Key Findings:

Analysis of California Senate Bill 159
HIV Prophylaxis

Summary to the 2019–2020 California State Legislature, April 19, 2019

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

AT A GLANCE

The version of California Senate Bill 159 analyzed by CHBRP would: (1) prohibit commercial plans and policies and CalPERS from placing prior authorization or step therapy requirements on the provision of medically necessary pre-exposure prophylaxis (PrEP) or post-exposure prophylaxis (PEP) to prevent HIV, and (2) expand scope of practice to enable pharmacists to independently furnish PrEP and PEP to all Californians, regardless of insurance status or type.

1. CHBRP estimates that in 2020, all of the 24.5 million Californians enrolled in state-regulated health insurance, along with 1.6 million enrollees in County Organized Health Systems (COHS) and 1.4 million enrollees in the Medi-Cal fee-for-service (FFS) program would have insurance subject to SB 159.
2. **Benefit coverage.**
   a. 100% of enrollees have coverage for PrEP and PEP without prior authorization or step therapy requirements at baseline, and therefore there would be no change in benefit coverage.
   b. At baseline, 0% of enrollees are able to obtain PrEP and PEP through a pharmacist without a prescription from another provider. Postmandate, benefit coverage will increase to 100%, meaning all enrollees will be able to seek PrEP and PEP directly from a pharmacist without needing to obtain a prescription from another provider.
   c. SB 159 would not exceed essential health benefits (EHBs).
3. **Utilization.** Utilization of PrEP will increase by 588 enrollees (from 29,395 at baseline to 29,982 postmandate) in commercial and CalPERS plans and by 180 enrollees (from 9,000 at baseline to 9,180 postmandate) in Medi-Cal. Utilization of PEP will increase by 121 enrollees (from 6,055 at baseline to 6,176 postmandate) in commercial and CalPERS plans and by an unknown number of enrollees in Medi-Cal.

AT A GLANCE, Cont.

4. **Expenditures.** SB 159 would increase total net annual expenditures by $11,802,000, or 0.0074%, for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a $11,328,000 increase in total health insurance premiums paid by employers and enrollees due to an increase in utilization of PrEP and PEP, adjusted by an increase in enrollee expenses for covered benefits.
5. **Medical effectiveness.**
   a. There is *clear and convincing evidence* PrEP is effective in preventing HIV transmission and lowering the risk of HIV among high-risk groups with moderate or high adherence.
   b. There is *limited evidence* that PEP is effective in preventing HIV transmission following occupational and nonoccupational exposures.
   c. There is *insufficient evidence* to assess the impact of prohibiting prior authorization or step therapy on prescription of and adherence to PrEP or PEP.
   d. There is *insufficient evidence* to assess either the ability or inability of pharmacists to safely and effectively prescribe PrEP or PEP.
6. **Public health.**
   a. SB 159 would produce no public health impact because carriers have established procedures for bypassing prior authorization requirements.
   b. In the first year postmandate, the additional enrollees using PrEP would result in a reduction of 25 new HIV cases. An unknown reduction would occur among new PEP users.
7. **Long-term impacts.** Utilization of PrEP and PEP will continue to increase as pharmacists obtain the required training and awareness of PrEP and PEP increases, eventually leveling out over time; therefore, the number of enrollees who will avoid contracting HIV will increase over time."

CONTEXT

Pre-exposure prophylaxis (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 unknown HIV status. The only Food and Drug Administration (FDA)-approved PrEP therapy is a single tablet combination therapy of tenofovir disoproxil fumarate and emtricitabine (brand name: Truvada®), which was approved by the FDA in 2012.[1] PrEP is indicated for specific groups practicing 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.

Post-exposure prophylaxis (PEP) is a short-term, daily therapy similar to PrEP. However, this regimen must be started within 72 hours of (suspected) HIV exposure and is only taken for 28 days. 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 (e.g., prison or health care systems), newborn children of HIV-positive mothers, MSM, and persons who inject drugs.

BILL SUMMARY

SB 159 was amended in the Senate on April 1, 2019, and again on April 11, 2019. This analysis incorporates the amendments made on April 1st. The amendments made on April 11th would alter the cost and public health impacts of SB 159.

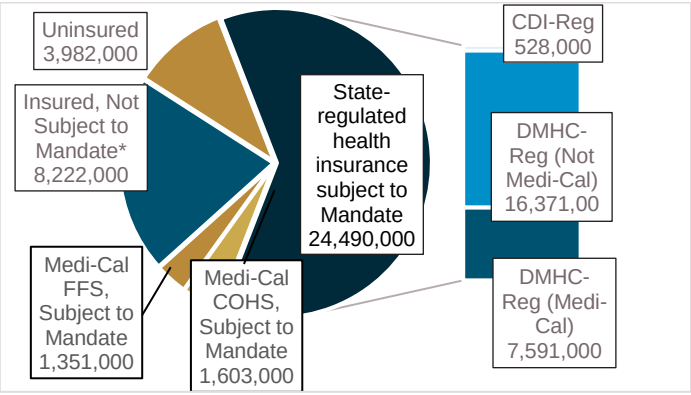
SB 159 as amended April 1st would: (1) prohibit commercial plans and policies and CalPERS from placing prior authorization or step therapy requirements on the provision of medically necessary PrEP or PEP to prevent HIV, and (2) expand scope of practice to enable pharmacists to independently furnish PrEP and PEP to all Californians, regardless of insurance status or type.

For pharmacists to independently prescribe PrEP or PEP, they must complete a training program that addresses the use of PrEP and PEP. Pharmacists must also abide by specified requirements, such as screening enrollees for HIV, providing patient education, and performing specified laboratory tests.

The version of SB 159 as amended on April 11th would enable pharmacists to independently furnish the initial 30-day supply of PrEP and requires pharmacists to refer enrollees to primary care providers or clinics for additional PrEP prescriptions and the recommended testing and education. The bill still enables pharmacists to independently furnish PEP and leaves the provisions prohibiting prior authorization and step therapy unchanged. Additional analysis of these provisions will be provided in a forthcoming CHBRP analysis.

Figure A notes how many Californians have health insurance that would be subject to SB 159.

Figure A. Health Insurance in CA and SB 159



Source: California Health Benefits Review Program, 2019.
Notes: *Medicare beneficiaries, enrollees in self-insured products, etc.

IMPACTS

Benefit Coverage, Utilization, and Cost

The United States Preventive Services Task Force released a draft recommendation that persons at high risk of HIV acquisition should be offered PrEP by clinicians with an A grade. Should this draft recommendation be finalized in 2019, plans and policies will be required to provide coverage for PrEP without cost sharing as early as 2020.

Benefit Coverage

CHBRP found 100% of enrollees subject to SB 159 have health insurance that is fully compliant with the provision of SB 159 that prohibits prior authorization and step therapy for PrEP and PEP.

[1] Refer to CHBRP's full report for full citations and references.

Pharmacists are not currently able to independently furnish PrEP and PEP. Therefore, benefit coverage for this provision of SB 159 would increase from 0% at baseline to 100% postmandate. However, some pharmacists working in a collaborative practice agreement (CPA) are currently able to furnish PrEP and PEP independently to enrollees under the terms of the CPA.

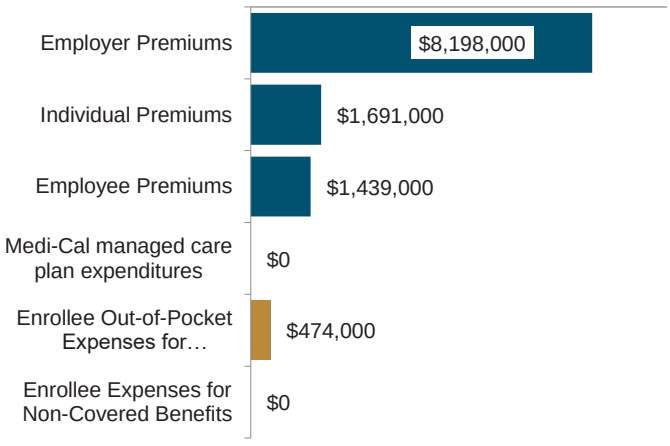
Utilization

At baseline, it is estimated there are 29,395 users of PrEP and 6,055 users of PEP with commercial and CalPERS coverage. Postmandate, CHBRP assumes the projected utilization will increase by 2% due to increased access to PrEP and PEP directly from a pharmacist. Postmandate, it is estimated there would be 29,982 users of PrEP and 6,176 users of PEP.

Expenditures

SB 159 would increase total net annual expenditures by $11,802,000, or 0.0074%, for enrollees with Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated policies. This is due to a $11,328,000 increase in total health insurance premiums paid by employers and enrollees due to an increase in utilization of PrEP and PEP, adjusted by an increase in enrollee expenses for covered and/or noncovered benefits.

Figure B. Expenditure Impacts of SB 159



Source: California Health Benefits Review Program, 2019.

Medi-Cal

Medications to treat and prevent HIV/AIDS are mostly "carved out" of Medi-Cal managed care and the County Organized Health Systems (COHS) into the Medi-Cal fee-for-service (FFS) program.

Medi-Cal currently prohibits utilization management practices for PrEP and PEP.

Recent changes to the Welfare and Institutions Code enable pharmacists to bill Medi-Cal FFS for services associated with the independent furnishing for specific categories of prescriptions, such as required counseling, lab work, and education. The rate of reimbursement for these services is required to be at least 85% of the fee schedule for physician services under the Medi-Cal program.

CHBRP estimates that utilization of PrEP will increase from 9,000 baseline to 9,180 postmandate (2% utilization increase). The increase in utilization is estimated to increase state Medi-Cal expenditures by $1,257,000.

CHBRP is unable to estimate utilization changes of PEP within Medi-Cal due to lack of data.

CalPERS

Employer expenditures for CalPERS are expected to increase by $249,000 (0.0080%) in the first year postmandate. Employer premiums would increase by $0.0397 per member per month (PMPM), and employee premiums would increase by $0.0076 PMPM.

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 159.

Medical Effectiveness

This medical effectiveness review summarizes findings from evidence on: (1) the effectiveness of PrEP and PEP in preventing HIV/AIDS, (2) the impact of removing prior authorization and step therapy on the likelihood that health professionals with prescribing authority will prescribe PrEP and PEP, (3) the impact of removing prior authorization

and step therapy on uptake and adherence of PrEP and PEP, (4) the ability of pharmacists to prescribe PrEP and PEP safely and effectively, and (5) any harms or adverse events associated with PrEP, PEP, or other HIV prevention therapies.

- 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 occupational and nonoccupational exposures.
- There is *insufficient evidence* that prohibiting prior authorization or step therapy increases the likelihood that health professionals with prescribing authority will prescribe PrEP or PEP, improve adherence to PrEP or PEP, or improve outcomes for people taking PrEP or PEP.
    - However, there is *limited evidence* that prior authorization requirements for medications used to treat HIV delay receipt of care.
- There is *insufficient evidence* to determine whether pharmacists can safely and effectively prescribe PrEP or PEP.

Public Health

CHBRP estimates SB 159 would produce no public health impact because carriers have established procedures for bypassing prior authorization requirements. It is possible that enrollees encounter prior authorization requirements and are not able to obtain the bypass for immediate authorization for PrEP. Therefore, it is possible the prohibition of prior authorization will enable more enrollees to obtain PrEP more quickly.

In the first year postmandate, CHBRP estimates 768 additional enrollees will obtain PrEP through pharmacists, which would result in a reduction of 25 new HIV cases. For the 121 additional enrollees who will obtain PEP through pharmacists, a small reduction in the number of new HIV cases would be expected as well. This estimate is supported by limited evidence that pharmacists are able to safely and effectively prescribe PrEP and provide related services and that the availability of these services from pharmacists will result in an increase in utilization (2%) of PrEP and PEP. The increase in utilization is dampened by limited adoption of the requirements to independently furnish PrEP and PEP by pharmacists and pharmacies within the first year postmandate.

Approximately 38,295 enrollees subject to SB 159 use PrEP premandate, far below the population that meets criteria for PrEP. Although enabling pharmacists to independently furnish PrEP would increase utilization by 2% in the first year postmandate, utilization could continue to increase as more pharmacists take the required training. However, barriers such as lack of reimbursement for associated services such as patient counseling and lab tests could limit future utilization increases.

Long-Term Impacts

CHBRP estimates utilization of PrEP and PEP will continue to increase as pharmacists obtain the required training and awareness of PrEP and PEP increases, eventually leveling out; therefore, the number of enrollees who will avoid contracting HIV will increase over time.

Should utilization of PrEP continue to increase, CHBRP estimates that SB 159 could alter geographic- and stigma-related disparities by improving access to PrEP through alternative locations.

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 blacks and Hispanics, 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 engaged in HIV prevention and seek PrEP from pharmacists.

Essential Health Benefits and the Affordable Care Act

SB 159 would not require coverage for a new state benefit mandate, since PrEP and PEP are already covered medications, but instead expands which providers can furnish PrEP and PEP and specifies terms of utilization management. Therefore, SB 159 appears not to exceed the definition of essential health benefits (EHBs) in California and would not trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in qualified health plans in Covered California.