PrEP showed a greater reduction in HIV infection risk compared to intermediate-adherence, and low-adherence did not lower their risk of HIV infection (Fonner et al., 2016). More details about these studies can be found in CHBRP's analyses of SB 159 (CHBRP, 2019) and SB 1021 (CHBRP, 2018).

A large meta-analysis, Chou et al. (2019; 10 studies; 3,177 subjects) evaluated rates of adherence to daily tenofovir-based oral PrEP in U.S. primary care settings (daily tenofovir-based oral PrEP use ranged from 6 months to 2 years). Three observational studies of U.S. MSM ($n = 908$) reported adherence to daily tenofovir-based oral PrEP of 66% to 90%, two observational studies of younger U.S. MSM ($n = 272$; mean age 16–20 years) found adherence to daily tenofovir-based oral PrEP of approximately 50% at 12 weeks and 22% to 34% at 48 weeks. This review also included a meta-analysis reporting that greater adherence was associated with greater efficacy (6 trials, RR with adherence $\geq 70\%$: 0.27 [95% CI: 0.19–0.39]; versus 3 trials, RR with adherence $< 70\%$ and $> 40\%$: 0.51 [95% CI: 0.38–0.70], versus 2 trials, RR with adherence $< 40\%$: 0.93 [0.72–1.20]; $P < 0.001$).

Allison et al. (2022; 29 studies; 8,679 subjects) conducted a meta-analysis that synthesized study findings regarding the proportion of adolescents and young adults who were adherent to daily tenofovir-based oral PrEP and factors moderating adherence. This meta-analysis reported that across studies, 64% (95% CI: 0.57–0.71) of young adults (average age = 23.8 years) demonstrated adequate daily tenofovir-based oral PrEP adherence. Subgroup analyses revealed that adherence was lower in young cisgender women (46%) than young men who have sex with men (65%) and serodiscordant⁵⁶ heterosexual couples (98%).

⁵⁵ Dried blood spot testing (DBS) is a form of biosampling where blood samples are blotted and dried on filter paper. The dried samples can easily be shipped to an analytical laboratory and analyzed using various methods (<https://www.frontiersin.org/articles/10.3389/fmicb.2020.00373/full>).

⁵⁶ A serodiscordant couple is a romantic or sexual relationship where one person within the couple is living with HIV and the other person is not.

This review reported that adherence was higher in studies initiated after 2012 (70%) than earlier studies (47%) and no difference in adherence based on participant age, country, or strategies to promote adherence.

Alternative dosing regimens

CHBRP previously identified research showing that alternative dosing regimens are associated with higher rates of adherence to F/TDF-based oral PrEP including 2-1-1 (or on demand) PrEP as an alternative to daily pills (Molina et al., 2015, 2017).

CHBRP found more recent studies examining on-demand dosing. In a large systematic review and meta-analysis, Chou et al. (2019) report that one RCT (n = 179) of mostly U.S. MSM (97%) reported higher adherence with daily (48%) than with intermittent (31%) or event-driven (17%) PrEP during weeks in which sex was reported. A cohort study (Vuylsteke et al., 2019; 200 MSM subjects) examining on-demand versus daily F/TDF-based oral PrEP reported that, at 18-month follow-up, 75.4% of the participants were on daily and 24.6% were on event-driven PrEP. No new HIV was diagnosed in either group at follow-up (18 months).

In a trial comparing on demand F/TDF-based oral PrEP to daily F/TDF-based oral PrEP (Molina et al., 2022; 3,065 subjects), subjects selected their dosing schedule (50.5% of participants opted for daily dosing and 49.5% opted for on-demand dosing). At the end of study (median follow-up 22.1 months; over 5,623 person-years), there were six seroconversions⁵⁷ (3 daily F/TDF-based oral PrEP, 3 on-demand F/TDF-based oral PrEP; all were MSM). Overall HIV-1 incidence was 1.1 cases (95% CI: 0.4–2.3) per 1,000 person-years and did not differ between daily F/TDF-based oral PrEP and those using on-demand F/TDF-based oral PrEP (IRR = 1.00, 95% CI: 0.13–7.49; p = 0.99).

Summary of findings regarding effectiveness of PrEP to Prevent HIV/AIDS: There is *clear and convincing evidence* from 15 fair- and high-quality RCTs and two observational studies that F/TDF-based oral PrEP is effective in preventing HIV transmission and lowering the risk of HIV among users with moderate or high adherence.

Figure 1. Effectiveness of PrEP



PEP

PEP is a 28-day course of three antiretroviral medications that is initiated within 72 hours of a known or suspected nonoccupational exposure to an active HIV infection. For nonoccupational exposures, CDC guidelines recommend a 28-day course (for otherwise healthy adults and adolescents) of tenofovir disoproxil fumarate (tenofovir DF or TDF) (300 mg) with emtricitabine (200 mg) once daily plus raltegravir (RAL) 400 mg twice daily or dolutegravir (DTG) 50 mg daily.

CHBRP did not identify any new studies about the effectiveness of PEP that were published after the 2019 report on SB 159 (CHBRP, 2019). The previous literature search found that people exposed to HIV, either in occupational or nonoccupational contexts, who took PEP were less likely to contract HIV (Bryant et al., 2009; Cardo et al., 1997; Schechter et al., 2004; Young et al., 2007). However, Ford et al. (2014)

⁵⁷ The transition from infection with HIV to the detectable presence of HIV antibodies in the blood. When seroconversion occurs (usually within a few weeks of infection), the result of an HIV antibody test changes from HIV negative to HIV positive.

observed low PEP completion among occupational and nonoccupational exposures (56%), which Fonner et al. (2016) found to be associated with a 45% HIV transmission risk reduction. Adherence to PEP was highest among nonoccupational exposures, children, and MSM (Fonner et al., 2016). Although rare, several instances of potential PEP failures — defined as HIV seroconversion following timely initiation and perfect adherence — have been described in the medical literature. One systematic review and one prospective study both determined that PEP failures accounted for 0.04% of seroconversions (Ford et al., 2014; Thomas et al., 2015). Full details of the previous literature search can be found in CHBRP’s report on SB 1021 (CHBRP, 2018).

Summary of findings regarding effectiveness of PEP to prevent HIV/AIDS: There is *limited evidence* that PEP is effective in preventing HIV transmission following occupational and nonoccupational exposures.

Figure 2. Effectiveness of PEP



Effectiveness of Pharmacists’ Prescribing of PrEP and PEP

In the previous report on SB 159, CHBRP (2019) identified one study that documented pharmacists’ ability to prescribe PrEP and PEP safely and effectively. As described in the report, Tung et al. (2018) assessed the impact of a pharmacist-managed HIV PrEP clinic in Seattle, Washington. In this community pharmacy setting, pharmacists were able to initiate and manage F/TDF under a collaborative practice agreement (CPA) with a physician medical director. Researchers found high levels of adherence to medications by using mean proportion of days covered (PDC) ratio to measure adherence to PrEP. Among the 581 patients who filled their prescriptions at the onsite pharmacy and had a reportable mean PDC ratio, 90% had a PDC of more than 80%. Furthermore, there were no HIV seroconversions among the 372 patients that actively received pharmacist services throughout the duration of the study (35 months).

CHBRP found two recent studies that describe the implementation of PrEP interventions within pharmacies on the initiation, retention, and seroconversion of PrEP with a pharmacist prescription.

In an observational cohort study (Miller et al., 2022; 59 PrEP subjects) of a pharmacist-led PrEP service within a primary care practice (utilizing a CPA to enable ordering medications, lab tests, and immunizations⁵⁸), researchers examined electronic health record data on PrEP. This program administered F/TDF then F/TAF once it was approved and is considering including CAB-LA, but no patients have been prescribed it yet through this initiative. All patients were referred because of sexual risk factors. Almost half (48.7%) of referred patients initiated PrEP therapy and 28.9% were referred for continuation of current therapy. Of those who engaged with pharmacist-led PrEP management, 33.9% (20/59) were retained in care for at least 1 year. There were no occurrences of seroconversion during pharmacist management.

Havens et al. (2019; 60 subjects) assessed the impact of a pharmacist-managed HIV PrEP clinic allowing participating pharmacists to serve as PrEP providers through the utilization of a CPA. A CPA specifying

⁵⁸ In this study when a patient initiates PrEP therapy the pharmacist completes a 1-month outreach, typically as a telephone call, to assess for any side effects, access issues, and adherence concerns. If the patient is unresponsive to outreach attempts, follow-up occurs during the routine monitoring appointment at 3 months. During each 3-month follow-up appointment, the pharmacist assesses for any changes to risk behaviors, evaluates for signs or symptoms of an acute HIV infection or STI, identifies any medication management issues, and orders appropriate monitoring lab tests (HIV testing, STI testing, serum creatinine, lipid panel) in accordance with CDC clinical practice guidelines.

pharmacist responsibilities within the pharmacist-led PrEP program was completed between the university-based HIV medical providers and each participating PrEP pharmacist. The researchers reported that retention within the pharmacy program fell throughout the duration of the study with 73%, 58%, 43%, and 28% of the participants retained at 3, 6, 9, and 12 months, respectively. Among participants retained throughout the study, adherence to F/TDF remained high with a mean medication possession ratio of 93%. There were no HIV seroconversions among the patients that received pharmacist services throughout the duration of the study (12 months).

Summary of findings regarding safety and effectiveness of pharmacists' prescribing of PrEP or PEP: There is *limited evidence* that pharmacists can safely and effectively prescribe PrEP. CHBRP found three observational studies that found strong adherence to PrEP and no seroconversions among people who obtained PrEP from a pharmacist-managed PrEP clinic.

Figure 3. Findings Regarding Safety and Effectiveness of Pharmacists' Prescribing of Oral PrEP



CHBRP did not find any research regarding safety and effectiveness of pharmacists' prescribing of injectable PrEP (i.e., CAB-LA).

Summary of findings regarding safety and effectiveness of pharmacists' prescribing of injectable PrEP: There is *insufficient evidence* regarding safety and effectiveness of pharmacists' prescribing of injectable PrEP (i.e., CAB-LA).

Figure 4. Findings Regarding Safety and Effectiveness of Pharmacists' Prescribing of Injectable PrEP



CHBRP did not find any research regarding safety and effectiveness of pharmacists' prescribing of PEP.

Summary of findings regarding safety and effectiveness of pharmacists' prescribing of PEP: There is *insufficient evidence* regarding safety and effectiveness of pharmacists' prescribing of PEP.

Figure 5. Findings Regarding Safety and Effectiveness of Pharmacists' Prescribing of PEP



Effectiveness of a Difference Between a 60- and 90-day Supply Furnished by a Pharmacist for PrEP

CHBRP did not find any research that shows a difference between a 60- and 90-day supply of PrEP furnished by a pharmacist.

Summary of findings regarding safety and effectiveness of a difference between a 60- and 90-day supply furnished by a pharmacist for PrEP: There is *insufficient evidence* that shows a difference between a 60- and 90-day supply furnished by a pharmacist for PrEP.

Figure 6. Findings Regarding Safety and Effectiveness of a Difference Between a 60- and 90-day Supply of Pharmacist-Furnished PrEP

NOT EFFECTIVE		INSUFFICIENT EVIDENCE				EFFECTIVE	
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing	

Harms of PrEP and PEP

Harms of PrEP

Because PrEP has been shown to be safe and effective in reducing the risk of sexual HIV acquisition, the current CDC guidelines recommend that all sexually active adult and adolescent patients should receive information about PrEP and it is recommended for use in people with substantial ongoing risk of HIV exposure and acquisition. Furthermore, the CDC recommends that clinicians should reinforce patient understanding that the benefits of PrEP medication use outweigh its reported risks and that the schedule of follow-up monitoring visits is designed to address any potential medication-related harm in a timely manner (CDC/USPHS, 2021).

The previous CHBRP report for SB 159 (CHBRP, 2019) reported no difference in the risk of developing serious AEs between participants who received PrEP as compared with placebo (odds ratio = 1.02, 95% CI: 0.92–1.13; p = 0.76). A recent systematic review and metaanalysis reported no difference between PrEP versus placebo or no PrEP for risk of serious AEs (12 trials, N = 18,292; RR = 0.93 [95% CI: 0.77–1.12]; I² = 56%), and researchers reported that most adverse events were mild and reversible (Chou et al., 2019). Mayer et al. (2020) reported that both F/TDF and F/TAF groups had similar rates of AEs, (169 in F/TDF vs. 138 in F/TAF). Investigators reported that most AEs associated with the study drug were rare (3 in F/TDF vs. 5 F/TDF).

Landovitz et al. (2021) reported serious AEs in 241 participants (5.3% overall), evenly distributed between both CAB-LA and F/TDF groups. CAB-LA was well tolerated with injection site reactions (e.g., pain, tenderness, induration at the site) the most commonly occurring adverse event. Nearly all AEs were mild or moderate severity.

Kidney

CHBRP’s SB 159 analysis (CHBRP, 2019) reported that findings regarding the impact of PrEP on kidney health were inconclusive. More recently, a large systematic review and meta-analysis found evidence that PrEP was associated with increased risk of renal adverse events (12 trials, N=18170; RR = 1.43 [95% CI: 1.18–1.75]; I² = 0%; ARD = 0.56% [95% CI: 0.09%–1.04%]; Chou et al., 2019).

Mayer et al. (2020; 5857 subjects) reported that both daily F/TAF and daily F/TDF renal AEs leading to discontinuation were rare (2 in the F/TAF group and 6 in the F/TDF group) and F/TAF was statistically significantly superior to F/TDF in all six renal biomarker safety endpoints at 96 week follow up.

Bone mineral density

CHBRP's SB 159 analysis (CHBRP, 2019) reported that findings regarding the impact of F/TDF on bone mineral density were inconclusive. More recently, Chou et al 2019 reported that PrEP (F/TDF) was associated with a non-statistically significant increased risk of fracture (7 trials, N = 15,241; RR = 1.23 [95% CI: 0.97–1.56]; $I^2 = 0\%$).

Mayer et al. (2020; 5,857 subjects) reported that daily oral F/TAF was superior to daily oral F/TDF in all six prespecified bone mineral density safety endpoints. In the bone mineral density sub analysis of 383 participants, at 48 weeks, a significant difference in the percentage change in hip bone mineral density ($p < 0.0001$) and spine bone mineral density ($p < 0.0001$) from baseline was observed between the two groups. In 96 week follow up, F/TAF continued to show superiority F/TDF in all but one of the six prespecified bone mineral density and renal biomarkers. In an extension of the Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN) Protocols 110 (aged 18–22 years) and 113 (aged 15–17 years) examining F/TDF in MSM with high HIV risk, Havens et al. (2020; 91 participants) reported that HIV negative men (aged 15–22 years) who lost bone mineral density during F/TDF clinical trials, showed significant recovery 48 weeks following PrEP discontinuation and were at baseline levels at follow up (96 weeks after study initiation).

A recent conference presentation reporting data from a bone density substudy of the HPN 083 RCT (Brown et al., 2023; 254 subjects) comparing bone density markers for subjects taking CAB-LA versus oral F/TDF reported that, at week 105 follow up, compared to baseline, participants in the oral F/TDF group saw a median decline in bone mineral density (–0.5 to –1%) versus an increase in bone mineral density (+0.5 to +1.5%) for participants in the CAB-LA group.

Digestive tolerability

CHBRP's SB 159 analysis (CHBRP, 2019) included a systematic review (2018) reporting that PrEP users commonly experience abdominal pain, diarrhea, nausea, vomiting, and other digestive symptoms in the first few weeks of treatment. Based on the studies cited, the time frame within which this “start-up syndrome” is resolved ranges from 1 to 3 months.

Chou et al., 2019 reported that oral PrEP was associated with an increased risk gastrointestinal adverse events (12 trials; RR = 1.63 [95% CI: 1.26–2.11]; $I^2 = 43\%$; ARD = 1.95% [95% CI: 0.48%–3.43%]).

Sexual risk compensation

Sexual activity is one of the primary ways in which HIV/AIDS may be contracted. The theory of risk compensation suggests that people behave in response to their perceived level of risk; increases in risk lead to more cautious behavior, and the opposite occurs for decreases in risk. Under this theory, availability and/or uptake of HIV prophylaxis may cause people at risk for HIV infection to engage in riskier sexual practices because they believe that their risk for contracting HIV is substantially lower than before. CHBRP identified studies on the impact of PrEP on several measures of sexual risk compensation: condomless sex, incidence of sexually transmitted infections, and number of sexual partners.

Condom Use: The previous CHBRP report for SB 159 (CHBRP, 2019) presented inconclusive evidence on the impact of PrEP uptake on condom use during sexual intercourse. Only one RCT found that a larger proportion of participants in the immediate treatment group reported receptive condomless anal sex with 10 or more partners at a statistically significant level relative to the deferred treatment group (21% vs. 12%, $p = 0.03$) while non-RCT studies' findings vary substantially.

Incidence of STIs: Chou et al. (2019; 5 trials) reported no significant difference between PrEP versus placebo or no PrEP in risk of sexually transmitted infections. Two trials (n=5291) reported on any bacterial STI (1.07 (0.80-1.44), 4 trials (n = 10775) reported on syphilis (1.07 (0.98-1.18); 5 trials (n = 9296) reported on chlamydia (RR 1.07 (0.94-1.22)) and 5 trials (n = 9296) reported on gonorrhea (RR 1.15 (0.97-1.37). There was no significant difference between PrEP vs. placebo in risk of herpes simplex virus infection (3 trials; n = 4088; RR = 0.85, 95% CI: 0.67–1.07) or hepatitis C virus infection (2 trials; n = 896; RR = 0.73, 95% CI: 0.25–2.10).

The occurrence of overall incidence of new rectal or urethral gonorrhea, new rectal or urethral chlamydia, or syphilis was similar for CAB-LA and F/TDF groups (Landovitz et al., 2021).

Changes in number of sexual partners

The previous CHBRP report for SB 159 (CHBRP, 2019) presented a preponderance of evidence that PrEP uptake does not lead to a difference in the number of sexual partners.

Reproductive outcomes

The previous CHBRP report for SB 1021 (CHBRP, 2018) reported that pooled analysis was not possible to assess the effectiveness of hormonal contraception among women taking PrEP as compared with women randomized to placebo due to differences in study design. However, raw data suggested that pregnancies resulting from contraception failures may have been higher among PrEP users in both trials (FEM-PrEP: RR = 1.48; Partners PrEP: RR = 1.32).

No trial of PrEP enrolled pregnant women; however, in rare cases, women have become pregnant while enrolled. Chou et al. (2019; 3 trials) reported no significant difference between PrEP versus placebo or no PrEP in risk of adverse pregnancy-related outcomes. In studies where women were withdrawn from PrEP because of pregnancy, PrEP was not associated with increased risk of spontaneous abortion (RR = 1.09, 95% CI: 0.79–1.50; I^2 = 0%).

In one trial that enrolled women, pregnancy incidence was low with both CAB-LA and F/TDF, with no congenital abnormalities observed (Delany-Moretlwe et al., 2022).

Antiretroviral drug resistance

HIV resistance to first-line HIV medications for treatment is an important consideration for high-risk PrEP users because the medications that comprise PrEP are also commonly used to treat active HIV infections. Resistance to the drugs, due to long-term low-dose exposure during PrEP, could limit a person's treatment options if they develop a subsequent HIV infection. The systematic review CHBRP cited in its report on SB 1021 identified six RCTs that have assessed the incidence of drug resistance to antiretroviral medications among participants who underwent HIV seroconversion following PrEP use (CHBRP, 2018). The authors reported that overall drug resistance was low, occurring among only 2% of the 533 participants who experienced HIV seroconversion across all study arms. A meta-analysis of drug resistance data from these RCTs found that the risk of developing resistance to either of the PrEP medications was significantly higher among PrEP users with an undetected pre-existing HIV infection at enrollment (RR = 3.34, 95% CI: 1.11–10.06; p = 0.03). PrEP use was not significantly associated with drug resistance detected among persons who experienced HIV seroconversion post-randomization (Fonner et al., 2016).

Recent research has reported that HIV resistance is a more significant issue for CAB-LA PrEP (Marzinke et al., 2021, Marzinke et al., 2023) than oral daily F/TDF PrEP. CAB-LA PrEP exposure showed significantly more delayed HIV diagnoses, resulting in undetected infection, delayed antiretroviral therapy, and emergence of drug resistance.

Lipid function

Mayer et al. (2022) reported that participants randomized to F/TAF had increases in fasting triglycerides while participants receiving F/TDF had declines. The number and percentage of subjects who initiated lipid-lowering agents was two-fold higher in the F/TAF group compared to the F/TDF group (43 [1.6%] vs. 21 [0.8%]; $p = 0.008$). In 96 week follow up, participants in the F/TAF group showed significantly more weight gain (median weight gain 1.7 kg vs. 0.5 kg, $p < 0.0001$) than the F/TDF.

Landovitz et al. (2021) reported no significant changes fasting glucose or lipid parameters when comparing participants receiving CAB injections to those receiving F/TDF. In a post hoc analysis, there was a significant increase in weight gain, compared to the F/TDF group with an annual mean increase in body weight of 1.23 kg per year (95% CI, 1.05 to 1.42) in the CAB-LA group, versus an increase of 0.37 kg (95% CI, 0.18 to 0.55) in the F/TDF group.

Harms of PEP

Adverse events resulting from antiretroviral medication toxicities are the most common harm associated with PEP and may account for up to 70% of PEP discontinuations and lapses in adherence (Thomas et al., 2015). Compared with earlier antiretroviral medications used as PEP, the currently recommended regimen (i.e., F/TDF plus raltegravir) has the lowest observed discontinuation rate due to adverse events (1.9%; 95% CI: 0.0%–3.8%) (Ford et al., 2015). Therefore, the following discussion of adverse events is specific to this regimen since it is most likely to be used in clinical practice.

CHBRP cited two prospective observational safety studies concerning PEP adverse events in its report on SB 1021 (CHBRP, 2018). Both studies found that all adverse events were resolved upon completion of PEP. Mayer et al. (2012) found that most reported adverse events were of mild-to-moderate grade, and the most commonly reported side effects were nausea/vomiting (27%), diarrhea (21%), headache (15%), and fatigue (14%). McAllister et al. (2014) reported that during treatment, the most common self-reported side effects were mild to moderate fatigue (37%), diarrhea (25%), and nausea (24%). Muscle pain accounted for 9% of self-reported adverse events. Elevated levels of alanine aminotransferase were detected in 19% of participants, but no cases of clinical hepatitis developed. No other serious adverse events were detected.

Although the two studies met CHBRP's inclusion criteria and had similar findings, the generalizability of these findings to the overall population of PEP users may be limited. Sample sizes were small (100 persons or fewer), made up almost entirely of men, relied primarily on patient self-reporting, and were exclusively conducted in nonoccupational settings.

No studies about sexual risk compensation in response to PEP use were found.

Table 6. Summary of Harms

Potential Harm	F/TDF	F/TAF	LA-CAB
Kidney	Increased risk of renal adverse events, small decreases in renal function mostly reversed when PrEP was discontinued	Increased risk of renal adverse events, small decreases in renal function mostly reversed when PrEP was discontinued	No increased risk of renal adverse events
Bone	Associated with a non-statistically significant increased risk of fracture	F/TAF was superior to F/TDF in bone mineral density safety endpoints	CAB-LA was superior to F/TDF in bone density measures
Sexual risk/STI	No difference vs. placebo or no PrEP	No difference vs. placebo or no PrEP	No difference CAB-LA vs. F/TDF groups

Condom Use	<i>Inconclusive evidence</i>	<i>Insufficient evidence</i>	<i>Insufficient evidence</i>
Digestive tolerability	Associated with an increased risk gastrointestinal adverse events	<i>Insufficient evidence</i>	No risk
Antiretroviral drug resistance	Resistance to antiretrovirals due to long-term low-dose exposure during treatment	Resistance to antiretrovirals due to long-term low-dose exposure during treatment	Significant resistance to antiretrovirals due to long-term low-dose exposure during treatment
Reproductive outcomes	No significant difference	No significant difference	No significant difference
Lipid function	Decreases in fasting triglycerides and weight	Increases in fasting triglycerides and weight	Significantly increased weight gain

Source: California Health Benefits Review Program, 2023, based on studies included in this medical effectiveness review.

Key: CAB-LA = cabotegravir extended-release injectable suspension; F/TAF = emtricitabine and tenofovir alafenamide; F/TDF = emtricitabine and tenofovir disoproxil fumarate; PrEP = preexposure prophylaxis; STI = sexually transmitted infection.

Summary of findings regarding harms of PrEP or PEP: Researchers reported that most serious adverse events associated with PrEP and PEP were mild and reversible. Despite these adverse events, the CDC recommends 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 (CDC/USPHS, 2021).

Summary of Findings

Overall, CHBRP found that there is *clear and convincing evidence* that PrEP is effective in preventing HIV transmission and lowering the risk of HIV across all high-risk groups.

There is *clear and convincing evidence* from that PrEP is effective in preventing HIV transmission and lowering the risk of HIV among users with moderate or high adherence. Effectiveness is moderated by adherence; moderate or high adherence are both associated with high protection from PrEP.

There is *limited evidence* that PEP is effective in preventing HIV transmission following nonoccupational exposures.

There is *limited evidence* that pharmacists can safely and effectively furnish daily oral PrEP. CHBRP found three observational studies which found strong adherence to PrEP and no seroconversions among people who obtained PrEP from a pharmacist-managed PrEP clinic.

There is *insufficient evidence* that pharmacists can safely and effectively furnish PEP or injectable PrEP.

There is *insufficient evidence* that shows a difference in safety and effectiveness between a 60- and 90-day supply of pharmacist-furnished PrEP and PEP.

While there are harms associated with PrEP and PEP, the CDC recommends 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.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As noted in the *Policy Context* section, SB 339 would also authorize a pharmacist to furnish up to a 90-day course of preexposure prophylaxis (PrEP) (and beyond a 90-day course under certain conditions). SB 339 would also require DMHC-regulated health plans and CDI-regulated health policies 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 addition to commercial enrollees, more than 73% of enrollees associated with CalPERS and more than 80% of Medi-Cal beneficiaries are enrolled in DMHC-regulated plans.⁵⁹ As noted in the *Policy Context* section, SB 339 would impact benefit coverage for these CalPERS enrollees and Medi-Cal beneficiaries.

This section reports the potential incremental impacts of SB 339 on estimated baseline benefit coverage, utilization, and overall cost.

Analytic Approach and Key Assumptions

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); and
- Any increase in cabotegravir (CAB-LA) furnishing by pharmacists would be limited by pharmacists' ability to provide private consultation and administration of the intramuscular injection.

As discussed in the *Policy Context* section, the California Legislature enacted SB 159 in 2019, which mandated coverage for PrEP and PEP for 60 days when furnished by a pharmacist. Following the enactment of SB 159 (2019), nearly all DMHC-regulated plans and CDI-regulated policies enacted coverage for PrEP and PEP furnished by a pharmacist. In a study released by the California HIV/AIDS Policy Research Centers (CHAPRC) in February 2023 examining the implementation of SB 159 (2019), only 11% of pharmacists reported initiating PrEP and 13% reported initiating PEP under the new law (CHAPRC, 2023). 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 (Bellman et al., 2022). Based on 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 (Bellman et al., 2022; CHAPRC, 2023); and
- The increase in utilization postmandate would be due to:
 - A shift transferring PrEP/PEP prescriptions currently issued by primary care providers to being furnished by a pharmacist; and
 - 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.

For further details on the underlying data sources and methods used in this analysis, please see Appendix C.

⁵⁹ For more detail, see CHBRP's resource *Sources of Health Insurance in California*, available at http://chbrp.org/other_publications/index.php.

Baseline and Postmandate Benefit Coverage

At baseline, 97% of enrollees with health insurance that would be subject to SB 339 have coverage for pharmacist-furnished PrEP and PEP, including testing and screening services. The 3% of enrollees who do not have coverage compliant with SB 339 at baseline are concentrated in DMHC-regulated individual plans.

Postmandate, 100% of enrollees would have coverage for PrEP/PEP furnished by a pharmacist, including any testing or screening services needed for determining eligibility.

Baseline and Postmandate Utilization

Almost all — 95.6% — commercial/CalPERS enrollees in plans and policies regulated by DMHC or CDI have a pharmacy benefit regulated by DMHC or CDI that covers both generic and brand-name outpatient prescription medications.⁶⁰ For Medi-Cal beneficiaries in DMHC-regulated managed care plans, the pharmacy benefit is separate and is administered by DHCS under the program Medi-Cal Rx. Therefore, these beneficiaries have a pharmacy benefit that is not subject to DMHC regulation. Among commercial/CalPERS enrollees, 1.2% do not have a pharmacy benefit and 3.2% have a pharmacy benefit that is not regulated by DMHC or CDI. Because SB 339 does not require creation of a pharmacy benefit but only compliant benefit coverage when a pharmacy benefit is present, DMHC-regulated plans and CDI-regulated policies that at baseline either have benefit coverage for enrollees without a pharmacy benefit or have a pharmacy benefit that is not regulated by DMHC or CDI are compliant.

Using Milliman analysis of claims data, CHBRP estimates that at baseline 4,462 enrollees had PrEP furnished by pharmacists. These enrollees had 14,216 oral PrEP prescriptions, along with 80 CAB-LA injections. There are 2,111 enrollees receiving PEP from pharmacists at baseline utilizing 5,592 PEP prescriptions annually (see Table 1). At baseline, pharmacists performed 1,470 PrEP-associated services and 832 PEP-associated services. It should be noted that one enrollee may have several PrEP- or PEP-related services from the same pharmacist.

Postmandate, because of the barriers to pharmacist participation identified in the Analytic Approach and Key Assumptions section above, CHBRP estimates that the number of enrollees in DMHC-regulated plans or CDI-regulated policies receiving oral PrEP furnished by a pharmacist would increase by 134 in the first year for a total of 4,595 enrollees. Among these enrollees, there would be an increase in oral PrEP furnished by a pharmacist of 426 for a total postmandate of 14,643 prescriptions, and the number of CAB-LA injections would increase by 48 to a total of 128 postmandate. The estimated number of PrEP-associated services would increase by 1,481 to a total of 2,951 postmandate. Enrollees who receive oral PEP from a pharmacist would increase by 63 for a total of 2,174 prescriptions postmandate. The number of oral PEP prescriptions would increase by 168 for a total of 5,760 prescriptions postmandate and PEP-associated services would increase by 1,026 for a total of 1,859 services postmandate.

Baseline and Postmandate Per-Unit Cost

Because of the limited increase in utilization due to limitations on provider capacity, per-unit costs are not expected to change postmandate. As seen in Table 1, average annual prescription cost for oral PrEP is \$6,477.57 and for the injectable CAB-LA is \$12,938.02. The average annual cost for oral PEP is \$444.59. The average annual cost for PrEP-related consultations is \$635.52, for HIV screenings is \$83.94, for other screenings and tests is \$338.70, and for other vaccinations \$27.60. The average annual cost for PEP-related consultations is \$475.51, for HIV screenings is \$151.93, for other screenings and tests is \$460.62, and for other vaccinations is \$126.72.

⁶⁰ For more detail, see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at http://chbrp.org/other_publications/index.php.

Baseline and Postmandate Expenditures

Table 8 and Table 9 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

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.

Premiums

Changes in premiums as a result of SB 339 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 8, and Table 9), with health insurance that would be subject to SB 339.

Premium increases for DMHC-regulated commercial plans ranged from \$0.0053 PMPM for individual plans to \$0.0061 PMPM for large-group plans. Among CDI-regulated commercial policies, premium increases ranged from \$0.0048 PMPM for individual policies to \$0.0056 PMPM for large-group policies. Premium increases among Covered California plans and policies range from \$0.0042 PMPM for CDI-regulated individual policies to \$0.0055 PMPM for DMHC-regulated small-group plans.

For enrollees associated with CalPERS in DMHC-regulated plans, premiums would be expected to increase by \$0.0061 PMPM. For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, premiums would be expected to increase by \$0.0062 PMPM for plans that cover both enrollees under age 65 and plans that cover ages 65+.

Enrollee Expenses

SB 339-related changes in cost sharing for covered benefits (deductibles, copays, etc.) and out-of-pocket expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 8, and Table 9) with health insurance that would be subject to SB 339 expected to use the relevant tests and screening for PrEP/PEP eligibility as well as PrEP/PEP during the year after enactment.

CHBRP projects no change to copayments or coinsurance rates but does project an increase in utilization of PrEP/PEP and testing associated with eligibility, and therefore an increase in enrollee cost sharing.

It is possible that some enrollees incurred expenses related to PrEP/PEP for which coverage was denied, but CHBRP cannot estimate the frequency with which such situations occur and so cannot offer a calculation of impact.

Enrollee expenses would be expected to increase for DMHC-regulated commercial plans, and ranged from \$0.0004 PMPM for large group plans to \$0.0014 PMPM for individual plans. Among CDI-regulated commercial policies, projected increases in enrollee expenses range from \$0.0008 PMPM for large group policies to \$0.0016 PMPM for individual policies. Enrollee expenses would also be expected to increase among Covered California plans and policies, and range from \$0.0012 PMPM for DMHC-regulated small-group plans to \$0.0016 PMPM for CDI-regulated individual policies.

For enrollees associated with CalPERS in DMHC-regulated plans, expenses would be expected to increase by \$0.0004 PMPM. For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there would be no increases in expenses in all plans.

Average enrollee out-of-pocket expenses per user

For enrollees with coverage at baseline, CHBRP estimates that 0.03% of all enrollees have out-of-pocket expenses associated with PrEP and PEP furnished by a pharmacist. Changes in enrollees' annual out-of-pocket expenses would range from enrollees in DMHC- or CDI-regulated large group plans and policies seeing a reduction of \$0.13, to enrollees in individual plans and policies who would experience an increase in out-of-pocket expenses for covered services of \$1.26 (see Table 7).

Table 7. Impact of SB 339 on Average Annual Enrollee Out-of-Pocket Expenses Per User

	Large Group	Small Group	Individual	CalPERS	Medi-Cal
Enrollees with baseline benefit coverage	100.0%	98.4%	72.6%	100.0%	100.0%
% of enrollees with out-of-pocket expenses impact due to SB 339 (a)	0.030%	0.030%	0.030%	0.030%	0.030%
Avg. annual out-of-pocket expenses impact for enrollees (b)	-\$0.13	-\$0.25	\$1.26	-\$0.13	\$0.00
Enrollees new benefit coverage	0.0%	1.6%	27.4%	0.0%	0.0%
% of enrollees with out-of-pocket expenses impact due to SB 339 (a)	0.000%	0.030%	0.030%	0.000%	0.000%
Avg. annual out-of-pocket expenses impact for enrollees (b)	\$617.32	\$1,644.23	\$1,886.64	\$605.72	\$0.00

Source: California Health Benefits Review Program, 2023.

Notes: Average enrollee out-of-pocket expenses include expenses for both covered and noncovered benefits.

(a) Not including impacts on premiums.

(b) Benefit coverage for Medi-Cal beneficiaries does not generally include any cost sharing.

Key: CalPERS = California Public Employees' Retirement System.

Should an enrollee not meet their annual deductible,⁶¹ the enrollee may be required to pay the full unit cost of a prescription. If the enrollee's cost sharing for the year equates to the annual out-of-pocket maximum,⁶² this would result in the enrollee having no further cost sharing for the year.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies would remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

⁶¹ For estimates of enrollees in plans and policies with deductibles, see CHBRP's resource *Deductibles in State-Regulated Health Insurance*, available at https://chbrp.org/other_publications/index.php.

⁶² For most enrollees in most plans and policies regulated by DMHC or CDI, applicable copays and coinsurance is limited to \$250, or \$500 for enrollees in the "bronze plans" available from Covered California, the state's ACA marketplace (H&SC 1342.73; IC 10123.1932). Cost sharing could be higher for an enrollee in a plan or policy that includes a deductible.

While both oral PrEP and CAB-LA have been shown with *clear and convincing evidence* to prevent HIV infection and PEP has *limited evidence* to support that it prevents HIV infection (see *Medical Effectiveness* section), CHBRP could not identify any research literature that quantified the expected offset of AIDS-related illnesses that would be prevented, particularly in the first year, after starting oral PrEP or CAB-LA. This uncertainty is due to the wide variation of when, if untreated, HIV infection would result in an AIDS-related illness, and the large number of potential conditions. Therefore, potential offsets in the first year postmandate due to prevention of HIV infection could not be quantified.

Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 8, and Table 9), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 339.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of SB 339.

How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

With baseline coverage of 97% of enrollees in DMHC-regulated plans and CDI-regulated policies, there is no measurable shifting of costs to other payers. CHBRP is aware of public programs that are focused on HIV/AIDS-related expenses, which could include PrEP/PEP, but these programs are tailored to provide low-cost services to people who are uninsured and are therefore outside of CHBRP's analysis. CHBRP is aware that the AIDS Drug Assistance Program (ADAP), which pays for AIDS-related drug costs for Californian adults who meet income eligibility and are not enrolled in Medi-Cal or other insurance at the time of enrollment in ADAP, may also inadvertently provide coverage for PrEP and PEP to commercially insured enrollees. CHBRP is unable to quantify how many enrollees in DMHC-regulated plans or CDI-regulated policies are using this program rather than their insurance, potentially for reasons concerning privacy of medical information.

Table 8. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2024

	DMHC-Regulated						CDI-Regulated			Total
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS (b)	Medi-Cal (excludes COHS) (c) Under 65 65+		Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Total enrollees in plans/policies subject to SB 339	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Premiums										
Average portion of premium paid by employer (e)	\$515.14	\$453.07	\$0.00	\$581.85	\$254.61	\$543.16	\$558.79	\$561.94	\$0.00	\$98,619,779,000
Average portion of premium paid by enrollee	\$133.01	\$195.66	\$692.32	\$113.49	\$0.00	\$0.00	\$205.72	\$183.57	\$672.54	\$42,580,425,000
Total premium	\$648.15	\$648.74	\$692.32	\$695.34	\$254.61	\$543.16	\$764.51	\$745.50	\$672.54	\$141,200,203,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	\$44.62	\$138.02	\$181.01	\$49.17	\$0.00	\$0.00	\$113.02	\$200.40	\$223.68	\$14,964,510,000
Expenses for noncovered benefits (f)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
Total expenditures	\$692.76	\$786.76	\$873.33	\$744.50	\$254.61	\$543.16	\$877.53	\$945.90	\$896.22	\$156,164,713,000

Source: California Health Benefits Review Program, 2023.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.1% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.⁶³ CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.

(d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.⁶⁴

(e) In some cases, a union or other organization, or Medi-Cal for its beneficiaries.

(f) Includes only those expenses that are paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that would be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

⁶³ For more detail, see CHBRP's resource *Estimates of Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at http://chbrp.org/other_publications/index.php.

⁶⁴ For more detail, see CHBRP's resource *Sources of Health Insurance in California*, available at http://chbrp.org/other_publications/index.php.

Table 9. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2024

	DMHC-Regulated						CDI-Regulated			Total
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS (b)	Medi-Cal (excludes COHS) (c)		Large Group	Small Group	Individual	
					Under 65	65+				
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Total enrollees in plans/policies subject to Sb 339	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Premiums										
Average portion of premium paid by employer (e)	\$0.0049	\$0.0039	\$0.0000	\$0.0051	\$0.0062	\$0.0062	\$0.0041	\$0.0038	\$0.0000	\$1,287,000
Average portion of premium paid by enrollee	\$0.0013	\$0.0017	\$0.0053	\$0.0010	\$0.0000	\$0.0000	\$0.0015	\$0.0012	\$0.0048	\$353,000
Total premium	\$0.0061	\$0.0056	\$0.0053	\$0.0061	\$0.0062	\$0.0062	\$0.0056	\$0.0051	\$0.0048	\$1,640,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	\$0.0004	\$0.0012	\$0.0014	\$0.0004	\$0.0000	\$0.0000	\$0.0008	\$0.0014	\$0.0016	\$125,000
Expenses for noncovered benefits (f)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
Total expenditures	\$0.0066	\$0.0067	\$0.0066	\$0.0066	\$0.0062	\$0.0062	\$0.0065	\$0.0064	\$0.0064	\$1,765,000
Percent change										
Premiums	0.0009%	0.0009%	0.0008%	0.0009%	0.0024%	0.0011%	0.0007%	0.0007%	0.0007%	0.0012%
Total expenditures	0.0009%	0.0009%	0.0008%	0.0009%	0.0024%	0.0011%	0.0007%	0.0007%	0.0007%	0.0011%

Source: California Health Benefits Review Program, 2023.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).
(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.1% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.⁶⁵ CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).
(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.
(d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.⁶⁶
(e) In some cases, a union or other organization, or Medi-Cal for its beneficiaries.
(f) Includes only those expenses that are paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that would be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.
Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

⁶⁵ For more detail, see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at http://chbrp.org/other_publications/index.php.

⁶⁶ For more detail, see CHBRP's resource *Sources of Health Insurance in California*, available at http://chbrp.org/other_publications/index.php.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, SB 339 would update the current definition of preexposure prophylaxis (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. It would also authorize a pharmacist to furnish up to a 90-day course of PrEP, and beyond a 90-day course under certain conditions. In addition, SB 339 would mandate coverage for postexposure prophylaxis (PEP) when furnished by a pharmacist. SB 339 would also require health plans regulated by DMHC and health policies regulated by CDI to reimburse for all services and testing related to the furnishing of PrEP and PEP at 100% the rate of those delivered by physicians.

The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate). This section estimates the short-term impact⁶⁷ 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. See *Long-Term Impacts* for discussion of disparities and social determinants of health.

Estimated Public Health Outcomes

Measurable health outcomes relevant to SB 339 include HIV risk reduction, HIV incidence and transmission, and quality of life.

As presented in the *Medical Effectiveness* section:

- 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, as both are associated with high protection from PrEP.
- There is *limited evidence* 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 and *insufficient evidence* that they can safely furnish injectable 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.

As presented in *Benefit Coverage, Utilization, and Cost Impacts* section, at baseline 97% of enrollees with health insurance subject to SB 339 have coverage for PrEP/PEP when furnished by a pharmacist, inclusive of any testing or screening services needed for determining eligibility (see Table 1). Postmandate, 100% of enrollees would have coverage for PrEP/PEP furnished by a pharmacist, inclusive of any testing or screening services needed for determining eligibility. CHBRP estimates SB 339 would result in a 3% upper bound increase in utilization but is unable to estimate how much of the increase is due to the shift in transfer of PrEP/PEP furnishment by primary care providers to pharmacists versus uptake by new users of PrEP/PEP. CHBRP estimates there would be an increase in the number of enrollees who obtain PrEP (134) and PEP (63) and related services provided by a pharmacist. Therefore, SB 339 is expected to result in an increase of pharmacist-initiated oral PrEP prescriptions (426), CAB-LA injections (48), and associated services (1,481) comprised of consultations, HIV screenings, other related screenings and tests, and other vaccinations. Similarly, SB 339 is expected to result in an increase pharmacist-initiated oral PEP prescriptions (168) and associated services (1,026) comprised of consultations, HIV screenings, other related screenings and tests, and other vaccinations.

⁶⁷ CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

Pharmacist Provision of HIV Prophylaxis

As presented in the *Background on Antiretrovirals for the Prevention of HIV/AIDS* section, per the passage of SB 159 in 2019, in order for pharmacists to be able to independently furnish PrEP and PEP in California, they must complete a 90-minute HIV preventative care training and provide services to enrollees including testing for HIV and STIs,⁶⁸ counseling and education, and additional laboratory tests.

Postmandate, CHBRP anticipates that additional pharmacies and pharmacists would adapt their pharmacy infrastructure to allow for the initiation and furnishment of PrEP and PEP, given reimbursement for their associated services by commercial carriers and the expanded authorization to furnish PrEP for up to a 90-day course. An increase in the provision of PrEP/PEP and related services and testing by pharmacists is likely to be small due to barriers that SB 339 does not address (which are also described in the *Background on Antiretrovirals for the Prevention of HIV/AIDS* and *Benefit Coverage, Utilization, and Cost Impacts* sections).

It is important to note that pharmacists are not set up to automatically bill for associated services (e.g., lab tests and patient counseling) specific to Medi-Cal.⁶⁹ Furthermore, there is currently no mechanism in place for pharmacists to bill commercial health plans for associated services. In order for pharmacists to be reimbursed for associated medical services (e.g., provision of HIV preventative services), postmandate, pharmacies would need to develop and implement a billing mechanism to bill all DMHC-regulated health plans and CDI-regulated policies for their associated services. Should additional Collaborative Practice Agreements be established and/or pharmacies establish the billing mechanism to bill DMHC- and CDI-regulated health plans and policies for their associated services, additional time would be needed for pharmacists to participate in HIV preventative training and adapt their day-to-day pharmacy practices to furnish PrEP and PEP.

It should also be noted that the language of SB 339 provides the California Board of Pharmacy until July 1, 2024 to adopt emergency regulations related to implementation of the bill. Pharmacists may need additional time beyond the first year postmandate to adapt their practices to those regulations and complete any training required by the regulations.

In the first year postmandate, CHBRP estimates there would be an increase in the number of enrollees who obtain PrEP (134) and PEP (63) and related services provided by a pharmacist. Given the anticipated increase in utilization, 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 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). This overall increase in utilization (3%; an upper boundary estimate) is supported by *limited evidence* that pharmacists can safely and effectively furnish daily oral PrEP and *insufficient evidence* that pharmacists can safely and effectively furnish PEP and injectable PrEP.

Potential Harms of SB 339

When data are available, CHBRP estimates the marginal change in relevant harms associated with interventions affected by the proposed mandate. As discussed in the *Medical Effectiveness* section, in the case of SB 339, there is *inconclusive evidence* to suggest that an increase in the use of PrEP could result in harm. There is *inconclusive evidence* that condom use is lower among users of PrEP and that incidence of STIs are higher among users of PrEP. While some users may experience harms in the form of higher rates of STIs, rates of STIs overall are higher among the population targeted for PrEP use.

⁶⁸ Under SB 159, passed in 2019, pharmacists may order tests if a Collaborative Practice Agreement (CPA) has been established. Under SB 409, passed in 2021, pharmacists may conduct CLIA-waived tests, including HIV and STI testing.

⁶⁹ To bill for pharmacy-associated services (e.g., labs and patient counseling) specific to Medi-Cal, pharmacists must also be credentialed by Medi-Cal (Communication with M. Stebbins, April 2023).

Users of PrEP do not experience higher rates of adverse events from the medications, higher rates of antiretroviral drug resistance, or poorer reproductive outcomes compared to nonusers. There is a *preponderance of evidence* that PrEP uptake does not lead to a difference in the number of sexual partners.

However, potential harms associated with the use of PEP include adverse events resulting from medication toxicities. The currently recommended regimen for PEP has the lowest observed adverse events. Reactions to the medications include side effects consisting of nausea/vomiting, diarrhea, headache, and fatigue. Despite the possible side effects, *limited evidence* shows that the benefits of taking PEP to avoid developing HIV postexposure outweigh the harms.

Impact on Disparities⁷⁰

As described in the *Background on Antiretrovirals for the Prevention of HIV/AIDS* section, disparities exist by race/ethnicity, gender identity/sexual orientation, and geographic location. CHBRP is unable to estimate SB 339's impact on disparities related to race/ethnicity, gender/identity/sexual orientation, and geographic location in utilization of PrEP within the first 12 months postmandate due to limited data. (For a discussion of potential impacts beyond the first 12 months of implementation [including SDoH], see *Long-Term Impacts*.)

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.

Impact on Racial or Ethnic Disparities

As discussed in the *Background on Antiretrovirals for the Prevention of HIV/AIDS* section, although Black and Latino Californians are at highest risk of contracting HIV, utilization of PrEP is highest among White Californians. CHBRP found *limited evidence* that discusses the impact of PrEP furnishment by a pharmacist on racial/ethnic disparities in antiretroviral utilization for HIV prevention.

The impact of SB 339 on reducing documented disparities among racial and ethnic groups (see the *Background on Antiretrovirals for the Prevention of HIV/AIDS* section) is unknown because limited data are available to estimate changes in the utilization of PrEP and related services among newly covered enrollees.

Impact on Sexual Orientation and Gender Identity Disparities

As discussed in the *Background on Antiretrovirals for the Prevention of HIV/AIDS* section, MSM and transgender women are at highest risk for contracting HIV but have among the lowest initiation and continuation rates of PrEP. PrEP is most effective when adherence to the regimen is high. CHBRP found *limited evidence* that discusses the impact of PrEP furnishment by a pharmacist on sexual orientation/gender identity disparities in antiretroviral utilization for HIV prevention.

The extent to which sexual orientation and gender identity disparities may be impacted by SB 339 is unknown because limited data are available to estimate changes in the utilization of PrEP and related services among newly covered enrollees.

⁷⁰ For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts* document here: <https://www.chbrp.org/about/analysis-methodology/public-health-impact-analysis>.

Impact on Geographic Location

As discussed in the *Background on Antiretrovirals for the Prevention of HIV/AIDS* section, individuals residing in rural areas have lower PrEP uptake in comparison to those residing in urban areas in California. CHBRP found *limited evidence* that discusses the impact of PrEP furnishment by a pharmacist on geographic disparities in antiretroviral utilization for HIV prevention.

The extent to which geographic disparities may be impacted by SB 339 is unknown because limited data are available to estimate changes in the utilization of PrEP and related services among newly covered enrollees.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of SB 339, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization Impacts

Utilization may increase over time past the first year postmandate depending on whether pharmacists are able to establish the billing systems and contractual arrangements to be able to bill for testing and services needed to furnish preexposure prophylaxis (PrEP) and preexposure prophylaxis (PEP). While CHBRP is unable to quantify these potential impacts, the financial incentives for pharmacists under SB 339 may encourage more take-up of these systems by pharmacists than has been seen in the past.

Cost Impacts

Expected increases in costs would be proportional to any further increases in utilization. If those potential increases do not materialize in the long term due to the limiting factor of enrollees who are eligible for an interested in taking PrEP or PEP, then the cost would also remain constant postmandate. There is also the potential of some offset to cost increases due to the potential avoidance of HIV infection or AIDS-related conditions in the long term. According to Paltiel et al. (2023), for every 1% change in rates of administering PrEP among men who have sex with men (MSM), between 114 and 137 HIV infections are avoided, depending on the medical effectiveness of PrEP. Avoiding HIV infections is known to prevent AIDS-related conditions, including mortality, within a 3-year timeframe (see the *Medical Effectiveness* section) but the potential impacts are not quantifiable.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments), whereas other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects (beyond 12 months postmandate) to the public's health that would be attributable to the mandate, including impacts on disparities, premature death, and economic loss.

In the case of SB 339, CHBRP estimates utilization of PrEP and PEP continue to increase 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.

Impacts on Disparities

In the case of SB 339, evidence demonstrates that disparities in utilization of PrEP exist by racial and ethnic groups, gender identity and sexual orientation, and geographic location. Moreover, perceived stigma from providers is a substantial barrier for PrEP-eligible patients.

Periodically, health insurance mandates can influence disparities, which can mediate health inequities. Evidence presented in the *Background on Antiretrovirals for the Prevention of HIV/AIDS* section indicates that geographic location and provider stigma are associated with lower utilization of PrEP. Enabling pharmacists to initiate and furnish PrEP while also being reimbursed for their associated services may improve access to enrollees residing in rural areas due to increased availability. Additionally, if an enrollee perceives judgement from their primary care provider, they could instead turn to their pharmacist for HIV preventive care. Although the pharmacist would need to record the provision of PrEP in the enrollee's record, the enrollee must consent for the pharmacist to notify the enrollee's primary care provider. If the patient does not have a primary care provider or does not consent to primary care provider notification, the pharmacist must provide the patient with a list of primary care providers within the region.

Should utilization of PrEP continue to increase over the long term, CHBRP estimates that SB 339 could alter geographic- and stigma-related disparities by improving access to PrEP via alternate and/or more proximal locations (especially among individuals with transportation barriers).

However, other factors unrelated to insurance coverage of PrEP may limit utilization by PrEP-targeted populations. Awareness and knowledge of PrEP remain lowest among MSM and transgender women, as well as among Black and Latino persons, the groups that have the highest risk of contracting HIV. In order for independent furnishing of PrEP by pharmacists to increase utilization, patients need to be aware of HIV prevention measures within pharmacies and seek PrEP from pharmacists.

APPENDIX A TEXT OF BILL ANALYZED

The California Senate Committee on Health requested that CHBRP analyze SB 339, as amended on March 14, 2023.

AMENDED IN SENATE MARCH 14, 2023

CALIFORNIA LEGISLATURE— 2023–2024 REGULAR SESSION

SENATE BILL

NO. 339

**Introduced by Senator Wiener
(Coauthor: Assembly Member Low)**

February 07, 2023

An act to amend Section 4052.02 of the Business and Professions Code, to amend Section 1342.74 of the Health and Safety Code, to amend Section 10123.1933 of the Insurance Code, and to amend Section 14132.968 of the Welfare and Institutions Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 339, as amended, Wiener. HIV preexposure *prophylaxis and postexposure* prophylaxis.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law authorizes a pharmacist to furnish at least a 30-day supply of HIV preexposure prophylaxis, and up to a 60-day supply of those drugs if certain conditions are met. *Existing law also authorizes a pharmacist to furnish postexposure prophylaxis to a patient if certain conditions are met.*

This bill would authorize a pharmacist to furnish up to a 90-day course of preexposure prophylaxis, or preexposure prophylaxis beyond a 90-day course, if specified conditions are met. The bill would require the California State Board of Pharmacy to adopt emergency regulations to implement these provisions by July 1, 2024.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law prohibits a health care service plan or health insurer from covering preexposure prophylaxis that has been furnished by a pharmacist in excess of a 60-day supply once every 2 years.

Existing law provides for the Medi-Cal program administered by the State Department of Health Care Services and under which qualified low-income individuals receive health care services pursuant to a schedule of benefits. The existing schedule of benefits includes coverage for preexposure prophylaxis as pharmacist services, limited to no more than a 60-day supply furnished by a pharmacist once every 2 years, *and includes coverage for postexposure prophylaxis*, subject to approval by the federal Centers for Medicare and Medicaid Services. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions.

This bill would require a health care service plan and health insurer to cover preexposure prophylaxis *and postexposure prophylaxis* furnished by a pharmacist, including costs for the pharmacist's services and related ~~testing~~ *testing ordered by the pharmacist, and reimburse pharmacist services at 100% of the fee schedule for physician services*. The bill would include preexposure prophylaxis furnished by a pharmacist as pharmacist services on the Medi-Cal schedule of benefits. Because a willful violation of these provisions by a health care service plan would be a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 4052.02 of the Business and Professions Code is amended to read:

4052.02.(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV preexposure prophylaxis in accordance with this section.

(b) For purposes of this section, “preexposure prophylaxis” means a prescription drug approved by the federal Food and Drug Administration or recommended by the federal Centers for Disease Control and Prevention to reduce a person’s chance of contracting HIV.

(c) For purposes of this section, “CDC guidelines” means the “2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline,” or any subsequent guidelines or recommendations published by the federal Centers for Disease Control and Prevention.

(d) Before furnishing preexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information

about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(e) A pharmacist may furnish up to a 90-day course of preexposure prophylaxis if all of the following conditions are met:

- (1) The patient is HIV negative, as documented by a negative HIV test result obtained consistent with CDC guidelines. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of providers and clinics in the region.
- (2) 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.
- (3) The patient does not report taking any contraindicated medications.
- (4) The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis, 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 childbearing capacity.
- (5) The pharmacist notifies the patient that the patient may need to be seen by a primary care provider to receive subsequent prescriptions for preexposure prophylaxis and that a pharmacist may not furnish a 90-day course of preexposure prophylaxis to a single patient more than once every two years unless the pharmacist ensures that the patient receives testing and followup care consistent with CDC guidelines.
- (6) 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.
- (7) The pharmacist does not furnish more than a 90-day course of preexposure prophylaxis to a single patient more than once every two years, unless directed otherwise by a prescriber.
- (8) 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.

(f) A pharmacist may furnish preexposure prophylaxis beyond a 90-day course if all of the following conditions are met:

(1) The pharmacist ensures that the patient receives testing and followup 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.

(2) 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.

(3) 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.

(g) A pharmacist initiating or furnishing preexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(h) The board, by July 1, 2024, shall adopt emergency regulations to implement this section 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. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

SEC. 2. Section 1342.74 of the Health and Safety Code is amended to read:

1342.74. (a) (1) Notwithstanding Section 1342.71, a health care service plan shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health care service plan to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.

(b) Notwithstanding any other law, a health care service plan shall not prohibit, or permit a delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing preexposure prophylaxis or postexposure prophylaxis.

(c) A health care service plan shall cover preexposure prophylaxis *and postexposure prophylaxis* that has been furnished by a pharmacist, as authorized in ~~Section 4052.02~~ *Sections*

4052.02 and 4052.03 of the Business and Professions Code, including costs for the pharmacist's services and related ~~testing~~. testing ordered by the pharmacist. The rate of reimbursement for pharmacist services shall be at 100 percent of the fee schedule for physician services.

(d) This section does not require a health care service plan to cover preexposure prophylaxis or postexposure prophylaxis by a pharmacist at an out-of-network pharmacy, unless the health care service plan has an out-of-network pharmacy benefit.

SEC. 3. Section 10123.1933 of the Insurance Code is amended to read:

10123.1933. (a) (1) Notwithstanding Section 10123.201, a health insurer shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health insurer to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.

(b) Notwithstanding any other law, a health insurer shall not prohibit, or permit a contracted pharmacy benefit manager to prohibit, a pharmacist from dispensing preexposure prophylaxis or postexposure prophylaxis.

(c) ~~Notwithstanding subdivision (b), a~~ A health insurer shall cover preexposure prophylaxis and postexposure prophylaxis that has been furnished by a pharmacist, as authorized in ~~Section 4052.02~~ Sections 4052.02 and 4052.03 of the Business and Professions Code, including costs for the pharmacist's services and related ~~testing~~. testing ordered by the pharmacist. The rate of reimbursement for pharmacist services shall be at 100 percent of the fee schedule for physician services.

SEC. 4. Section 14132.968 of the Welfare and Institutions Code is amended to read:

14132.968. (a) (1) Pharmacist services are a benefit under the Medi-Cal program, subject to approval by the federal Centers for Medicare and Medicaid Services.

(2) The department shall establish a fee schedule for the list of pharmacist services.

(3) The rate of reimbursement for pharmacist services shall be at 85 percent of the fee schedule for physician services under the Medi-Cal program, except for medication therapy management (MTM) pharmacist services as described in Section 14132.969.

(b) (1) The following services are covered pharmacist services that may be provided to a Medi-Cal beneficiary:

(A) Furnishing travel medications, as authorized in clause (3) of subparagraph (A) of paragraph (10) of subdivision (a) of Section 4052 of the Business and Professions Code.

(B) Furnishing naloxone hydrochloride, as authorized in Section 4052.01 of the Business and Professions Code.

(C) Furnishing self-administered hormonal contraception, as authorized in subdivision (a) of Section 4052.3 of the Business and Professions Code.

(D) Initiating and administering immunizations, as authorized in Section 4052.8 of the Business and Professions Code.

(E) Providing tobacco cessation counseling and furnishing nicotine replacement therapy, as authorized in Section 4052.9 of the Business and Professions Code.

(F) Initiating and furnishing preexposure prophylaxis, as authorized in Section 4052.02 of the Business and Professions Code.

(G) Initiating and furnishing postexposure prophylaxis, as authorized in Section 4052.03 of the Business and Professions Code.

(H) Providing MTM pharmacist services in conjunction with the dispensing of qualified specialty drugs, as described in Section 14132.969.

(2) Covered pharmacist services shall be subject to department protocols and utilization controls.

(c) A pharmacist shall be enrolled as an ordering, referring, and prescribing provider under the Medi-Cal program prior to rendering a pharmacist service that is submitted by a Medi-Cal pharmacy provider for reimbursement pursuant to this section.

(d) (1) The director shall seek any necessary federal approvals to implement this section. This section shall not be implemented until the necessary federal approvals are obtained and shall be implemented only to the extent that federal financial participation is available.

(2) This section neither restricts nor prohibits any services currently provided by pharmacists as authorized by law, including, but not limited to, this chapter, or the Medicaid state plan.

(e) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section, and any applicable federal waivers and state plan amendments, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action. By July 1, 2021, the department shall adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Commencing July 1, 2017, the department shall provide a status report to the Legislature on a

semiannual basis, in compliance with Section 9795 of the Government Code, until regulations have been adopted.

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

APPENDIX B LITERATURE REVIEW METHODS

This appendix describes methods used in the literature review conducted for this report. A discussion of CHBRP's system for medical effectiveness grading evidence follows.

Studies of the effects of PrEP/PEP for the prevention for HIV were identified through searches of PubMed, CINAHL Complete, Scopus, Web of Science Core Collection, EconLit, and Business Source Complete. The search was limited to abstracts of studies published in English. The search was limited to studies published from 2019 to present, because CHBRP had previously reviewed this literature using the same search terms in 2019 for the SB 159 analysis.

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

Medical Effectiveness Review

The medical effectiveness literature review returned abstracts for 474 articles, of which 77 were reviewed for inclusion in this report. A total of 20 new studies since 2019 were included in the medical effectiveness review for SB 339.

Medical Effectiveness Evidence Grading System

In making a “call” for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach*.⁷¹ To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- *Clear and convincing evidence;*
- *Preponderance of evidence;*
- *Limited evidence;*
- *Inconclusive evidence;* and
- *Insufficient evidence.*

A grade of *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.

⁷¹ Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *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.

APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc, the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.⁷² Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.⁷³

This appendix describes analysis-specific data sources, estimation methods, caveats, and assumptions used in preparing this cost impact analysis.

Analysis-Specific Data Sources

Current coverage of preventive services and testing associated with the provision of HIV preexposure and postexposure prophylaxis (PrEP and PEP) was assessed by a survey of the largest commercial and managed Medi-Cal organizations in California. Responses to this survey represented 70.3% of commercial and 56.9% of managed Medi-Cal organizations enrollees with health insurance that can be subject to state benefit mandates. As necessary, CHBRP extrapolated from responses of similarly situated plans/policies.

For this analysis, CHBRP relied on CPT[®] codes to identify relevant services. CPT copyright 2022 American Medical Association. All rights reserved. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. CPT is a registered trademark of the American Medical Association.

The bill specifies coverage of preventive services and testing associated with the provision of PrEP and PEP. CHBRP identified PrEP and PEP by National Drug Code (NDC).

PrEP:

Descovy	6195820021	6195820022	6195820051	7051802300	
Truvada	35356007003	35356007006	35356007030	50090087000	50090087002
	50090087003	50436070101	52959096903	54569558800	54569558802
	54569558803	54868514100	55045348103	61919066902	61958070101
	61958070301	61958070401	61958070501	66336003203	68258198303
Cabotegravir	49702248				

PEP:

Biktarvy	5009062470	6195825011	6195825012	6195825013	6195825051
Prezista	5380806721	5380807731	5456960860	5486859690	5486863690
	5967656201	5967656301	5967656401	5967656501	5967656630

⁷² CHBRP's authorizing statute, available at https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

⁷³ See method documents posted at <https://www.chbrp.org/about/analysis-methodology/cost-impact-analysis>; in particular, see 2022 Cost Analyses: Data Sources, Caveats, and Assumptions.

Tivicay	4970222613 6729618183	4970222713	4970222813	4970225537	5380811301
Isentress/ Isentress HD	6022761 6360361 5486801170 6729612356	6047361 5009010850 6191970602 6729612357	6047761 5380806501 6191970604 6729612358	6308001 5456960340 6191970606 6807121136	6360360 5456960341 6633621406 7651911306

For each identified claim for PrEP or PEP, CHBRP identified associated testing and preventive services by CPT or HCPCS code, as shown below.

Testing:

HIV	80081	81400	86689	86701	86702	86703	87389	87390	87391	87534
	87535	87536	87537	87538	87539	87806	87901	87903	87904	87906
	88363	G0298	G0432	G0433	G0435	G0475				

Renal Function 80069

Sexually	G0450	87210	86631	86632	87110	87270	87320	87490	87491	87492
Transmitted	87810	87590	87591	87592	87850	86592	86593	86694	86695	86696
Infection	87623	87624	87625	87220	87660	87661				

Lipid Panel 80061

Hep B	86704	86705	86706	86707	87340	87341	87350	87515	87516	87517
	87912									

Hep C 80055 80074 86803 87520 87521 87522 87902

Pregnancy 81025 84163

Vaccinations:

Hepatitis A 90632 90633 90634 90636 90730

Hepatitis B 90371 90731 90739 90740 90743 90744 90745 90746 90747 90748
90759

Meningococcal 90619 90620 90621 90644 90733 90734

COVID-19 91300 91301 91302 91303 91304 91305 91306 91307 91308 91309
91310 91311 91312 91313 91314 91315 91316 91317

HPV 90649 90650 90651

Vaccine Administration:

General 90460 90461 90471 90472 90473 90474 G9141 90470 90465 90466
90467 90468

COVID-19 0001A 0002A 0003A 0004A 0011A 0012A 0013A 0021A 0022A 0031A
0034A 0041A 0042A 0051A 0052A 0053A 0054A 0064A 0071A 0072A
0073A 0081A 0082A 0094A

Detailed Cost Notes regarding Analysis-Specific Caveats and Assumptions

The analytic approach and key assumptions are determined by the subject matter and language of the bill being analyzed. As a result, analytic approaches may differ between topically similar analyses, and therefore the approach and findings may not be directly comparable.

Analysis-Specific Caveats and Assumptions

Methodology and Assumptions for Baseline Benefit Coverage

- The population subject to the mandated offering includes all individuals with health insurance regulated by the DMHC or CDI, including commercial, CalPERS, and Medi-Cal.
- CHBRP surveyed managed commercial plans and insurers to determine the percentage of the population with coverage for services and testing related to the provision of PrEP and PEP. The responses indicated 100% coverage for all services and testing within all small-group and large-group markets, while coverage in the Individual markets varied from 0% to 96%, depending on market and service.
- CHBRP surveyed managed Medi-Cal organizations to determine the percentage of the population with coverage for services and testing related to the provision of PrEP and PEP, and found coverage of 100% for all associated testing and preventive services.

Methodology and Assumptions for Baseline Utilization

- The average annual utilization for PrEP and PEP (by NDC code) and associated services and testing (by CPT¹¹ or HCPCS codes) were identified in Milliman's proprietary 2021 Milliman Consolidated Health Cost Guidelines Sources Database (CHSD) for commercial members in California. Due to low utilization of these codes in the Medicaid data, the utilization rate from the Medi-Cal population was assumed equal to Commercial rate.
- Medi-Cal Oral PrEP utilization was assumed to be entirely Truvada.
- The utilization rates were trended at 5.00% annually from 2021 to 2024.
- Injectable PrEP, cabotegravir (CAB), was approved in October 2021 and hence is not usefully present in the 2021 Milliman CHSD. CHBRP assumed CAB would capture 10% of oral PrEP utilization.
- CHBRP found limited claims for pharmacist-provided screening and preventive care in the CHSD claims data. CHBRP also could not distinguish between physician-issued and pharmacist-issued prescriptions for PrEP and PEP. CHBRP assumed that pharmacists provide 2% of all PrEP- and PEP-associated screenings and 5% of consultations and vaccinations in the baseline. No assumption about the division of prescriptions between physician-issued and pharmacist-issued was required for this bill.

Methodology and Assumptions for Baseline Cost

- CHBRP calculated the average California commercial cost per service for PrEP and PEP (by NDC code) and associated services and testing (by CPT or HCPCS codes) using Milliman's proprietary 2021 Consolidated Health Cost Guidelines™ Sources Database (CHSD).
- The average costs per service were trended at 2.85% annually from 2021 to 2024.

Methodology and Assumptions for Baseline and Postmandate Cost Sharing

- CHBRP assumed cost sharing for PrEP, PEP, and associated services and testing performed by primary care physicians would be equal to the average cost-sharing percentage for each market segment both in the baseline and postmandate.
- CHBRP assumed that pharmacist-provided services and testing did not incur cost sharing in the baseline.

- CHBRP assumed that pharmacist-provided services and testing would incur cost sharing equal to the average market segment cost sharing postmandate.

Methodology and Assumptions for Postmandate Utilization

- CHBRP assumed the utilization rate for enrollees with coverage postmandate is equal to the utilization rate for enrollees with coverage at baseline.
- CHBRP assumed that utilization of PrEP and PEP and associated services and testing would increase by 3% as a result of SB 339. This increase was assumed to accrue entirely to pharmacist-provided services.

Methodology and Assumptions for Postmandate Cost

- CHBRP assumed the average cost per service provided by primary care physicians would not change as a result of SB 339.
- CHBRP assumed that associated services and testing performed by pharmacists is not reimbursed in the premandate baseline.
- CHBRP assumed that these services would be reimbursed at the primary care physician rate postmandate.

Determining Public Demand for the Proposed Mandate

CHBRP reviews public demand for benefits by comparing the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask plans and insurers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

Second-Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of SB 339 would have a substantially different impact on utilization of either the tests, treatments, or services for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second-year impacts and determined the second year's impacts of SB 339 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures are due to population changes between the first year postmandate and the second year postmandate.

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A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing researchers and analysts who are **Task Force Contributors** to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, **Milliman**, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

Faculty Task Force

Paul Brown, PhD, University of California, Merced
Timothy T. Brown, PhD, University of California, Berkeley
Janet Coffman, MA, MPP, PhD, *Vice Chair for Medical Effectiveness*, University of California, San Francisco
Todd Gilmer, PhD, University of California, San Diego
Sylvia Guendelman, PhD, LCSW, University of California, Berkeley
Elizabeth Magnan, MD, PhD, *Vice Chair for Public Health*, University of California, Davis
Sara McMenamin, PhD, *Vice Chair for Medical Effectiveness and Public Health*, University of California, San Diego
Joy Melnikow, MD, MPH, University of California, Davis
Aimee Moulin, MD, University of California, Davis
Jack Needleman, PhD, University of California, Los Angeles
Mark A. Peterson, PhD, University of California, Los Angeles
Nadereh Pourat, PhD, *Vice Chair for Cost*, University of California, Los Angeles
Dylan Roby, PhD, University of California, Irvine
Marilyn Stebbins, PharmD, University of California, San Francisco
Jonathan H. Watanabe, PharmD, MS, PhD, University of California, Irvine

Task Force Contributors

Bethney Bonilla, MA, University of California, Davis
Danielle Casteel, MA, University of California, San Diego
Shana Charles, PhD, MPP, University of California, Los Angeles, and California State University, Fullerton
Margaret Fix, MPH, University of California, San Francisco
Naomi Hillery, MPH, University of California, San Diego
Jeffrey Hoch, PhD, University of California, Davis
Julia Huerta, BSN, RN, MPH, University of California, Davis
Michelle Keller, PhD, MPH, University of California, Los Angeles
Jacqueline Miller, University of California, San Francisco
Marykate Miller, MS, University of California, Davis
Katrine Padilla, MPP, University of California, Davis
Amy Quan, University of California, San Francisco
Dominique Ritley, MPH, University of California, Davis

Emily Shen, University of California, San Francisco
Riti Shimkhada, PhD, University of California, Los Angeles
Meghan Soulsby Weyrich, MPH, University of California, Davis
Steven Tally, PhD, University of California, San Diego
Sara Yoeun, MPH, University of California, San Diego

National Advisory Council

Lauren LeRoy, PhD, Strategic Advisor, L. LeRoy Strategies, Chair
Stuart H. Altman, PhD, Professor of National Health Policy, Brandeis University, Waltham, MA
Deborah Chollet, PhD, Senior Fellow, Mathematica Policy Research, Washington, DC
Allen D. Feezor, Former Deputy Secretary for Health Services, North Carolina Department of Health and Human Services, Raleigh, NC
Charles “Chip” Kahn, MPH, President and CEO, Federation of American Hospitals, Washington, DC
Jeffrey Lerner, PhD, President Emeritus, ECRI Institute Headquarters, Plymouth Meeting, PA; Adjunct Senior Fellow, Leonard Davis Institute of Health Economics, University of Pennsylvania
Donald E. Metz, Executive Editor, *Health Affairs*, Bethesda, MD
Dolores Mitchell, (Retired) Executive Director, Group Insurance Commission, Boston, MA
Marilyn Moon, PhD, Senior Fellow, Retired, American Institutes for Research, Washington, DC
Carolyn Pare, (Retired) President and CEO, Minnesota Health Action Group, Bloomington, MN
Richard Roberts, MD, JD, Professor Emeritus of Family Medicine, University of Wisconsin-Madison, Madison, WI
Alan Weil, JD, MPP, Editor-in-Chief, *Health Affairs*, Bethesda, MD

CHBRP Staff

Garen Corbett, MS, Director
John Lewis, MPA, Associate Director
Adara Citron, MPH, Principal Policy Analyst
An-Chi Tsou, PhD, Principal Policy Analyst
Victor Garibay, Policy Associate
Karen Shore, PhD, Contractor*

California Health Benefits Review Program
MC 3116
Berkeley, CA 94720-3116
info@chbrp.org
(510) 664-5306

*Independent Contractor working with CHBRP to support analyses and other projects.

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

Garen Corbett, MS
Director

Please direct any questions concerning this document to: California Health Benefits Review Program; MC 3116; Berkeley, CA 94720-3116, info@chbrp.org, or www.chbrp.org