

# UC Office of the President

## Report to California Legislature

### **Title**

Analysis of California Senate Bill 159: HIV Prophylaxis

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### **Author**

California Health Benefits Review Program

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# California Health Benefits Review Program

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Analysis of California Senate Bill 159

HIV Prophylaxis

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A Report to the 2019–2020 California State Legislature

April 19, 2019

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# Key Findings:

## Analysis of California Senate Bill 159 HIV Prophylaxis

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



### 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.<sup>1</sup> 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.

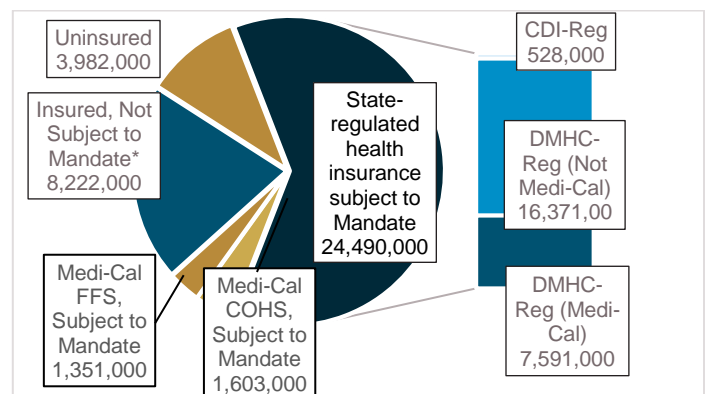
For pharmacists to independently prescribe PrEP or PEP, they must complete a training program that addresses the use of PrEP and PEP. Pharmacists must also abide by specified requirements, such as screening enrollees for HIV, providing patient education, and performing specified laboratory tests.

<sup>1</sup> Refer to CHBRP's full report for full citations and references.

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.

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.

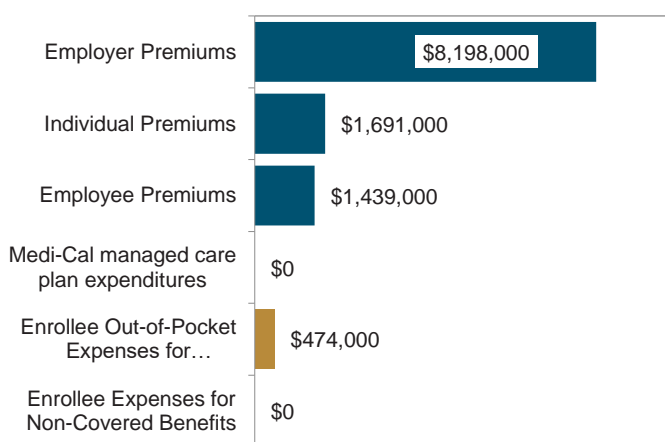
### Utilization

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.

A Report to the California State Legislature

Analysis of California Senate Bill 159  
HIV Prophylaxis

April 19, 2019

**California Health Benefits Review Program**  
MC 3116; Berkeley, CA 94720-3116  
[www.chbrp.org](http://www.chbrp.org)





## ABOUT CHBRP

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](http://www.chbrp.org).



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### Acknowledgments

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**Table 1.** SB 159 Impacts on Benefit Coverage, Utilization, and Cost, 2020

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
<b>Benefit coverage</b>				
Total enrollees with health insurance subject to state-level benefit mandates (a)	24,490,000	24,490,000	0	0%
Total enrollees with state-regulated OPD coverage (b)	23,427,000	23,427,000	0	0%
Total percentage of enrollees with health insurance subject to SB 159 (b)	100%	100%	0%	0%
Total percentage of enrollees with coverage for PrEP and PEP without prior authorization and step therapy	100%	100%	0%	0%
Total percentage of enrollees able to obtain PrEP and PEP directly from pharmacist	0%	100%	100%	100%
<b>Utilization and unit cost</b>				
Number of enrollees using PrEP	29,395	29,982	588	2%
Number of enrollees using PEP	6,055	6,176	121	2%
Scripts per user of PrEP	6.002	6.002	0.000	0%
Scripts per user of PEP (c)	10.410	10.410	0.000	0%
Average prescription drug regime cost per user (PrEP and PEP)	\$13,822.24	\$13,822.24	\$0.00	0%
Average number of lab tests per user of PrEP	3.597	3.597	0.000	0%
Average number of lab tests per user of PEP	2.534	2.534	0.000	0%
Average annual cost of lab tests per user of PrEP	\$139.30	\$139.30	\$0.00	0%
Average annual cost of lab tests per user of PEP	\$156.78	\$156.78	\$0.00	0%
<b>Expenditures</b>				
<u>Premiums by payer</u>				
Private employers for group insurance	\$86,438,375,000	\$86,446,324,000	\$7,949,000	0.0092%
CalPERS HMO employer expenditures (d) (e)	\$3,098,551,000	\$3,098,800,000	\$249,000	0.0080%
Medi-Cal Managed Care Plan expenditures	\$28,492,273,000	\$28,492,273,000	\$0	0.0000%
Enrollees with individually purchased insurance	\$12,045,324,000	\$12,047,015,000	\$1,691,000	0.0140%
Enrollees with group insurance, CalPERS	\$14,476,394,000	\$14,477,833,000	\$1,439,000	0.0099%

HMOs, Covered California, and Medi-Cal Managed Care (d)				
<b>Enrollee expenses</b>				
For covered benefits (deductibles, copayments, etc.)	\$14,750,880,000	\$14,751,354,000	\$474,000	0.0032%
For noncovered benefits (f)	\$0	\$0	\$0	0.00%
<b>Total expenditures</b>	<b>\$159,301,797,000</b>	<b>\$159,313,599,000</b>	<b>\$11,802,000</b>	<b>0.0074%</b>

Source: California Health Benefits Review Program, 2019.

Notes: Provision of PrEP and PEP are “carved out” of Medi-Cal Managed Care plans and COHS, and are instead provided through the fee-for-service program. There are approximately 10,545,000 enrollees in full-scope Medi-Cal in 2020. Although not shown in Table 1, 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 \$1,256,539. CHBRP is unable to estimate utilization changes of PEP due to lack of data.

(a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.<sup>2</sup>

(b) Health insurance that has no OPD benefit or has an OPD benefit not regulated by DMHC or CDI is considered compliant.<sup>3</sup>

(c) Occupational PEP may be covered through worker’s comp and therefore would not appear in this claims data. As a result, utilization of PEP may be higher on a per-person basis due to the nature of non-occupational exposure and the likelihood of repeat exposure.

(d) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

(e) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five (20.5%) of these enrollees has a pharmacy benefit not subject to DMHC.<sup>4</sup> 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).

(f) Includes only those expenses that are paid directly by enrollees to providers for services related to the mandated benefit that are not currently covered by insurance. In addition, this only includes those expenses that will 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; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organizations; OPD=Outpatient Prescription Drug; PEP = post-exposure prophylaxis; PrEP = pre-exposure prophylaxis.

<sup>2</sup> For more detail, see *Estimates of Sources of Health Insurance in California*, available at [http://chbrp.com/analysis\\_methodology/cost\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/cost_impact_analysis.php).

<sup>3</sup> For more detail, see *Estimates of Pharmacy Benefit Coverage*, available at [http://chbrp.com/analysis\\_methodology/cost\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/cost_impact_analysis.php).

<sup>4</sup> For more detail, see *Estimates of Pharmacy Benefit Coverage*, available at [http://chbrp.com/analysis\\_methodology/cost\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/cost_impact_analysis.php).

## POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)<sup>5</sup> conduct an evidence-based assessment of the medical, financial, and public health impacts of SB 159, HIV Prophylaxis. 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.

### Bill-Specific Analysis of SB 159, HIV Prophylaxis

If enacted, SB 159 as amended April 1, 2019, would affect the health insurance of enrollees in Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated policies, in addition to Medi-Cal beneficiaries receiving benefits through the Medi-Cal Managed Care plans, County Organized Health Systems (COHS), and the fee-for-service (FFS) program.

#### Bill Language Summary

SB 159 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.

For pharmacists to independently prescribe PrEP or PEP, they must complete a training program that addresses the use of PrEP and PEP.

A pharmacist can furnish an initial course PrEP if the pharmacist:

- Screens the patient for HIV and confirms a negative test result or determines the patient has recently had a negative HIV test;
- Provides counseling to the patient on the ongoing use of PrEP consistent with the most recent Centers for Disease Control and Prevent (CDC) guidelines, which may include education about side effects, adherence to the drug regimen, and the importance of timely testing and treatment, and additional topics as applicable; and
- Documents the services provided in the patient's health record and notifies the patient's primary care provider. If the patient does not have a primary care provider or refuses to consent to this notification, the pharmacist shall provide a list of health care service providers to contact regarding ongoing care.

A pharmacist can renew<sup>6</sup> a prescription for PrEP if the pharmacist:

- Ensures the patient is clinically eligible for use of PrEP consistent with the most recent CDC guidelines, which may include providing or determining the patient has received timely testing and treatment, as applicable, for HIV, kidney function, hepatitis B and C, sexually transmitted infections, and pregnancy for women of child-bearing capacity.

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<sup>5</sup> CHBRP's authorizing statute is available at <http://chbrp.org/faqs.php>.

<sup>6</sup> SB 159 bill language states "refill." However, pharmacists currently have the authority to refill a PrEP prescription that is issued by another provider with prescribing authority. "Renew" refers to the pharmacist's ability to newly write a prescription when an enrollee's prior prescription expired or they used all of the allowed refills.

- Documents the services provided in the patient's health record and notifies the patient's primary care provider. If the patient does not have a primary care provider or refuses to consent to this notification, the pharmacist shall provide a list of health care service providers to contact regarding ongoing care.

A pharmacist can furnish PEP if the pharmacist:

- Screens the patient and determines the exposure meets the clinical criteria for consideration of PEP consistent with the most recent guidelines from the CDC;
- Provides HIV testing or determines the patient is willing to receive an HIV test;
- Provides counseling to the patient regarding side effects and adherence to the drug regimen and testing; and
- Documents the services provided in the patient's health record and notifies the patient's primary care provider. If the patient does not have a primary care provider or refuses to consent to this notification, the pharmacist shall provide a list of health care service providers to contact regarding follow up care.

### *Medi-Cal*

The provision enabling pharmacists to furnish PrEP and PEP also applies to all Medi-Cal beneficiaries through alterations to the Welfare and Institutions code. Medications to treat and prevent HIV/AIDS are mostly "carved out" of Medi-Cal managed care<sup>7</sup> and the County Organized Health Systems (COHS) into the Medi-Cal fee-for-service program. Therefore, even though the SB 159 provision prohibiting prior authorization and step therapy applies to Medi-Cal Managed Care Plans because they are regulated by DMHC, enrollees seeking and obtaining HIV prophylaxis will actually receive benefits through the Medi-Cal fee-for-service program.

The full text of SB 159 as amended April 1, 2019, can be found in Appendix A.

### *April 11th amendments*

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.

### **Relevant Populations**

Although all health plans and policies regulated by DMHC or CDI would be subject to SB 159, plans and policies without a pharmacy benefit would not have to comply with the provision prohibiting prior authorization and step therapy. The bill would require compliance from the health insurance of the 23.4 million enrollees in DMHC-regulated plans or CDI-regulated policies that include an outpatient

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<sup>7</sup> Some beneficiaries, such as those receiving benefits through the AIDS Healthcare Foundation Medi-Cal Managed Care Plan (Positive Healthcare California), receive HIV treatment and preventive medication through Medi-Cal Managed Care.

prescription drug pharmacy benefit.<sup>8</sup> Plans and policies with an OPD benefit that is not regulated by DMHC or CDI are considered compliant for this analysis. Enrollees receiving health insurance through Medi-Cal Managed Care Plans would have coverage subject to this provision of SB 159, however, as mentioned above, medications to prevent HIV are carved out of managed care and are furnished through the FFS program.

Because SB 159 also expands the *scope of practice* for pharmacists through amendments to the Business and Professions Code, the bill would affect all Californians, regardless of whether they are enrolled in a DMHC-regulated plan or CDI-regulated policy. However, CHBRP focuses on Californians who will have health insurance regulated by the state. If enacted, SB 159 would affect the health insurance of approximately 24.5 million enrollees (63% of all Californians). This represents 100% of the 24.5 million with health insurance regulated by DMHC or CDI. An additional 1.6 million COHS beneficiaries and 1.4 million persons receiving benefits through the Medi-Cal FFS program would also be impacted by SB 159.

## Interaction With Existing Requirements

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

### California Policy Landscape

#### *California law and regulations*

Current law requires health insurance coverage of single-tablet combination preventive HIV medications if they are as effective as multitablet regimens.<sup>9</sup> Plans and policies are prohibited from using utilization management practices that rely on a multitablet regimen instead of a single-tablet drug regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and equally or more likely to result in adherence to a drug regimen. CHBRP analyzed the impact of these provisions in 2018.<sup>10</sup>

Scope of practice for pharmacists is regulated through section 4052 of the Business and Professions Code. Pharmacists are currently able to independently furnish:

- Naloxone hydrochloride;<sup>11</sup>
- Hormonal contraceptives;<sup>12</sup>
- Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States;<sup>13</sup>
- Vaccines listed on the routine immunization schedules recommended by the Advisory Committee on Immunization Practice;<sup>14</sup> and

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<sup>8</sup> For more information, see CHBRP's *Estimates of Pharmacy Benefit Coverage in California for 2020*, available at <http://chbrp.com/2019%20Estimates%20of%20Pharmacy%20Benefit%20FINAL%200304.pdf>.

<sup>9</sup> H&SC Section 1342.71 and IC Section 10123.193.

<sup>10</sup> CHBRP's analysis of SB 1021 Prescription Drugs is available at: [http://chbrp.org/completed\\_analyses/index.php](http://chbrp.org/completed_analyses/index.php).

<sup>11</sup> BPC Section 4052.01.

<sup>12</sup> BPC Section 4052.3.

<sup>13</sup> BPC Section 4052.

<sup>14</sup> BPC Section 4052.8.



- Nicotine replacement products approved by the Food and Drug Administration (FDA) for use by prescription.<sup>15</sup>

The Business and Professions code specifies that for all services listed above, pharmacists must obtain additional training approved by the California State Board of Pharmacy and pharmacists must notify the patient's primary care provider or record the information in the patient's medical record.

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. Pharmacists operating under a CPA may currently initiate or adjust the drug regimen of a patient pursuant to a specific written order or authorization made by the individual's treating prescriber.<sup>16</sup> Thus, under existing law, pharmacists can currently furnish PrEP and PEP independently if they have a CPA with a patient's physician.

### Medi-Cal

As mentioned above, HIV medications are carved out of Medi-Cal Managed Care and COHS, and are provided through the FFS program. Medi-Cal currently prohibits utilization management practices for PrEP and PEP.<sup>17</sup>

Recent changes to the Welfare and Institutions Code<sup>18</sup> enable pharmacists to bill Medi-Cal FFS for services associated with the independent furnishing of the above listed 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.

### *Similar requirements in other states*

CHBRP is not aware of other states that have passed or introduced laws enabling pharmacists to independently furnish HIV prophylaxis medications. However, many states allow pharmacists to furnish HIV prophylaxis medications under collaborative practice agreements or under the direction of a licensed health care provider, such as a physician or nurse practitioner (NP). New York's State Board of Regents amended scope of practice, effective March 2017, allowing pharmacists acting under a non-patient-specific standing order from a licensed physician or NP to dispense an initial 7 days of PEP medications (New York State Department of Health, 2017).

Washington enacted a law in 2015 that requires health insurers to recognize pharmacists as billable providers, therefore enabling pharmacists to bill for services provided in conjunction with prescriptions.<sup>19</sup> One pharmacy in Seattle, the Kelley-Ross Pharmacy, established a Collaborative Drug Therapy Agreement with an HIV specialist physician, which allows trained pharmacists to perform specific functions, including initiating and monitoring PrEP in line with national guidelines.

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<sup>15</sup> BPC Section 4052.9.

<sup>16</sup> BPC Sections 4052.2 and 4052.6..

<sup>17</sup> Department of Health Care Services (DHCS). 2017. Erroneous Treatment Delays and Denials for HIV PrEP and PEP. Available at [http://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom\\_26539.asp](http://files.medi-cal.ca.gov/pubsdoco/newsroom/newsroom_26539.asp). Accessed on April 7, 2019.

<sup>18</sup> WIC 14132.968.

<sup>19</sup> Chapter 237, 2015 Laws, Washington State.

## Federal Policy Landscape

### *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 159 may interact with requirements of the ACA as presently exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).<sup>20</sup>

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law and regulations.

### Essential Health Benefits

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 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.

### Federally Selected Preventive Services

The ACA requires that nongrandfathered group and individual health insurance plans and policies cover certain preventive services without cost sharing when delivered by in-network providers and as soon as 12 months after a recommendation appears in any of the following:<sup>21</sup>

- 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 Centers for Disease Control and Prevention (CDC).

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<sup>20</sup> The ACA requires nongrandfathered small-group and individual market health insurance — including, but not limited to, QHPs sold in Covered California — to cover 10 specified categories of EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: [http://www.chbrp.org/other\\_publications/index.php](http://www.chbrp.org/other_publications/index.php).

<sup>21</sup> More information is available on CHBRP’s website under “Resources”: [www.chbrp.org/other\\_publications/index.php](http://www.chbrp.org/other_publications/index.php).

USPSTF released a draft recommendation with an A grade<sup>22</sup> that persons at high risk of HIV acquisition should be offered PrEP by clinicians.<sup>23</sup> 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.

## Prior Authorization and Step Therapy for PrEP and PEP

Prior authorization and step therapy are both forms of utilization management practices plans or policies may put in place to control costs. Prior authorization is a utilization management tool that requires providers to submit documentation of medical need to the health plan for approval of coverage for some prescription drugs. Step therapy is a utilization management tool that requires an enrollee to try and fail one or more formulary-required drugs prior to receiving coverage for the initially prescribed drug. Step therapy protocols usually recommend starting with a drug that is less expensive (generics) and/or has more “post-marketing safety experience.”

## Analytic Approach and Key Assumptions

Currently, Truvada is the only FDA-approved combination, single-tablet medication for use as PrEP and PEP. Additionally, the CDC guidelines recommend daily doses of PrEP. Research underway suggests that additional forms of PrEP may emerge in the near future, and dosing recommendations for oral PrEP may expand to include “on demand” dosing. CHBRP discusses how variations in dosing impact the effectiveness of PrEP and PEP but excludes discussion of new modalities because they are not FDA approved and would not be available within CHBRP’s projected time frame. Should new combination HIV Prophylactic drug therapies come on the market in future years, they would fall under the purview of SB 159.

CHBRP has assumed SB 159 would not affect the health insurance of enrollees in plans or policies that do not include a pharmacy benefit. Less than 5% of all enrollees in plans and policies regulated by DMHC or CDI have no pharmacy benefit through their state-regulated health insurance,<sup>24</sup> though the figure is higher among commercial and CalPERS enrollees, about 7%. For this analysis, those enrollees are considered to have health insurance compliant with SB 159.

If plans and policies contract with a pharmacy benefit manager (PBM) to provide outpatient prescription drug benefits, PBMs would also be required to implement the prohibition of utilization management or step therapy protocols for PrEP and PEP.<sup>25</sup>

SB 159 enables pharmacists to bill Medi-Cal FFS for services associated with furnishing PrEP and PEP, including counseling, laboratory testing, and ongoing monitoring. However, pharmacists are not currently able to bill commercial health plans and policies for associated services, and therefore CHBRP assumes pharmacists would not receive reimbursement for these additional required services. As is the case when a pharmacist provides counseling associated with the furnishing of hormonal contraception, under existing law pharmacists can only bill commercial plans and policies for the cost of filling the hormonal contraception prescription.

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<sup>22</sup> An A grade indicates the USPSTF recommends the services and there is high certainty that the net benefit is substantial.

<sup>23</sup> USPSTF. Draft recommendation statement: prevention of HIV infection: PrEP. 2018. Available at <https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>. Accessed April 2, 2019.

<sup>24</sup> For more information, see CHBRP’s *Estimates of Pharmacy Benefit Coverage in California for 2020*, available at: <http://chbrp.com/2019%20Estimates%20of%20Pharmacy%20Benefit%20FINAL%200304.pdf>.

<sup>25</sup> Communication with DMHC and CDI, March 2019.

SB 159 requires pharmacists to record the dispensing of PrEP and PEP in an enrollee's health record. However, it is unclear whether this bill requires the recording to take place in an enrollee's medical health record or within the pharmacy record. For pharmacists that operate within a closed system, such as Kaiser Permanente, the medical and pharmacy records may be linked and accessible in the internal system. However, the requirement for the pharmacist to record the furnishing of PrEP and PEP may conflict with an enrollee's desire for this service to remain unknown to their primary care provider. Pharmacists that practice in a community pharmacy may not have the direct capability to record the provision of PrEP and PEP in an enrollee's medical record, other than by notifying the health insurance company or the enrollee's primary care provider.

## BACKGROUND ON HIV PROPHYLAXIS

SB 159, as amended April 1st, prohibits commercial plans and policies from placing utilization management requirements on combination HIV prophylaxis medications and enables pharmacists to independently furnish HIV prophylaxis to Californians. This background section provides contextual information 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 cells (one type of white blood cell known as T cells), which are integral to the body's immune function. Left untreated, opportunistic infections including infection-related cancers, will eventually compromise the health of an individual and lead to death. HIV invades and effectively destroys CD4 cells during the virus replication process. The acute HIV infection stage (within the first 2 to 4 weeks of exposure, where flu-like symptoms may occur) is a highly contagious stage because of a large amount of virus in the body. This is followed by a latent/asymptomatic period (lasting up to 10 years if untreated) where the virus replicates at a significantly slower rate; however, the individual remains contagious. Acquired immune deficiency syndrome (AIDS) is the most serious stage of HIV infection, where the body's immune system is severely compromised with a CD4 count below 200 cells/mm (HHS, 2017).

There is no cure for HIV/AIDS; however, lifelong, highly active antiretroviral therapy (HAART) stops the disease progression by reducing the viral load in the blood stream and enables individuals to maintain a functional immune system. Due to the effectiveness of HAART treatments, people living with HIV now 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 interest for this provision is the pool of Californians that meet the Centers for Disease Control and Prevention's indications for PrEP and PEP (CDPH, 2016). In particular, men who have sex with men (MSM), transgender women, African Americans, Latinos, and persons who inject drugs have the highest prevalence of HIV, and continue to be at highest risk for contracting HIV.

#### *PrEP population*

The California Department of Public Health, Office of AIDS, estimated that between 221,528 and 238,628 Californians would meet the criteria for PrEP (CDPH, 2016), which is about double the prevalence of people living with HIV in California (132,405 in 2016) (CDPH, 2018). The incidence of HIV (newly diagnosed cases) has remained close to 5,000 cases per year (of which 88% are male) since 2012 (CDPH, 2018). See Table 2 for estimates of Californians at risk of HIV infection who would be candidates for PrEP.

**Table 2.** Estimated Number of Californians at High Risk of HIV Infection in California, 2016

Population	Estimated Number of Californians With Indication for PrEP
MSM	103,779 – 120,879
High-risk heterosexuals	105,541
Persons who inject drugs	12,208
<b>Total</b>	<b>221,528 – 238,628</b>

Source: California Health Benefits Review Program, 2019, based on CDPH, 2018.

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

Key: MSM = men who have sex with men; PrEP = pre-exposure 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 (i.e., 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).

## Medications to Prevent HIV/AIDS

### What Are Pre-Exposure Prophylaxis (PrEP) and Post-Exposure Prophylaxis (PEP)?

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. Pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) are two relatively new additions to the public health prevention toolbox, which also includes education, needle exchanges, and condom programs. Both strategies involve using anti-retroviral medications that prevent HIV from penetrating the CD4 cells. 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 HAART for people living with HIV. See Table 3 for summary comparison.

### *PrEP*

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 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. 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. PrEP is indicated for specific groups practicing high-risk behaviors, including a subset of: MSM,<sup>26</sup> heterosexual men and women<sup>27</sup>; and persons who inject drugs if they share needles and/or have high risk

<sup>26</sup> Subset of MSM recommended to use PrEP includes adult men without acute or HIV-established infection, with male sex partners in past 6 months, not in a monogamous partnership with a HIV-negative man, AND at least one of the following: any anal sex without condoms or STI diagnosed in past 6 months (USPHS, 2018).

<sup>27</sup> Adult without acute or HIV-established infection, any sex with opposite sex partners in the past 6 months, not in a monogamous partnership with recently tested HIV-negative partner, AND at least one of the following: a man who is

partners<sup>28</sup> (USPHS, 2018). Providers may prescribe only tenofovir disoproxil fumarate for certain subpopulations with drug–drug contraindications (e.g., women taking oral contraceptives, or persons who inject drugs on medication-assisted therapy) due to its effectiveness among these subpopulations.

Practice guidelines for PrEP, updated by the U.S. Public Health Service in 2017, recommend that 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.

### *PEP*

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. In combination with the single tablet, Truvada®, 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 (e.g., prison or health care systems), newborn children of HIV positive mothers, MSM, and persons who inject drugs. PEP is not routinely recommended for HIV-negative individuals practicing high-risk behaviors; frequent PEP treatment may increase an individual's resistance to HAART, thus making the management of HIV more difficult should they seroconvert (CDC, 2018c). See Table 3 for a summary comparison of PrEP and PEP.

There are several national clinical practice guidelines for PEP, in addition to the 2014 World Health Organization guidelines (Ford et al., 2015). In the United States, the Centers for Disease Control and Prevention issued PEP guidelines for nonoccupational exposure (nPEP) and the U.S. Public Health Service issued guidelines for occupational exposure (oPEP) (CDC, 2018e; Kuhar et al., 2018). Each guideline recommends a different HIV-risk assessment tool (e.g., health care workers are at lower risk for contracting HIV from an occupational needle stick than an individual exposed to HIV through receptive unprotected anal intercourse). However, once risk is deemed high enough for treatment (according to exposure status), the recommended PEP treatments are the same for occupational and nonoccupational exposures (CDC, 2018e).

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behaviorally bisexual, infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are persons who inject drugs or are bisexual male partner, is in an ongoing relationship with an HIV-positive partner, or STI diagnosed in past 6 months.

<sup>28</sup> Adult without acute or established HIV infection, any injection of drugs not prescribed by a clinician in past 6 months AND at least one of the following: any sharing of injection drug equipment in past 6 months or risk of sexual acquisition of HIV.



**Table 3.** Summary of PrEP and PEP Regimens for the Prevention of HIV Infection

HIV Pre-Exposure Prophylaxis (PrEP)	HIV Post-Exposure Prophylaxis (PEP)
<p><b>Reasons for Initiation</b></p> <p>PrEP is recommended for seronegative persons, before possible exposure, who think they may have repeated exposure to HIV. Examples of situations meeting this standard include for protection of HIV-negative partner in serodiscordant couples; MSM with multiple partners, sex workers, and PWID who share needles.</p>	<p><b>Reasons for Initiation</b></p> <p>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.</p>
<p><b>Preferred regimens</b></p> <ul style="list-style-type: none"> <li>Preferred regimen is a combination therapy in a single pill (tenofovir disoproxil fumarate), and emtricitabine (Truvada®) taken once daily for as long as the patient has intimate exposure to HIV-positive individuals.</li> </ul>	<p><b>Preferred regimens</b></p> <ul style="list-style-type: none"> <li><u>For adults:</u> Truvada® (once daily) with raltegravir (twice daily) or dolutegravir (once daily) as, initiated within 72 hours of suspected exposure and continued for 28 days.</li> <li><u>Newborns:</u> zidovudine for 4 weeks (low risk) or zidovudine and lamivudine for 6 weeks (high risk with untreated HIV-positive mother) initiated as close to birth as possible (6–12 hours).</li> </ul>
<p><b>Concurrent care recommended</b></p> <p>Baseline HIV test; quarterly blood panels for Truvada® refill authorization, pregnancy test, HIV test or risk assessment, and adherence; blood tests every 3 months for kidney/liver effects and STI tests; annual appointments to evaluate effectiveness and adherence to therapy protocol.</p>	<p><b>Concurrent care recommended</b></p> <p>Baseline HIV test; follow-up appointment with HIV test; counseling on risk behavior reduction.</p>
<p><b>Effectiveness</b></p> <p>With proper PrEP adherence, risk of HIV infection may be reduced by 92% for MSM, 90% for heterosexual men and women, and by 70% for PWID.</p>	<p><b>Effectiveness</b></p> <p>Most effective when initiated as close to exposure as possible. Not effective if started after 72 hours of exposure.</p>

Source: California Health Benefits Review Program, 2019, based on CDC, 2017; USPHS, 2018; and PTPWPPT, 2018.

Key: PWID = persons who inject drugs; STI = sexually transmitted infection.

### Provider Awareness of and Willingness to Prescribe PrEP

Provider awareness of and willingness to prescribe PrEP is equally important to patient uptake of the regimen (Tuller, 2018). A 2015 survey of 1,501 U.S. clinicians (36% family/general practitioners, 31% internists, 17% nurse practitioners, and 17% obstetrician/gynecologists) found that 22% of clinicians had read the CDC guidelines for PrEP and that 79% were willing to prescribe PrEP to a negative partner in an HIV discordant couple (61% for couples planning to conceive); 66% were willing to prescribe for MSM; 63% for persons who inject drugs, and 34% for patients diagnosed with a sexually transmitted infection (STI). The participating clinicians had limited knowledge of PrEP with more than 50% of true/false questions receiving an incorrect or “don’t know” response (Smith et al., 2016).

One barrier to pharmacists currently prescribing PrEP or PEP is lack of knowledge. Studies have found that among surveyed pharmacists, less than half were knowledgeable or familiar with PrEP, and more than three-quarters indicated they did not have or were unsure if they had sufficient knowledge to counsel patients with a PrEP prescription (Broekhuis et al., 2018; Okoro and Hillman, 2018). Okoro and Hillman (2018) found that pharmacists' primary concerns with implementing PrEP initiatives were with identifying appropriate candidates (19.5%), patient adherence (16.3%), cost (14.8%), and developing antiretroviral resistance (12.7%). Broekhuis et al. (2018) found that pharmacists were most concerned about the time burden, inadequate compensation for services, and providing services outside of their skill set.

Pharmacists who receive PrEP training have greater knowledge, more favorable attitudes of PrEP, and more prepared and familiar with prescribing guidelines, which is associated with higher confidence in PrEP counseling (Meyerson et al., 2019; Przybyla et al., 2019). Following additional training, 54% of pharmacists indicated that they were fairly or very likely to provide PrEP services as part of a collaborative practice agreement with 63% indicating online continuing education as their preferred method of learning about PrEP (Balano et al., 2008; Okoro and Hill, 2018).

## Disparities<sup>29</sup> and Social Determinants of Health<sup>30</sup> in Prevention of HIV/AIDS

### Disparities

#### *Racial/ethnic disparities*

The CDC's 2018 analysis of U.S. PrEP prescriptions, prevalence of high-risk behaviors, and HIV prevalence found disparities between African American and Latino uptake rates as compared with uptake rates of whites (CDC, 2018d). They estimated that 500,000 African Americans and almost 300,000 Latinos were eligible for PrEP based on CDC clinical guidelines, but 7,000 PrEP prescriptions were filled for African Americans and 7,600 PrEP prescriptions were filled for Latinos at retail/mail order pharmacies (Smith et al., 2017). Whites experienced a similar unmet need, although the gap was smaller with 42,000 PrEP prescriptions filled among 300,000 whites who met the CDC guidelines. Limitations to the study included no documentation of insurance status and no ascertainment of patient assistance programs used, or prescriptions filled through military health systems or closed managed care systems.

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<sup>29</sup> 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.


<sup>30</sup> CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from Healthy People 2020, 2015; CDC, 2014). See CHBRP's SDoH white paper for further information:

[http://www.chbrp.org/analysis\\_methodology/docs/Incorporating\\_Relevant\\_Social\\_Determinants\\_of\\_Health\\_in\\_CHBRP\\_Analyses\\_Final\\_to\\_WEBSITE\\_033016.pdf](http://www.chbrp.org/analysis_methodology/docs/Incorporating_Relevant_Social_Determinants_of_Health_in_CHBRP_Analyses_Final_to_WEBSITE_033016.pdf).

**Figure 1.** Estimated Number of Adults Who Could Potentially Benefit From PrEP, United States, 2015

	Gay, bisexual, or other men who have sex with men	Heterosexually active adults	Persons who inject drugs	Total by race/ethnicity
Black/African American, non-Hispanic	309,190	164,660	26,490	500,340
Hispanic/Latino	220,760	46,580	14,920	282,260
White, non-Hispanic	238,670	36,540	28,020	303,230
<b>Total who could potentially benefit from PrEP</b>	<b>813,970</b>	<b>258,080</b>	<b>72,510</b>	<b>1,144,550</b>

Notes: PrEP=pre-exposure prophylaxis; data for "other race/ethnicity" are not shown



U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention

Source: CDC, 2018d.

Key: PrEP = pre-exposure prophylaxis.

California’s racial/ethnic disparities in use of PrEP are similar to those reported at the national level. A study by Harawa et al. (2018) demonstrates disparities that might also occur among Californians with private coverage. It finds that although PrEP uptake by Medi-Cal users was 25 times greater in 2016 than in 2012 (9 per million Medi-Cal enrollees in 2012 to 228 per million in 2016), the uptake rate among races was varied, with some groups at higher risk having lower uptake rates. For example, the disparity between black/African American and white Medi-Cal beneficiaries’ uptake widened between 2013 and 2016; black/African American uptake increased from 14.6 per million to 282 per million while white uptake increased from 16.6 per million to 447 per million. The greatest rate increase occurred among Hispanics (who also experience a disproportionate share of HIV infection), but they still had the lowest utilization rate (106 per million) in 2016. Uptake rates for Asian and “other” Medi-Cal beneficiaries were 229 per million and 306 per million, respectively. This racial/ethnic disparity is present in the general population as well with African Americans representing 44% of new HIV infections but 13% of PrEP users; similarly, Latinos represented 24% of new infections but 18% of PrEP users while whites accounted for 25% of new HIV diagnoses but 62% of PrEP users (Tuller, 2018). CHBRP found no studies identifying racial/ethnic disparities in PEP use across the population.

*Sexual orientation/identity*

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 U.S. are living with HIV (CDC, 2018a). MSM represent about 2% of the U.S. population, but accounted for 67% of new HIV infections in 2016 (CDC, 2018b). 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.

## Social Determinants of Health

Two primary social determinants of health associated with the use of PrEP relate to geographic location and stigma:

### *Geography*

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). The Harawa et al. (2018) study reported that the 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.

### *Stigma*

Many PrEP-eligible patients report stigma as a significant barrier to initiating and maintaining PrEP use. Some with private insurance seek care through public clinics to avoid (perceived) judgment by their private primary care provider, yet the clinics re-refer them to the private provider. The aforementioned Fuller et al. (2018) study found that frontline PrEP workers expressed concern that these privately-insured individuals denied treatment from the clinic would not initiate PrEP with their private provider. Similarly, the frontline PrEP workers observed that individuals with high-deductible health insurance or higher incomes are ineligible for patient assistance programs, which was also perceived as a barrier to prompt and consistent PrEP use (Fuller et al., 2018).

### *Financial barriers*

Individuals with private coverage are more likely able to access PrEP, but many are incurring high out-of-pocket expenses that makes access and adherence unaffordable (Luthra and Gorman, 2018). In one study of young gay and bisexual men, 58.9% of respondents believe they could not afford PrEP, although 87.2% of participants said they would take PrEP if it were free (Pulsipher et al., 2016). This is likely to have a greater impact on individuals who are low-income or uninsured, although the existence of cost-sharing assistance programs is intended to help mitigate some of these financial barriers to access (Smith et al., 2017).

## Societal Impact of HIV/AIDS in California

The presence of HIV/AIDS in California/the United States creates a societal impact. In dollar terms, the societal impact can be indirect (lost wages, etc.) as well as direct (medical care, etc.). CHBRP is unable to find data that displays the larger societal impact of HIV/AIDS specifically. The *Benefit Coverage, Utilization, and Cost Impacts* estimates cost impacts on payers, including enrollees. Such figures represent a subset of the total societal impact related to HIV/AIDS.

## MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, SB 159, as amended April 1st, would authorize pharmacists to initiate and furnish pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for HIV/AIDS, prohibit commercial insurance plans and CalPERS from subjecting coverage of PrEP and PEP to prior authorization and step therapy, and expand the Medi-Cal schedule of benefits to include coverage for PrEP and PEP services provided by pharmacists. Additional information on HIV/AIDS is included in the *Background* section.

This medical effectiveness review summarizes findings from evidence<sup>31</sup> on: (1) the effectiveness of PrEP and PEP in preventing HIV/AIDS, (2) the impact of prohibiting prior authorization and step therapy on the likelihood that health professionals with prescribing authority will prescribe PrEP and PEP, (3) the impact of prohibiting 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.

### Research Approach and Methods

Studies of the effectiveness and potential harms of PrEP and PEP, and the impact of drug utilization management techniques on prescription, uptake, adherence, and the safety and effectiveness of pharmacist prescribing of PrEP and PEP were identified through searches of PubMed, the Cochrane Library, Web of Science, Embase, and Scopus. The website for the Agency for Healthcare Research and Quality (AHRQ), an organization that produces systematic reviews and meta-analyses, was also searched.

The search was limited to abstracts of studies published in English and conducted in the United States and other developed countries. For studies related to the effectiveness of PrEP and PEP, the search was limited to studies published from 2018 to present because CHBRP had previously conducted thorough literature searches on these topics in 2018 for SB 1021. Because the analysis of SB 1021 did not address the impact of prior authorization or step therapy on prescription of PrEP or PEP, or adherence to PrEP or PEP, the search for these studies was limited to 2012 to present. 2012 was chosen as the starting point because the FDA-approved Truvada® for PrEP treatment in 2012. The search for articles on the safety and effectiveness of provision of PrEP and PEP by pharmacists was also limited to studies published from 2012 to present. The literature review also included articles on prior authorization and pharmacist prescribing published prior to 2012 that were recommended by the content expert and the peer faculty reviewer.

Of the 557 articles found in the literature search, 27 were reviewed for potential inclusion, and 11 were included in the review of medical effectiveness for SB 159. The other articles were eliminated because they did not focus on therapies for HIV prevention, were of poor quality, or did not report findings from clinical research studies. While reviewing the 27 articles for potential inclusion, 8 articles cited by these articles were identified for potential inclusion, and 7 were included in this report. Based on recommendations from content experts, an additional 13 articles were reviewed for potential inclusion, two of which were included. Eighteen references from CHBRP's report on SB 1021 were also included in this report.

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<sup>31</sup> Much of the discussion below is focused on reviews of available literature. However, as noted on page 11 of the Medical Effectiveness analysis and research approach document (posted [here](#)), 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.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature. 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. Are HIV prevention therapies (i.e., PrEP and PEP) effective in preventing HIV transmission?
  - a. Does the effectiveness of HIV prevention therapies vary at different levels of adherence?
2. Does prohibiting prior authorizations increase the likelihood that health professionals with prescribing authority will prescribe PrEP or PEP?
  - a. Does prohibiting prior authorizations improve uptake and adherence to PrEP or PEP among potential users?
3. Does prohibiting step therapy increase the likelihood that health professionals with prescribing authority will prescribe PrEP or PEP?
  - a. Does prohibiting step therapy improve uptake and adherence to PrEP or PEP among potential users?
4. Can pharmacists safely and effectively prescribe PrEP or PEP?
5. What are the harms or adverse events associated with PrEP or PEP?

## Methodological Considerations

CHBRP's literature review for PrEP focused on Truvada because it is the only FDA-approved therapy for PrEP in the United States. Truvada is a single-pill combination of two HIV medications, tenofovir disoproxil fumarate (TDF) and emtricitabine (FTC). More recent trials evaluating off-label use of pre-existing antiretroviral medications for PrEP regimens or new methods of dispensing Truvada, such as injections or implantables, are excluded from CHBRP's review since they are not the standard of care recommended in guidelines and have not been approved by the FDA for PrEP. There are no drug regimens specifically approved by the FDA for PEP, due to ethical and practical considerations with attaining the data necessary to do so. Therefore, CHBRP uses the PEP regimen recommended in the 2016 United States Public Health Service guidelines for nonoccupational exposures — the most recent PEP-related guidelines issued — as the treatment standard for this review (see the *Background* section for more information on guidelines for PrEP and PEP).

Literature on PEP discusses occupational exposures separately from nonoccupational exposures. However, because there is a common body of literature that informs PEP drug selection, the recommended regimen and dose for PEP is similar for all risk groups across all major PEP practice guidelines relevant to United States populations. Moreover, the evidence base for PEP treatments is comprised primarily of studies with lower-quality research designs (i.e., uncontrolled cohorts or case-control studies) or studies of PEP use in animal models; therefore, the certainty of the conclusions drawn from the evidence is limited. For these reasons, CHBRP evaluated treatment effectiveness only for a general PEP population; however, the extent to which PEP may be differentially effective due to adherence issues between groups is noted when applicable.



Additionally, health outcomes such as HIV incidence, risk of contracting HIV, and HIV transmission were explored specifically in relation to PrEP and 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, STI testing, etc.).

## Outcomes Assessed

The effectiveness of pre-exposure and post-exposure prophylaxis for HIV prevention is assessed using the following outcomes:

1. HIV incidence
2. HIV risk reduction
3. HIV transmission
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<sup>32</sup>

### Effectiveness of Medications That Prevent HIV/AIDS

#### *PrEP*

As previously mentioned, this report builds off of the analysis completed for SB 1021. No new randomized control trials (RCTs) have been conducted since the writing of this analysis, which identified a systematic review and meta-analysis of 14 relevant RCTs and 3 observational studies. Overall, RCTs demonstrated a reduction in relative risk of contracting HIV among PrEP users, and observational studies demonstrated lower HIV incidence rates among PrEP users compared to no-PrEP controls.

However, HIV incidence was influenced by adherence. Results from a meta-regression of seven RCTs show that adherence to PrEP was a significant moderator of PrEP effectiveness (regression coefficient = -0.02,  $p < 0.0001$ ). The meta-regression also showed higher HIV infection risk reduction among high-adherence PrEP users compared to intermediate-adherence PrEP users, and that low-adherence PrEP users did not receive a protective effect (Fonner et al., 2016). More details about these studies can be found in the SB 1021 analysis. Many factors are associated with PrEP adherence. Grant et al. (2014), a 72-week open-label extension of three RCTs conducted in Brazil, Ecuador, Peru, South Africa, Thailand, and the United States (ATN 082, iPrEx, US Safety Study) found that having a known HIV-positive partner

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<sup>32</sup> The following figures in this section summarize CHBRP's findings regarding the strength of the evidence for the effects of policies regarding PrEP and PEP addressed by SB 159. For test, treatments, and services for which CHBRP concludes that there is clear and convincing, preponderance, limited, or inconclusive evidence, the placement of the highlighted box indicates the strength of the evidence. If CHBRP concludes that evidence is insufficient, a figure that states "Insufficient Evidence" will be presented.



was a predictor of adherence (95% CI = 1.05–1.99,  $p = 0.03$ ). A 48-week demonstration cohort study conducted in Brazil by Grinsztejn et al. (2018) found two predictors of long-term adherence: early adherence (consistently adhering to the regimen by week 4) to PrEP (95% CI = 1.88–5.65,  $p < 0.0001$ ), and reported sex with HIV-infected partners (95% CI = 1.06–2.94,  $p = 0.04$ ).

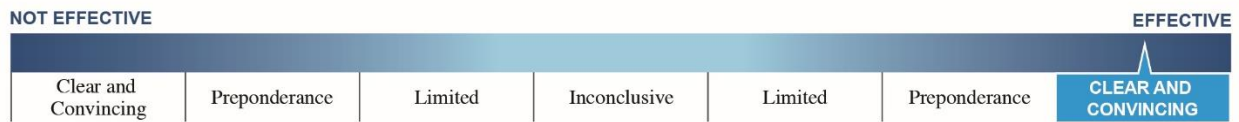
Researchers have studied several alternatives to standard dosing for PrEP (i.e., one tablet per day) to assess their effectiveness in protecting people from HIV. In a double-blind RCT (Molina et al., 2015) and an open-label extension of the RCT (Molina et al., 2017), the PrEP intervention consisted of two Truvada tablets taken 2 to 24 hours before sex, followed by a third pill 24 hours after the first drug intake and a fourth pill 24 hours later. Those engaging in multiple consecutive episodes of sexual intercourse were instructed to take one pill per day until the last sexual intercourse, and to then take the two post-exposure pills. In the 2015 study, this intervention was associated with a relative risk reduction of 86% (95% CI = 40–98,  $p = 0.002$ ) for HIV-1 infection compared to a placebo. In the 2017 study, it was associated with a relative risk reduction of 97% (95% CI = 81–100) for HIV-1 infection compared to a placebo. These RCTs did not assess the effectiveness of this “on demand” dosing regimen for PrEP relative to daily dosing.

Researchers have also examined whether alternative dosing regimens are associated with higher rates of adherence to PrEP. Maximizing adherence is important because higher adherence to PrEP is associated with a lower risk of contracting HIV. A randomized, open-label study conducted in Bangkok, Thailand and Harlem, New York City by Grant et al. (2018) found that the feasibility of nondaily dosing differed by study site. Participants were randomized to one of three dosing regimens: daily dosing (one tablet daily), time-driven dosing (one tablet twice weekly with a post-sex dose), or event-driven dosing (one tablet before and after sex). In Bangkok, daily and time-driven dosing had comparably high rates of adherence (85.4% vs. 79.4%,  $p = 0.42$ ), whereas the adherence rate for event-driven dosing was slightly lower than both (65.1%,  $p < 0.0001$  vs. daily) for men who have sex with men (MSM) and transgender women who have sex with men. By contrast, in Harlem, daily dosing had a statistically significant higher rate of adherence compared to time-driven dosing (65.1% vs. 46.5%,  $p < 0.0001$ ) and event-driven dosing (41.3%,  $p < 0.0001$  vs. daily).

The literature search identified one study related to the effect of a PrEP regimen on quality of life. Kapadia et al. (2018) used data from a RCT of potential PrEP regimens to evaluate the impact of those regimens on quality of life (QOL) in at-risk, HIV-uninfected U.S. women and men. The study found that there was no significant change in QOL score between the baseline assessment and any time during or at the end of the study; in other words, participating in a PrEP regimen did not alter self-perceived quality of life. The mean QOL score for women was 0.91 (95% CI = 0.89–0.93) at pre-PrEP baseline and 0.89 (95% CI = 0.86–0.91) at week 48 ( $p = 0.29$ ). The mean score for men was 0.95 (95% CI = 0.94–0.96) at pre-PrEP baseline and 0.94 (95% CI = 0.93–0.95) at week 48 ( $p = 0.14$ ).

**Summary of findings regarding PrEP for HIV prevention:** There is *clear and convincing evidence* from 13 fair- and high-quality RCTs and 3 observational studies that PrEP is effective in preventing HIV transmission and lowering the risk of HIV among users with moderate or high adherence. A single study found that PrEP does not affect self-perceived quality of life.

**Figure 2.** Effectiveness of PrEP for HIV Prevention



*PEP*

PEP is a 28-day course of three antiretroviral medications that is initiated within 72 hours of a known or suspected exposure to an active HIV infection. CDC guidelines recommend a combination of three medications from two drug classes used to treat HIV: nucleoside reverse transcriptase inhibitors (NRTIs) and integrase inhibitors. Truvada may be prescribed with raltegravir, an integrase inhibitor, as a PEP therapy. However, PEP use is considered off-label use of approved medication for HIV treatment because the FDA has not approved the CDC guidelines.

CHBRP did not identify any new studies about the effectiveness of PEP that were published after the report on SB 1021 was issued. The previous literature search found that those 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) 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.<sup>33</sup>

**Summary of findings regarding PEP for HIV prevention:** There is *limited evidence* from a single historical case-control study and low-quality observational studies that PEP, as recommended by guidelines, is effective in preventing HIV transmission following occupational and nonoccupational exposures. Adherence and follow-up in PEP studies is low overall, and therefore limits CHBRP’s ability to draw conclusions about the relationship between adherence and effectiveness for PEP as well as the frequency of PEP failures.

**Figure 3.** Effectiveness of PEP for HIV Prevention



<sup>33</sup> <http://analyses.chbrp.com/document/view.php?id=1340>

### Impact of Prior Authorization on PrEP or PEP

CHBRP found no studies that analyzed the impact of prior authorization of PrEP or PEP on use of PrEP or PEP or the health outcomes of people who receive these treatments, but did find one study that analyzed prior authorizations among patients at an HIV clinic who were prescribed medication to treat HIV. The clinic received 288 requests for prior authorization for 144 patients. Thirty-seven (13%) of the prior authorization requests were for HIV antiretroviral medications, and 32 (86%) of these were approved. All five denials of prior authorization for antiretroviral medications involved fixed-dose combinations of medications. In all cases, the health plan denied the authorization because its formulary included the single medications present in the fixed dose combinations. Across all types of medication, the average length of time to process a prior authorization was 3.1 days; this length of time differed between Medicaid (mean time required, 2.1 days) and commercial plans (mean time required, 6.3 days;  $p = 0.034$ ) (Raper et al., 2010). These delays constrained the clinic’s ability to promptly provide life-saving medications to people with HIV. Timeliness of receipt of medication is especially important for PEP because these medications must be initiated within 72 hours (3 days) of a known or suspected exposure to an active HIV infection in order for the drug regimen to have a chance to be effective.

**Summary of findings regarding impact of prior authorization of PrEP or PEP:** There is *insufficient evidence* that prohibiting prior authorization increases the likelihood that health professionals with prescribing authority will prescribe PrEP or PEP, improve adherence to PrEP or PEP, or improve health 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. It is possible that prohibiting prior authorization would enable people to obtain PrEP or PEP more quickly, which is especially important for PEP because PEP is only effective if it is initiated within 72 hours of known or suspected exposure to HIV.

**Figure 4.** Impact of Prior Authorization on Provision of PrEP and PEP



### Impact of Step Therapy on PrEP or PEP

CHBRP found no studies that analyzed step therapy of PrEP or PEP on use of PrEP or PEP or the health outcomes of people who receive these treatments.

**Summary of findings regarding impact of step therapy of PrEP or PEP:** There is *insufficient evidence* that prohibiting step therapy increases the likelihood that health professionals with prescribing authority will prescribe PrEP or PEP, improve adherence to PrEP or PEP, or improve health outcomes for people taking PrEP or PEP.

**Figure 5.** Impact of Step Therapy on Provision of PrEP and PEP



## Safety and Effectiveness of Pharmacist Prescribing of PrEP and PEP

CHBRP identified only one study that documented pharmacists' ability to prescribe PrEP and PEP safely and effectively. Tung et al. (2018) assessed the impact of a newly-implemented pharmacist-managed HIV PrEP clinic in Seattle, Washington. In this community pharmacy setting, pharmacists were able to initiate and manage Truvada under a collaborative practice agreement 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 on-site 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 (March 2015 to February 2018).

Due to the lack of studies of pharmacist prescribing of PrEP, CHBRP searched for literature on the safety and efficacy of pharmacist prescribing of oral contraceptives. CHBRP chose oral contraceptives because these medications are also used for prevention and because safe prescribing requires screening potential users for health conditions that would contraindicate use (e.g., pregnancy, severe or uncontrolled hypertension). One observational study of 26 pharmacists employed by two regional pharmacy chains in the Pacific Northwest and 214 women enrollees was identified (Gardner et al., 2008). The pharmacists prescribed oral contraceptives under a collaborative practice agreement with a physician. Although the pharmacists received 12 hours of training prior to prescribing, the study found that pharmacists made inappropriate prescribing decisions for seven women of the 195 women who were prescribed contraceptives. Five women had elevated blood pressure at the initial or 3-month visit, and two were taking other medications for which use of oral contraceptives is contraindicated. The collaborating physician notified the pharmacists to discontinue prescribing oral contraceptives to these women. All seven of these women were recent or current users of hormonal contraceptives, which suggests that the study's exclusion criteria were stricter than the criteria some prescribers use to determine which women can safely use oral contraceptives.

**Summary of findings regarding safety and effectiveness of pharmacists prescribing of PrEP or PEP:** There is *insufficient evidence* that pharmacists can safely and effectively prescribe PrEP or PEP. Only one observational study was identified which found strong adherence to PrEP and no seroconversions among people who obtained PrEP from a pharmacist-managed PrEP clinic. In that study, pharmacist furnishing of PrEP was conducted under a collaborative practice agreement with a physician.

**Figure 6.** Ability of Pharmacists to Safely and Effectively Prescribe PrEP and PEP

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

## Harms of Medications That Prevent HIV/AIDS

### *PrEP*

#### Adverse events

Among the 11 trials that evaluated the incidence of serious adverse events (AE), there was 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,  $p = 0.76$ ).

**Kidney:** Findings regarding the impact of PrEP on kidney health were inconclusive. Three studies reported slight decreases in kidney function among PrEP recipients that resolved after discontinuation of PrEP (Martin et al., 2015; Solomon et al., 2016; Tang et al., 2018). Similarly, a systematic review by Chan et al. (2018) found that in previously healthy individuals, PrEP was associated with a statistically significant but largely reversible decline in kidney function; differences between PrEP and placebo groups were resolved after PrEP was discontinued. Additionally, a meta-analysis by Yacoub et al. (2016) examined the risk of kidney-related adverse events in 17,222 individuals randomized to receive PrEP, and found that most of the kidney-related adverse events were classified as Grade 1, meaning that creatinine elevations only reached 1.1 to 1.3 times the upper limit of normal. In contrast, Siguier and Molina's systematic review (2018) cites inconsistent findings between PrEP and placebo groups in regards to creatinine levels. Siguier and Molina (2018) also point out that because the studies selected patients without underlying kidney disease, poor adherence to PrEP may have resulted in an underestimation of the rate of kidney-related adverse events.

Van Damme et al. (2012), a placebo-controlled RCT of HIV-negative African women, found that drug discontinuation rates due to kidney and liver function were higher in the PrEP group (4.7% in the PrEP group versus 3% in the placebo group,  $p = 0.051$ ). However, there were no significant differences between the two study groups in grade 3 or higher liver abnormalities or grade 2 or higher creatinine abnormalities.

**Bone Mineral Density:** Findings regarding the impact of PrEP on bone mineral density were inconclusive. Several studies found that PrEP users experienced declines in bone mineral density (BMD) (Kasonde et al., 2014; Liu et al., 2011). Siguier and Molina (2018) finds moderate decreases in hip and spine BMD in MSM and increased BMD in transgender individuals after 24 weeks (six months) of treatment. Chan et al. (2018) finds that while bone mineral density declines with PrEP use, increased bone fractures have not been demonstrated, and the changes are reversed after PrEP is discontinued. BMD decline may also be greater in adolescent PrEP users who have not achieved peak mass.

**Digestive Tolerability:** Siguier and Molina's systematic review (2018) finds 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.

#### Reproductive outcomes

A systematic review discussed in CHBRP's report on SB 1021 (Fonner et al., 2016) identified two RCTs that assessed the effectiveness of hormonal contraception among women taking PrEP as compared with women randomized to placebo. Due to differences in study design, pooled analysis was not possible. Analyses of 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). In study

subanalyses, however, the observed differences in crude pregnancy rates were attenuated after adjustment for contraceptive type, study site, and age (Callahan et al., 2015; Murnane et al., 2014).

A meta-analysis of adverse pregnancy outcomes, such as fetal loss and preterm birth, among women enrolled in these two RCTs showed that pregnancy-related adverse events did not differ between PrEP and placebo groups (RR=1.25, 95% CI = 0.64–2.45,  $p = 0.52$ ). Nor were differences in rates of adverse birth outcomes observed when PrEP users were stratified by adherence or PrEP regimen (i.e., Truvada or tenofovir-alone) (Fonner et al., 2016).

### Antiretroviral drug resistance

HIV resistance to first-line HIV medications for treatment, although not a direct harm, is an important consideration for high-risk PrEP users because the medications that comprise Truvada are also commonly used to treat active HIV infections. Resistance to Truvada, 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. Overall drug resistance was low, occurring among only 2% of the 533 participants who experienced HIV seroconversion across all study arms. In addition, 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).

### 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:** Findings regarding the impact of PrEP uptake on condom use during sexual intercourse were inconclusive. Only one RCT assessed whether condom use was associated with PrEP use. McCormack et al. (2016) randomized participants to immediately receiving PrEP or receiving deferred PrEP after 1 year. The study 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%,  $p = 0.03$ )

Across non-RCT studies, findings varied substantially. Two cohort demonstration studies found that the rate of condomless sex remained stable during the intervention period (Grinsztejn et al., 2018; Liu et al., 2016). One open-label extension study found that the rate of condomless anal sex decreased (Grant et al., 2014). Six prospective cohort studies reported increases in condomless anal sex in response to PrEP uptake (Lal et al., 2017; Molina et al., 2017; Montano et al., 2019; Morgan et al., 2018; Oldenburg et al., 2018; Zablotska et al., 2018).



Grov et al. (2018) surveyed MSM about their HIV status, HIV viral load, and PrEP use, as well as that of their recent casual male partners. The study found that HIV-negative men on PrEP engaged in condomless anal sex most commonly when their partners were also on PrEP, HIV-negative and not on PrEP, or HIV-positive with an undetectable viral load.

**Incidence of STIs:** Findings regarding the impact of PrEP uptake on incidence of sexually transmitted infections (STIs) among PrEP users were inconclusive. Three placebo-controlled RCT studies analyzed the impact of PrEP uptake on incidence of STIs (McCormack et al., 2016; Molina et al., 2015; Solomon et al., 2014). McCormack et al. (2016) detected no significant differences in rates of STIs among participants who received PrEP versus participants who received a placebo, after adjusting for the number of screenings participants received. Solomon et al. (2014) measured syphilis prevalence among participants in initial screening and follow-up appointments and found no difference in syphilis incidence between the PrEP and control groups.

Three studies found that STI incidence was high, but stable, for participants throughout the course of the study; in other words, there were no statistically significant increases in STI rates following initiation of PrEP (Liu et al., 2016; Molina et al., 2017; Zablotska et al., 2018).

Two studies in Seattle, Washington, and Melbourne, Australia, respectively, found significant increases in STI diagnoses in the first 12 months after being prescribed PrEP (Lal et al., 2017; Montano et al., 2019).

Grinsztejn et al. (2018) found that an STI diagnosis of rectal chlamydia, rectal gonorrhea, or incident syphilis at the end of the 48-week study intervention period did not have a statistically significant relationship with whether one's dried blood spot lab test showed a protective concentration of tenofovir diphosphate at week 48. In other words, achieving a high level of adherence (at least four doses per week of tenofovir) did not affect STI incidence.

**Changes in Number of Sexual Partners:** There is a preponderance of evidence that PrEP uptake does not lead to a difference in the number of sexual partners. Two RCTs indicated no difference, and one RCT found a small difference. McCormack et al. (2016) compared participants who were randomized to receive immediate PrEP treatment with participants who were randomized to receive deferred PrEP treatment after a 1 year waiting period. The authors found no statistically significant difference between the two groups at the 1-year mark. Additionally, Grant et al. (2014), an open-label extension of a prior RCT, found that the total number of sexual partners decreased during the study follow-up period in both the group receiving PrEP and the group not receiving PrEP. In contrast, Molina et al.'s (2015) placebo-controlled double-blind RCT found a small, but statistically significant, decrease in the number of sexual partners within the past 2 months in the placebo group.

Two other studies found no significant changes in the proportion of participants with regular sexual partners (Lal et al., 2017; Zablotska et al., 2018). Zablotska et al. (2018) expanded on this by also finding that there was no significant change in the proportion of respondents with multiple regular sex partners.

Lal et al. (2017) additionally found that throughout the 12-month study follow-up period, the proportion of participants reporting sex with casual partners remained stable, and there was no significant change in the number of sexual acts with casual partners. Montano et al. (2019) found no change in the reported number of sexual partners in the last 30 days between the initial PrEP appointment and the end of the 12-month study follow-up period. Similarly, Oldenburg et al. (2018) found no statistically significant difference in the total number of sexual partners across time (from the initial baseline clinic visit to the 3- and 6-month follow-up visits).

Two studies found that the mean number of reported sexual partners decreased in the previous 3 months and during the 48-week study follow-up period, respectively (Grinsztejn et al., 2018; Liu et al., 2016).



## *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., Truvada 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.<sup>34</sup> 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 (i.e., 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.

## **Summary of Findings**

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.

- Effectiveness is moderated by adherence; moderate or high adherence are both associated with protective benefits.
- Participating in a PrEP regimen is not associated with changes in self-perceived quality of life.
- PrEP is not significantly associated with poor reproductive health outcomes.
- Findings from studies of the effects of PrEP on kidney function and bone mineral density are inconclusive.
- Resistance to Truvada, due to long-term low-dose exposure during PrEP treatment, may limit a person's treatment options if they develop a subsequent HIV infection and occurs most frequently among persons with a pre-existing unknown active HIV infection when they initiated PrEP..
- Findings regarding the relationship between PrEP and sexual risk compensation (e.g., condomless sex, STI incidence, and changes in the numbers of sexual partners) are inconclusive.

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<sup>34</sup> <http://analyses.chbrp.com/document/view.php?id=1340>

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

- CHBRP is unable to draw conclusions about the relationship between adherence and effectiveness of PEP.
- PEP failures are rare, and can mostly be attributed to poor adherence, late initiation, and repeated exposure to HIV during treatment due to ongoing high-risk behaviors.
- Serious adverse events associated with PEP are rare and resolve following completion or cessation of treatment.

There is insufficient evidence to assess the impact of prior authorization and step therapy on prescription of and adherence to PrEP or PEP.

There is insufficient evidence to assess the ability of pharmacists to safely and effectively prescribe PrEP or PEP.

## BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, SB 159, as amended April 1st, would allow pharmacists to provide pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) to prevent HIV for DMHC-regulated health plans and CDI-regulated policies. SB 159 would also prohibit DMHC-regulated health plans and CDI-regulated policies from requiring prior authorization or step therapy for PrEP and PEP. This bill primarily affects outpatient prescription drug coverage, which is covered by most health insurance coverage as quantified in CHBRP's *Estimates of Pharmacy Benefit Coverage for 2020*.

Due to the amendments made on April 11, 2019, the impacts due to SB 159 would be substantially different from those presented here. Because pharmacist would be able to independently furnish only the first 30-days of a PrEP regimen, the costs associated with these services would be lower than included below. Additionally, utilization changes may be different than presented below. However, the impacts of independent furnishing of PEP by pharmacist would be similar. CHBRP is conducting further analysis of the impacts of the April 11th amendments.

This section reports the potential incremental impacts of SB 159, as amended on April 1st, on estimated baseline benefit coverage, utilization, and overall cost.

### *Key assumptions:*

- CHBRP assumes Truvada®, which is used for prevention of HIV/AIDS in PrEP and PEP, will continue to remain as the only single tablet preventive HIV/AIDS medication on the market in 2020 for the analysis of cost impact.
- CHBRP assumes a 2% increase in members utilizing Truvada due to the increase for access for Truvada through a pharmacist. This assumption was developed with input from CHBRP's content expert. Barriers such as lack of knowledge about PrEP, lack of reimbursement from commercial carriers for associated services and slow implementation of necessary processes within pharmacies may inhibit adoption by pharmacists, especially in the first year postmandate. Additionally, prescriptions obtained directly from pharmacists, such as oral contraceptives, experienced slow uptake when first implemented.
- As discussed in the *Policy Context* section, medications to prevent HIV are carved out of Medi-Cal Managed Care plans are provided through the fee-for-service (FFS) program. Therefore, the premiums paid for Medi-Cal Managed Care plans will not be impacted by this bill. CHBRP has provided estimates of the impact to the FFS program, where able.

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

### **Baseline and Postmandate Benefit Coverage**

Currently, there are 24,490,000 enrollees with health insurance subject to state-level benefit mandates and 24,490,000 of these enrollees (or 100%) have health insurance subject to SB 159. Approximately 0.9% of enrollees in DMHC-regulated plans and CDI-regulated policies have no coverage for outpatient prescription drugs (OPDs) and 3.4% have OPD coverage that is not regulated by DMHC or CDI. Such health insurance is considered to be compliant with SB159, and so no mandate-related change in benefit coverage or utilization would be expected for these enrollees.

Additionally, 1.6 million enrollees in the County Organized Health Systems (COHS) and 1.4 million persons receiving benefits through the Medi-Cal FFS program would also be impacted by SB 159.

Current benefit coverage of the provisions in SB 159 was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this CHBRP survey represent 74% of enrollees with commercial and CalPERS health insurance that can be subject to state mandates. Below is a summary of the findings related to baseline benefit coverage and projected postmandate 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. Thus, there is no change in the benefit coverage postmandate for this provision. While some carriers do have prior authorization requirements for PrEP, they also have established procedures for bypassing these requirements for the initial 30-day supply. Therefore, CHBRP has considered these plans to be in compliance with SB 159.

Pharmacists are not currently able to independently furnish PrEP and PEP. Benefit coverage for this provision of SB 159 would increase from 0% at baseline to 100% postmandate (see Table 1). 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.

## Baseline and Postmandate Utilization

MarketScan and Milliman's proprietary 2016 Consolidated Health Cost Guidelines Sources Database (CHSD) which contain Commercial claims, encounters, and enrollment data for the state of California were used to quantify the number of enrollees using PrEP and PEP. At baseline, it is estimated there are 29,395 users of PrEP and 6,055 users of PEP with commercial and CalPERS coverage. Post mandate, 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.

Provision of PrEP and PEP are "carved out" of Medi-Cal Managed Care plans and COHS and are instead provided through the fee-for-service program. There are approximately 10,545,000 enrollees in full-scope Medi-Cal in 2020. Although not shown in Table 1, 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.

Please refer to Appendix C for details on the methodology used to obtain utilization estimates.

## Baseline and Postmandate Per-Unit Cost

Baseline costs per annual PrEP and PEP drug regimen of \$13,822 were estimated using MarketScan and CHSD claims and enrollment data for California in 2016 trended to 2020 (see Table 1). Postmandate, CHBRP estimates that this per unit cost will remain constant as the projected increase in utilization should not cause the per unit cost to change. Baseline costs for associated HIV and laboratory tests were estimated to be \$139 annually for PrEP and \$157 annually for PEP. CHBRP assumed the Medi-Cal per-unit cost for both prescription drugs and laboratory tests is 50% of the commercial per-unit cost.

Table 4 and Table 5 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).

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 and/or noncovered benefits.

The increase in net annual expenditures includes costs associated with increased utilization for both PrEP and PEP, including cost of the medications and lab tests. It is unclear whether commercial and CalPERS health insurance plans and policies would reimburse pharmacists for the cost of the lab tests performed by the pharmacist, or if the pharmacist or enrollee would bear these costs. The increase in total net annual expenditures associated with lab tests is \$101,000.

CHBRP estimates total Medi-Cal expenditures would increase by \$1,257,000.

## Premiums

Changes in premiums as a result of SB 159 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 4, and Table 5), with health insurance that would be subject to SB 159. Increases in private insurance premiums range from a high of \$0.0620 PMPM among DMHC and CDI-regulated small group plans to a low of \$0.0022 PMPM among CDI-regulated large group policies.

Among publicly funded DMHC-regulated health plans, CHBRP estimates no change in DMHC-regulated Medi-Cal Managed Care premiums since PrEP and PEP are paid for by FFS Medi-Cal. CalPERS premiums are estimated to increase by \$0.0473 PMPM.

## Enrollee Expenses

SB 159-related changes in enrollee expenses for covered benefits (deductibles, copays, etc.) and enrollee expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 4, and Table 5) with health insurance that would be subject to SB 159 and would be expected to use PrEP and PEP and associated lab tests within the first year postmandate.

CHBRP projects no change to copayments or coinsurance rates but does project an increase in utilization of PrEP and PEP as well as associated tests and therefore an increase in enrollee cost sharing. Enrollee expenses for covered benefits are expected to increase between \$0.0020 for enrollees in CalPERS HMOs and \$0.0025 for enrollees in small group DMHC-regulated plans and CDI-regulated policies, as well individual market DMHC-regulated plans. However, should the draft 2019 USPSTF recommendations become final, health plans would be required to eliminate cost sharing for PrEP, although there may be cost sharing for required lab tests.

Medi-Cal enrollees do not have cost sharing and therefore would not see an increase in cost sharing.

CHBRP found that among enrollees with a copayment, about 80% of enrollees had copayments for Truvada that were less than or equal to \$50 per prescription; among enrollees with a coinsurance, about

96% had co-insurance of less than \$100 per prescription. Additionally, approximately 8% of claims include those where there is \$0 (no) copayment or co-insurance for Truvada prescription.

### **Out-of-Pocket Spending for Covered and Noncovered Expenses**

When possible, CHBRP estimates the marginal impact of the bill on out-of-pocket spending for covered and noncovered expenses, defined as uncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (e.g., deductibles, copayments, and coinsurance). CHBRP estimates that enrollees do not currently pay out-of-pocket for noncovered PrEP or PEP due to existing benefit coverage. Total out-of-pocket expenses for enrollees noncovered expenses will not change due to SB 159.

### **Potential Cost Offsets or Savings in the First 12 Months After Enactment**

CHBRP does not project any cost offsets or savings in health care that would result because of the enactment of provisions in SB 159. While the increase in utilization of PrEP and PEP in the first year postmandate may reduce the number of new HIV cases in California, the short-term impacts are likely to be negligible. However, should the increase utilization of PrEP and PEP result in avoided HIV transmission, the costs associated with HIV positive enrollees would decrease and offset some or all of the increased cost associated with PrEP and PEP.

### **Postmandate Administrative Expenses and Other Expenses**

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will 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.

### **Postmandate Changes in the Number of Uninsured Persons<sup>35</sup>**

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 4, and Table 5), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 159.

### **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 159.

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<sup>35</sup> See also CHBRP's [Uninsured: Criteria and Methods for Estimating the Impact of Mandates on the Number of Individuals Who Become Uninsured in Response to Premium Increases \(December 2015\)](http://chbrp.com/analysis_methodology/cost_impact_analysis.php), available at [http://chbrp.com/analysis\\_methodology/cost\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/cost_impact_analysis.php).

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

CHBRP estimates no measureable cost shifting to other payers since all enrollees have currently have coverage for PrEP and PEP.

However, for enrollees for whom cost sharing is burdensome, some external assistance may be available. Patient assistance programs offer copayment relief for private insurance enrollees if they meet certain financial requirements (Smith et al., 2017). Gilead Sciences Inc., manufacturer of Truvada, offers a patient assistance program that assists with patient co-payment expenses (Truvada for PrEP Medication Assistance Program). After the co-payment assistance threshold of \$7,200 per calendar year is met, the California Department of Public Health's PrEP Assistance Program provides wrap around coverage for any remaining PrEP medication copayments for the remainder of the calendar year.<sup>36</sup> CHBRP does not have access to any data to quantify the impact of financial support and patient assistance programs and how they impact enrollee expenses.

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<sup>36</sup> California Department of Public Health. Office of AIDS. PrEP-AP Program. Available at: [https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OA\\_adap\\_benefits\\_prepAP.aspx](https://www.cdph.ca.gov/Programs/CID/DOA/Pages/OA_adap_benefits_prepAP.aspx). Accessed on April 17, 2019.



**Table 4.** Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2020

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (c)	Large Group	Small Group	Individual	
<b>Enrollee counts</b>										
Total enrollees in plans/policies subject to state mandates (d)	10,565,000	3,099,000	2,184,000	523,000	6,796,000	795,000	318,000	108,000	102,000	24,490,000
Total enrollees in plans/policies subject to SB 159	10,565,000	3,099,000	2,184,000	523,000	6,796,000	795,000	318,000	108,000	102,000	24,490,000
<b>Premiums</b>										
Average portion of premium paid by employer	\$555.35	\$341.99	\$0.00	\$493.71	\$268.13	\$694.55	\$710.92	\$462.84	\$0.00	\$118,029,198,000
Average portion of premium paid by employee	\$39.66	\$205.44	\$437.39	\$94.04	\$0.00	\$0.00	\$250.37	\$202.64	\$475.67	\$26,521,718,000
Total premium	<b>\$595.01</b>	<b>\$547.43</b>	<b>\$437.39</b>	<b>\$587.76</b>	<b>\$268.13</b>	<b>\$694.55</b>	<b>\$961.29</b>	<b>\$665.48</b>	<b>\$475.67</b>	<b>\$144,550,916,000</b>
<b>Enrollee expenses</b>										
For covered benefits (deductibles, copays, etc.)	\$46.18	\$121.03	\$115.38	\$48.33	\$0.00	\$0.00	\$162.44	\$186.84	\$168.51	\$14,750,880,000
For noncovered benefits (e)	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0
<b>Total expenditures</b>	<b>\$641.19</b>	<b>\$668.46</b>	<b>\$552.77</b>	<b>\$636.08</b>	<b>\$268.13</b>	<b>\$694.55</b>	<b>\$1,123.73</b>	<b>\$852.31</b>	<b>\$644.18</b>	<b>\$159,301,796,000</b>

Source: California Health Benefits Review Program, 2019.

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

(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five (20.5%) of these enrollees has a pharmacy benefit not subject to DMHC.<sup>37</sup> 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) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.<sup>38</sup>

(e) 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 currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

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<sup>37</sup> For more detail, see *Estimates of Pharmacy Benefit Coverage*, available at [http://chbrp.com/analysis\\_methodology/cost\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/cost_impact_analysis.php).

<sup>38</sup> For more detail, see *Estimates of Sources of Health Insurance in California*, available at [http://chbrp.com/analysis\\_methodology/cost\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/cost_impact_analysis.php).

**Table 5.** Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2020

	DMHC-Regulated						CDI-Regulated			Total
	Privately Funded Plans (by Market) (a)			Publicly Funded Plans			Privately Funded Plans (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS HMOs (b)	MCMC (Under 65) (c)	MCMC (65+) (c)	Large Group	Small Group	Individual	
<b>Enrollee counts</b>										
Total enrollees in plans/policies subject to state mandates (d)	10,565,000	3,099,000	2,184,000	523,000	6,796,000	795,000	318,000	108,000	102,000	24,490,000
Total enrollees in plans/policies subject to SB 159	10,565,000	3,099,000	2,184,000	523,000	6,796,000	795,000	318,000	108,000	102,000	24,490,000
<b>Premiums</b>										
Average portion of premium paid by employer	\$0.0497	\$0.0387	\$0.0000	\$0.0397	\$0.0000	\$0.0000	\$0.0383	\$0.0431	\$0.0000	\$8,198,000
Average portion of premium paid by employee	\$0.0036	\$0.0233	\$0.0619	\$0.0076	\$0.0000	\$0.0000	\$0.0135	\$0.0189	\$0.0563	\$3,130,000
Total premium	\$0.0533	\$0.0620	\$0.0619	\$0.0473	\$0.0000	\$0.0000	\$0.0519	\$0.0620	\$0.0563	<b>\$11,328,000</b>
<b>Enrollee expenses</b>										
For covered benefits (deductibles, copays, etc.)	\$0.0023	\$0.0025	\$0.0025	\$0.0020	\$0.0000	\$0.0000	\$0.0022	\$0.0025	\$0.0023	\$474,000
For noncovered benefits (e)	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0.0000	\$0
<b>Total expenditures</b>	\$0.0556	\$0.0645	\$0.0644	\$0.0493	\$0.0000	\$0.0000	\$0.0541	\$0.0645	\$0.0586	<b>\$11,802,000</b>
<b>Percent change</b>										
Premiums	0.0090%	0.0113%	0.0142%	0.0080%	0.0000%	0.0000%	0.0054%	0.0093%	0.0118%	0.0078%
<b>Total expenditures</b>	0.0087%	0.0096%	0.0117%	0.0078%	0.0000%	0.0000%	0.0048%	0.0076%	0.0091%	0.0074%

Source: California Health Benefits Review Program, 2019.

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

(b) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five (20.5%) of these enrollees has a pharmacy benefit not subject to DMHC.<sup>39</sup> 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) Medi-Cal Managed Care Plan expenditures for members over 65 include those who are also Medicare beneficiaries. This population does not include enrollees in COHS.

(d) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.<sup>40</sup>

(e) 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 currently covered by insurance. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care; MCMC = Medi-Cal Managed Care.

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<sup>39</sup> For more detail, see *Estimates of Pharmacy Benefit Coverage*, available at [http://chbrp.com/analysis\\_methodology/cost\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/cost_impact_analysis.php).

<sup>40</sup> For more detail, see *Estimates of Sources of Health Insurance in California*, available at [http://chbrp.com/analysis\\_methodology/cost\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/cost_impact_analysis.php).

## PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, SB 159 as amended April 1st would authorize pharmacists to initiate and furnish pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP) for HIV/AIDS, prohibit commercial insurance plans from subjecting coverage of PrEP and PEP to prior authorization and step therapy, and expand the Medi-Cal schedule of benefits to include coverage and payment for PrEP and PEP provided by pharmacists.

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 impact<sup>41</sup> of SB 159 as amended on April 1st on utilization of PrEP and PEP, HIV incidence, HIV risk reduction, HIV transmission, quality of life, racial and ethnic disparities, and financial burden. See *Long-Term Impacts* for discussion of social determinants of health.

The public health impacts of SB 159 as amended on April 11th would be different than those presented below. While the Medical Effectiveness review would remain relevant, the differences in the cost impact analysis, as discussed above, would alter the public health impacts.

### Estimated Public Health Outcomes

Measurable health outcomes relevant to SB 159 include HIV transmission, adherence to PrEP and PEP regimens, HIV incidence, HIV risk reduction, and quality of life.

As presented in the *Medical Effectiveness* section:

- 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.
- There is limited evidence that PEP is effective in preventing HIV transmission following occupational and nonoccupational exposures.
- There is insufficient evidence to assess the impact of prohibiting prior authorization or step therapy on prescription of and adherence to PrEP or PEP.
- There is insufficient evidence to assess the ability of pharmacists to safely and effectively prescribe PrEP or PEP.

As presented in *Benefit Coverage, Utilization, and Cost Impacts*, 100% of enrollees subject to SB 159 have coverage for PrEP and PEP without prior authorization or step therapy requirements. Therefore, no utilization increase would occur due to SB 159 prohibiting these utilization management policies among DMHC-regulated plans and CDI-regulated policies. Conversely, pharmacists are not able to independently furnish PrEP and PEP at baseline, meaning 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. Due to this change in benefit coverage, utilization of PrEP and PEP will increase by 2%. 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

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<sup>41</sup> CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

(from 6,055 at baseline to 6,176 postmandate) in commercial and CalPERS plans and by an unknown number of enrollees in Medi-Cal.

### **Prohibition of Prior Authorization and Step Therapy**

According to CHBRP's content expert for SB 159, prior authorization requirements can result in a delay of obtaining PrEP of 24 to 48 hours. For enrollees seeking PrEP, some enrollees may fail to return to their provider or the pharmacy to fill the prescription, resulting in lower utilization of PrEP. As described in the *Benefit Coverage, Utilization, and Cost Impacts* section, 0% of enrollees currently have health insurance coverage that places prior authorization or step therapy requirements on the provision of PrEP or PEP. While some carriers indicated they do have formal prior authorization requirements in place, they stated they also authorize an immediate 30-day supply of Truvada while enrollees work with their providers to meet the prior authorization requirements or indicated the prior authorization requirements are being phased out.

Carriers indicated they did not place prior authorization requirements on the provision of PEP.

As stated in the *Medical Effectiveness* section, there is insufficient evidence to determine if prohibiting prior authorization for the provision of PrEP and PEP increases the likelihood that health professionals with prescribing authority will prescribe PrEP or PEP, improve adherence to PrEP or PEP, or improve health 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.

CHBRP estimates the provision of SB 159 that prohibits prior authorization and step therapy 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.

### **Pharmacist Provision of HIV Prophylaxis**

In order for pharmacists to be able to independently furnish PrEP and PEP in California postmandate, they must complete an approved education course and provide services to enrollees including testing for HIV, counseling and education, and additional laboratory tests. Should the education course be available immediately after SB 159 is signed into law, it will still take time for pharmacists to take the course and adapt their pharmacy practice to be able to furnish PrEP and PEP and provide the associated services. While pharmacists are able to bill Medi-Cal for the associated services (e.g. lab tests and patient counseling), there is currently no mechanism in place for pharmacists to bill commercial health plans for associated services, unless the pharmacist practices within a closed system, such as Kaiser Permanente.

It stands to reason that pharmacists in California would be willing to furnish PrEP, with additional training. However, as discussed in the *Background* section, barriers such as lack of knowledge about PrEP, lack of reimbursement from commercial carriers for associated services and slow implementation of necessary processes within pharmacies may inhibit adoption by pharmacists.

A 2017 study found that the HIV incidence among MSM who did not use PrEP was 50 per 1,000 and the HIV incidence among MSM who did use PrEP was 17 per 1,000, an absolute difference of 33 cases of HIV per 1,000 men (Allende and Acuna, 2017). While CHBRP is unable to discern the characteristics of new PrEP users due to the implementation of SB 159, assuming utilization and adherence of PrEP for all populations is similar to the utilization and adherence of the MSM population would be a best case scenario. If none of the estimated 768 new users of PrEP do not use PrEP, the findings of the 2017 study

suggest that 38 will seroconvert and become HIV positive. If the estimated 768 new users do use PrEP, the study findings suggest that 13 will seroconvert and become HIV positive, resulting in a reduction of 25 new cases of HIV, assuming that utilization and adherence among all new PrEP users is similar to that of MSM.

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.

### Utilization of PrEP

As discussed in the *Background* section, between 221,528 and 238,628 Californians would meet the criteria for PrEP, which is about double the prevalence of people living with HIV in California in 2016. Populations at high risk for contracting HIV include men who have sex with men (MSM), transgender women, African Americans, Latinos and persons who inject drugs.

The use of PrEP may vary according to individual characteristics. Morgan et al. (2018), a longitudinal cohort study conducted in the United States, found that those who reported more sex partners (AOR = 1.07, 95% CI = 1.03–1.12) and older individuals (AOR=1.18, 95% CI=1.07-1.30) were significantly more likely to have used PrEP in the past 6 months, whereas those with potentially hazardous marijuana use were significantly less likely to use have used PrEP in the past 6 months (AOR = 0.94, 95% CI = 0.89–0.99). No significant differences were found for race/ethnicity, education, other drug use, nor alcohol use.

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.

### Potential Harms From SB 159

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 159, 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. 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 non-users. 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



discontinuation rate due to 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 post-exposure outweigh the harms.

## Impact on Disparities<sup>42</sup>

Insurance benefit mandates that bring more state-regulated plans and policies to parity may change an existing disparity. As described in the *Background* section, disparities in utilization exist by race and ethnicity, and gender identity and sexual orientation. Although the impact of SB 159 on disparities is unknown due to lack of data, it possible that within the first 12 months postmandate, SB 159 could reduce some disparities in utilization of PrEP. (For 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 159 on the impact of disparities for utilization of PEP due to lack of data.

## Impact on Racial or Ethnic Disparities

As discussed in the *Background* section, although blacks and Hispanics in California are at highest risk of contracting HIV, utilization of PrEP is highest among white Californians. Although SB 159 may somewhat expand access to PrEP for enrollees by enabling them to access medications directly through a pharmacist, the impact of SB 159 is unknown.

It is possible SB 159 could reduce racial and ethnic disparities for high risk populations who do not have a usual source of care or are uncomfortable asking their usual source of care for a PrEP prescription. However, the impact of SB 159 on reducing documented disparities among racial and ethnic groups (see the *Background* section) is unknown because data are unavailable to estimate changes in the utilization of PrEP among enrollees by race or ethnicity.

## Impact on Sexual Orientation and Gender Identity Disparities

As discussed in the *Background* 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. Expanding access to PrEP through pharmacists could increase initiation and adherence due to MSM and transgender women seeking more anonymous care or choosing to go to an alternate provider.

The extent to which sexual orientation and gender identity disparities may be impacted by SB 159 is unknown because data are unavailable to estimate changes in the utilization of PrEP among these enrollees.

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<sup>42</sup>. For details about CHBRP's methodological approach to analyzing disparities, see the [Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts](http://chbrp.com/analysis_methodology/public_health_impact_analysis.php) document here: [http://chbrp.com/analysis\\_methodology/public\\_health\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/public_health_impact_analysis.php).

## LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact<sup>43</sup> of SB 159 as amended on April 1st, 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.

Amendments made to SB 159 on April 11th would alter the below impacts.

### Long-Term Utilization and Cost Impacts

#### Utilization Impacts

After the increase in utilization in the first 12 months, CHBRP estimates the utilization will increase gradually before leveling off. CHBRP assumes the gradual increase will be due to increased awareness of PrEP and PEP among enrollees and increased preparedness by pharmacists and pharmacies. However, after several years, CHBRP expects the utilization to level off because the rate of enrollees using PrEP and PEP will also remain generally consistent over time.

#### Cost Impacts

Over the long term, CHBRP assumes as utilization continues to increase, corresponding costs will also increase. CHBRP also assume that as utilization for PrEP and PEP increases, potentially fewer enrollees will contract HIV. Thus, the costs associated with HIV-positive enrollees would decrease and offset some or all of the increased cost associated with PrEP and PEP.

### 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 social determinants of health, premature death, and economic loss.

In the case of SB 159, 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..

#### Impacts on Disparities and the Social Determinants of Health<sup>44</sup>

In the case of SB 159, evidence shows that access to PrEP may be lower in rural areas compared to urban areas and perceived stigma from providers is a substantial barrier for PrEP-eligible patients.

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<sup>43</sup> See also CHBRP's *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at [http://www.chbrp.org/analysis\\_methodology/cost\\_impact\\_analysis.php](http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php).

<sup>44</sup> For more information about SDoH, see CHBRP's publication *Incorporating Relevant Social Determinants of Health into CHBRP Benefit Mandate Analyses* at [http://chbrp.com/analysis\\_methodology/public\\_health\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/public_health_impact_analysis.php).

Additionally, disparities in utilization of PrEP exist between racial and ethnic groups and by gender identity and sexual orientation.

Periodically, health insurance mandates can influence SDoH, which can mediate health inequities. Evidence presented in the *Background* section indicates that geography and provider stigma are associated with lower utilization of PrEP. Enabling pharmacists to independently furnish PrEP may improve access for enrollees in rural areas due to increased availability. Additionally, if an enrollee perceives judgement from their primary care provider, they would be able to turn to a pharmacist for 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.

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 alternate 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.

## APPENDIX A TEXT OF BILL ANALYZED

On February 28, 2019, the California Senate Committee on Health requested that CHBRP analyze SB 159.

SB 159 was introduced on January 23, 2019, amended on February 27, 2019 and amended on April 1, 2019. CHBRP, with agreement from the requesting Health Committee, has analyzed the text as it was amended on April 1, 2019.

SENATE BILL

No. 159

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**Introduced by Senator Wiener**  
**(Principal coauthors: Assembly Members Gipson and Gloria)**  
**(Coauthor: Assembly Member Chiu)**

January 23, 2019  
Amended in Senate February 27, 2019  
Amended in Senate April 1, 2019

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

### LEGISLATIVE COUNSEL'S DIGEST

SB 159, as amended, Wiener. HIV: preexposure and postexposure prophylaxis.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy, and makes a violation of these requirements a crime. Existing law generally authorizes a pharmacist to dispense or furnish drugs only pursuant to a valid prescription, except as provided, such as furnishing emergency contraceptives, hormonal contraceptives, and naloxone hydrochloride, pursuant to standardized procedures.

This bill would authorize a pharmacist to ~~initiate and~~ furnish preexposure prophylaxis and postexposure ~~prophylaxis if a~~ *prophylaxis, in specified amounts, if the* pharmacist completes a training program approved by the ~~board,~~ *board and* complies with specified requirements, such as assessing a patient and providing a patient with counseling and tests, ~~and provides these if~~ *those services can be provided* in a private and sanitary location. Because a violation of these requirements would be a crime, this bill would impose a state-mandated local program.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services, under which qualified low-income individuals receive health care services pursuant to a schedule of benefits, including pharmacist services, which are 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 expand the Medi-Cal schedule of benefits to include preexposure prophylaxis and postexposure prophylaxis as pharmacist services.

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 authorizes health care service plans and health insurers that cover prescription drugs to utilize reasonable medical management practices, including prior authorization and step therapy, consistent with applicable law. For combination antiretroviral drug treatments medically necessary for the prevention of AIDS/HIV, existing law prohibits plans and insurers, until January 1, 2023, from having utilization management policies or procedures that rely on a multitablet drug regimen instead of a single-tablet drug regimen, except as specified.

This bill would additionally prohibit plans and insurers from subjecting those drug treatments, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy. Because a willful violation of these provisions 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.

#### Digest Key

Vote: MAJORITY Appropriation: NO Fiscal Committee: YES Local Program: YES

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#### BILL TEXT

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

#### **SECTION 1.**

Section 4052.02 is added to the Business and Professions Code, to read:

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

(b) Before furnishing preexposure prophylaxis or postexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board ~~that addresses~~ *on* the use of preexposure prophylaxis and postexposure prophylaxis. The board shall consult with the California Pharmacists Association and the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(c) A pharmacist may furnish *an initial course of* preexposure prophylaxis *as determined by the federal Centers for Disease Control and Prevention guidelines* if the pharmacist completes all of the following:

(1) ~~Screens the patient for human immunodeficiency virus (HIV) and Provides HIV testing and confirms a negative test result or~~ determines ~~that~~ the patient has *recently* received a negative HIV test ~~within the last seven days. result consistent with the most recent guidelines from the federal Centers for Disease Control and Prevention. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall inform the patient that there are numerous treatment options available and identify followup testing and care that may be recommended, including contact information for medical and psychological services.~~

(2) Provides counseling to the ~~patient, including a side effect assessment,~~ *patient on the ongoing use of preexposure prophylaxis consistent with the most recent guidelines from the federal Centers for Disease Control and Prevention, which may include* education about side ~~effects of the medication~~ *effects, safety during pregnancy and breastfeeding, adherence to recommended dosing,* and the importance of ~~adhering to the drug regimen, timely~~ testing and treatment, as applicable, for ~~HIV and sexually transmitted diseases, behavioral risk reduction support, and pregnancy testing. HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of child-bearing capacity.~~

~~(3) Advises the patient on current guidelines and recommendations by the federal Centers for Disease Control and Prevention regarding ongoing use of the medication.~~

~~(4)~~

(3) Documents the services provided by the pharmacist in the patient's health record.

~~(5)~~

(4) 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 ~~a~~ *the patient's* primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact ~~for health care services.~~ *regarding ongoing care for preexposure prophylaxis.*

*(d) A pharmacist may refill a prescription pursuant to this section if, prior to refilling the prescription, the pharmacist completes all of the following:*

*(1) Ensures the patient is clinically eligible for use of preexposure prophylaxis consistent with the most recent guidelines from the federal Centers for Disease Control and Prevention, which may include providing or determining the patient has received timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of child-bearing capacity.*

*(2) Documents the services provided by the pharmacist in the patient's health record.*

*(3) 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 physicians and surgeons, clinics, or other health care service providers to contact regarding ongoing care for preexposure prophylaxis.*

~~(d)~~

*(e) A pharmacist may furnish a complete course or 30-day supply of postexposure prophylaxis if the pharmacist completes all of the following:*

*(1) Screens the patient ~~for HIV~~ and determines the exposure meets the clinical criteria for ~~use~~ *consideration* of postexposure prophylaxis consistent with the most recent guidelines from the federal Centers for Disease Control and Prevention.*

*(2) Provides HIV testing or determines the patient is willing to ~~receive an HIV test~~ *undergo HIV testing* consistent with the most recent guidelines from the federal Centers for Disease Control and Prevention.*

*(3) Provides counseling to the patient on the use of ~~the medication~~ *postexposure prophylaxis* consistent with the most recent guidelines from the federal Centers for Disease Control and Prevention, ~~including which may include~~ education about side ~~effects of the medication,~~ *effects, safety during pregnancy and breastfeeding, adherence to recommended dosing,* and the importance of ~~adhering to the drug regimen and testing~~ *timely testing and treatment, as applicable,* for HIV and sexually transmitted diseases.*

*(4) Notifies the patient's primary care provider of the postexposure prophylaxis treatment. If the patient does not have a primary care provider, or refuses consent to notify ~~a~~ *the patient's* primary*



care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact ~~for health care services.~~ *regarding followup care for postexposure prophylaxis.*

~~(e)~~

*(f)* A pharmacist initiating or furnishing preexposure prophylaxis or postexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board and the Medical Board of California.

~~(f) A pharmacist who provides~~

*(g)* ~~Notwithstanding any other law, a pharmacist is not required to provide the~~ counseling, assessments, or ~~tests, as prescribed in this section, shall ensure that these services are provided in a private and sanitary location, without interruption by others, and the pharmacist shall not be interrupted~~ *tests specified in subdivision (c), (d), or (e) if the pharmacist cannot conduct the counseling, assessments, or tests at a location that is sufficiently private to permit the pharmacist to comply with the federal Health Insurance Portability and Accountability Act and applicable state law governing the privacy of medical information, meets the sanitation standards under applicable law governing pharmacy practice, and allows the pharmacist to provide the services without being interrupted by others or called away to perform other duties.*

~~(g)~~

*(h)* The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with respect to its respective licensees.

~~(h)~~

*(i)* The board may adopt emergency regulations ~~to establish necessary procedures or protocols. These emergency regulations shall be developed~~ in accordance with the most current guidelines from the federal Centers for Disease Control and Prevention. 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 emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to Section 4005.

~~(i)~~

*(j)* This section does not limit a pharmacist's scope of practice described in Section 4052.2.

**SEC. 2.**

Section 1342.74 is added to the Health and Safety Code, immediately following Section 1342.73, to read:

**1342.74.** Notwithstanding Section 1342.71, a health care service plan shall not subject combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy.

**SEC. 3.**

Section 10123.1933 is added to the Insurance Code, immediately following Section 10123.1932, to read:

**10123.1933.** Notwithstanding Section 10123.201, a health insurer shall not subject combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy.

**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.

(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 and postexposure prophylaxis, as authorized in Section 4052.02 of the Business and Professions Code.

(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 medical effectiveness literature review conducted for this report. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

CHBRP's medical effectiveness review addressed: (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. Pertinent studies were identified through searches of PubMed, the Cochrane Library, Web of Science, Embase, and Scopus. The website for the Agency for Healthcare Research and Quality (AHRQ), an organization that produces systematic reviews and meta-analyses, was also searched.

The search was limited to abstracts of studies published in English and conducted in the United States and other developed countries. For studies related to the effectiveness of PrEP and PEP, the search was limited to studies published from 2018 to present because CHBRP had previously conducted thorough literature searches on these topics in 2018 for SB 1021. Because the analysis of SB 1021 did not address the impact of prior authorization or step therapy on prescription of PrEP or PEP or adherence to PrEP or PEP, the search for these studies was limited to 2012 to present. 2012 was chosen as the starting point because the FDA approved Truvada® for PrEP treatment in 2012. The search for articles on the safety and effectiveness of provision of PrEP and PEP by pharmacists was also limited to studies published from 2012 to present. The literature review also included articles on prior authorization and pharmacist prescribing published prior to 2012 that were recommended by the content expert and the peer faculty reviewer.

The literature on the effectiveness of PrEP did not include any new randomized controlled trials (RCTs), although new information about medication adherence and dosing regimens, which can impact the effectiveness of PrEP, was described. One new study was an extension of an RCT that examined PrEP's impact on patients' self-perceived quality of life. The literature search on the effectiveness of PEP did not include any new studies. CHBRP found no studies on the impact of removing prior authorization and step therapy for PrEP or PEP but did include one study that analyzed prior authorization for HIV treatment. CHBRP identified only one observational study describing pharmacists' ability to safely and effectively prescribe PrEP and also included one study on the safety and efficacy of pharmacists' prescription of oral contraceptives.

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.

Of the 557 articles found in the literature search, 27 were reviewed for potential inclusion, and 11 were included in the review of medical effectiveness for SB 159. The other articles were eliminated because they did not focus on therapies for HIV prevention, were of poor quality, or did not report findings from clinical research studies. While reviewing the 27 articles for potential inclusion, 8 articles cited by these articles were identified for potential inclusion, and 7 were included in this report. Based on recommendations from content experts, an additional 13 articles were reviewed for potential inclusion, 2 of which were included. Eighteen references from CHBRP's report on SB 1021 were also included in this report.

## 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*.<sup>45</sup> 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.

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.

## Search Terms

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<sup>45</sup> Available at: [http://chbrp.com/analysis\\_methodology/medical\\_effectiveness\\_analysis.php](http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php).

- Condom use
- Darunavir
- Dolutegravir
- Drug uptake
- HIV
- HIV discordant
- HIV exposure
- HIV prevention
- HIV transmission
- Intravenous (IV) drug use
- Multiple sexual partners
- Multi-tablet regimen
- PEP adherence
- PEP prescription
- Pre-exposure prophylaxis (PrEP)
- Pregnancy
- PrEP adherence
- PrEP prescription
- Prior authorization
- Post-exposure prophylaxis (PEP)
- Raltegravir
- Ritonavir
- Single tablet regimen
- Step therapy
- Treatment adherence
- Treatment resistance
- Truvada
- Utilization management
- Zidovudine

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

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm, Milliman, Inc.<sup>46</sup>

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.<sup>47</sup>

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

### Analysis-Specific Caveats and Assumptions

This section discusses the caveats and assumptions relevant to specifically to an analysis of SB 159's provision regarding the coverage of medications for the prevention of HIV/AIDS.

The population subject to the mandated offering includes enrollees in DMHC-regulated plans and CDI-regulated policies for large-group, small-group, and individual marketplace plans, CalPERS plans, and enrollees receiving benefits through Medi-Cal Managed Care plans, County Organized Health Systems (COHS), and the fee-for-service (FFS) program. As discussed in the Policy Context section, preventive HIV medications are carved out of Medi-Cal Managed Care plans and COHS, and are provided through the FFS program.

Baseline HIV prevention drug treatment Commercial costs and associated utilization were based on 2016 MarketScan® and Milliman's proprietary 2016 Consolidated Health Cost Guidelines Sources Database (CHSD) which contain Commercial claims, encounters, and enrollment data for the state of California. Because the potential impact change of this mandate affects those enrollees who use HIV drug for prevention purposes, the analysis was limited to enrollees that had not been diagnosed with HIV as of the date of the first HIV prevention drug usage in 2016.

- CHBRP assumes that if an individual is diagnosed as HIV positive, he/she cannot become HIV negative in the future. This is done because some of the HIV prevention drugs are also used by HIV-positive enrollees for treatment purposes.
- CHBRP expects that any mandate utilization changes from this component of the bill would be based on changes to current HIV prevention coverage.
- CHBRP expects that the cost per prescription remains the same between premandate and postmandate.
- CHBRP assumes that the mandate would not impact any forms of member cost sharing, such as deductibles, copays, and coinsurance.

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<sup>46</sup> CHBRP's authorizing statute, available at [http://chbrp.com/CHBRP%20authorizing%20statute\\_2018\\_FINAL.pdf](http://chbrp.com/CHBRP%20authorizing%20statute_2018_FINAL.pdf), requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

<sup>47</sup> See method documents posted here, [http://chbrp.com/analysis\\_methodology/cost\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/cost_impact_analysis.php); in particular, see *2019 Cost Analyses: Data Sources, Caveats, and Assumptions*.



- CHBRP assumes pharmacists that plan to complete the necessary training have completed it by January 1, 2020. The credentialing programs required may not be fully operational by January 1, 2020, so this assumption may overstate the impact for year 1.

Tables 6 and 7 list the diagnosis codes used to identify HIV-positive enrollees and drug product names used to identify HIV prevention drugs, respectively.

Prevention treatment of HIV used Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) codes identified with carrier coverage guidelines and reviewed by a content expert. Additionally, drug prevention treatment of HIV used National Drug Codes (NDC) codes identified using the Truven Health Analytics Red Book™ and reviewed by a content expert.

**Table 6.** Diagnosis Codes

Diagnosis Codes (ICD 9 and ICD-10)	Description
B20	HIV disease
042	HIV disease

**Table 7.** List of Medications to Prevent HIV

HIV Prevention Category	Drug Product Name
Pre-HIV exposure/post-HIV exposure	Truvada
Post-HIV exposure	Darunavir
Post-HIV exposure	Dolutegravir
Post-HIV exposure	Raltegravir
Post-HIV exposure	Ritonavir
Post-HIV exposure	Zidovudine

HIV prevention drug treatment users were categorized as pre-HIV exposure (PrEP) prevention and post-HIV exposure prevention (PEP). The PrEP exposure regimen is a single-tab Truvada® pill daily. The acute PEP prescription is a 28-day regimen of multitablet combination of NRTIs and integrase inhibitors. One or more of the post-HIV exposure drugs can also be used for acute exposure treatment. The majority of providers prescribe multi-drug PEP for all exposures (guidelines generally suggest that more than one of the post-HIV exposure drugs should be used, e.g., Truvada plus another drug), however clinicians experienced in PEP management may on occasion prescribe a modified regimen (e.g., Truvada only for PEP for lower risk exposure). Because Truvada-only is rarely used for PEP, CHBRP assumed Truvada-only users observed in the MarketScan and CHSD datasets were PrEP exposure prevention treatment users. If an HIV-negative enrollee uses at least one of the post-HIV exposure exclusive drugs (not Truvada), that user is considered a post-exposure user for the remainder of the year. Another post-exposure prevention strategy addresses fetal exposure during pregnancy and birth. In general, this requires the baby receive a 4- to 6-week course of zidovudine, which is on occasion (but rarely) used in combination with another drug.

Baseline prescription drug unit costs were trended at an annual rate of 6.2% from 2016 to 2020 based on the “2017 Drug Trend Report” by Express Scripts for HIV drugs and recent Truvada trend. The 6.2%

trend represents the 2017 HIV drug trends for the commercial population represented within the report. The analysis assumes that the unit cost per drug does not change postmandate.

Additionally, lab tests are required both prior to prescribing HIV PrEP or PEP and on a quarterly basis for monitoring purposes. Table 8 lists the lab tests assumed to be associated with the provision or monitoring of HIV PrEP and PEP.

**Table 8.** List of Lab Tests for Provision or Monitoring of HIV PrEP and PEP

CPT Code	Description
80047	Metabolic panel ionized ca
80048	Metabolic panel total ca
80053	Comprehen metabolic panel
80069	Renal function panel
80074	Acute hepatitis panel
82565	Assay of creatinine
86689	Htlv/hiv confirm antibody
86701	HIV-1 antibody
86702	HIV-2 antibody
86703	Hiv-1/hiv-2 result antibody
86704	Hep b core antibody total
86705	Hep b core antibody igm
86705	Hep b surface antibody
87340	Hepatitis b surface ag ai
87341	Hepatitis b surface ag ia
87389	Hiv-1 ag w/hiv-1 & hiv-2 ab
87390	Hiv-1 ag ia
87391	Hiv-2 ag ia
87517	Hepatitis b dna quant
87534	Hiv-1 dna dir probe
87535	Hiv-1 probe&reverse trnscrpj
87536	Hiv-1 quant&revrse trnscrpj
87537	Hiv-2 dna dir probe
87538	Hiv-2 probe&revrse trnscripj
87539	Hiv-2 quant&revrse trnscripj
87900	Phenotype infect agent drug
87901	Genotype DNA HIV reverse t
87912	Genotype DNA hepatitis b

Baseline lab test unit costs were trended at an annual rate of 2% from 2016 to 2020, based on the December 2018 medical component of CPI.

The analysis assumed that utilization rates per 1,000 enrollees change postmandate only due to increased access. Baseline utilization rates per 1,000 were developed based on MarketScan and CHSD data for members not diagnosed with HIV and who also use the HIV prevention drugs. Baseline utilization was estimated to increase 2% postmandate due to the increased access.

Carrier surveys were administered to estimate the percentage of enrollees who had HIV-outpatient drug prevention coverage. Results from the CHBRP current coverage questionnaire for health plans and insurers indicate 100% on-formulary coverage for HIV PrEP and PEP, respectively. Carrier surveys also indicated that there was no pre-authorization or step therapy protocols for HIV PrEP and PEP. Therefore, no additional utilization changes were modeled.

### **Determining Public Demand for the Proposed Mandate**

This subsection discusses public demand for the benefits SB 159 would mandate. Considering the criteria specified by CHBRP's authorizing statute, CHBRP reviews public demand for benefits relevant to a proposed mandate in two ways. CHBRP:

- Considers the bargaining history of organized labor; and
- Compares 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.

On the basis of conversations with the largest collective bargaining agents in California, CHBRP concluded that unions currently do not include cost-sharing arrangements for description treatment or service. In general, unions negotiate for broader contract provisions such as coverage for dependents, premiums, deductibles, and broad coinsurance levels.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS currently 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 carriers 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**

In order to develop Table 9, CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of SB 159 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. To generate this table, CHBRP reviewed the literature and consulted content experts about the possibility of varied second year impacts and applied what was learned to a projection of a second year of implementation.

As displayed in Table 9, the second year's impacts of SB 159 would be substantially the same as the impacts in the first year (see Table 1).

**Table 9.** SB 159 Impacts on Benefit Coverage, Utilization, and Cost, 2021

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
<b>Benefit coverage</b>				
Total enrollees with health insurance subject to state-level benefit mandates (a)	24,395,000	24,395,000	0	0%
Total enrollees with health insurance subject to SB 159 (b)	100%	100%	0%	0%
Total percentage of enrollees with coverage for PrEP and PEP without prior authorization and step therapy	100%	100%	0%	0%
Total percentage of enrollees able to obtain PrEP and PEP directly from pharmacist	0%	100%	100%	100%
<b>Utilization and unit cost</b>				
Number of enrollees using PrEP	32,322	32,968	646	2%
Number of enrollees using PEP	6,658	6,791	133	2%
Scripts per user of PrEP	6.002	6.002	0.000	0%
Scripts per user of PEP (c)	10.410	10.410	0.000	0%
Average prescription drug regime cost per user (PrEP and PEP)	\$14,679.22	\$14,679.22	\$0.00	0%
Average number of lab tests per user of PrEP	3.597	3.597	0.000	0%
Average number of lab tests per user of PEP	2.534	2.534	0.000	0%
Average annual cost of lab tests per user of PrEP	\$142.08	\$142.08	\$0.00	0%
Average annual cost of lab tests per user of PEP	\$159.92	\$159.92	\$0.00	0%
<b>Expenditures</b>				
<u>Premiums by payer</u>				
Private employers for group insurance	\$90,700,422,000	\$90,709,715,000	\$9,293,000	\$90,700,422,000
CalPERS HMO employer expenditures (d)	\$3,234,903,000	\$3,235,195,000	\$292,000	\$3,234,903,000
Medi-Cal Managed Care Plan expenditures	\$29,186,401,000	\$29,186,401,000	\$0	\$29,186,401,000
Enrollees with individually purchased insurance	\$13,111,153,000	\$13,113,109,000	\$1,956,000	\$13,111,153,000
Enrollees with group insurance, CalPERS HMOs, Covered	\$15,255,718,000	\$15,257,401,000	\$1,683,000	0.0110%

California, and Medi-Cal Managed Care (e)				
<b>Enrollee expenses</b>				
For covered benefits (deductibles, copayments, etc.)	\$15,636,259,000	\$15,636,812,000	\$553,000	0.0035%
For noncovered benefits (f)	\$0	\$0	\$0	0.00%
<b>Total expenditures</b>	<b>\$167,124,856,000</b>	<b>\$167,138,633,000</b>	<b>\$13,777,000</b>	<b>0.0082%</b>

Source: California Health Benefits Review Program, 2019.

Notes: Provision of PrEP and PEP are “carved out” of Medi-Cal Managed Care plans and COHS and are instead provided through the fee-for-service program. There are approximately 10,545,000 enrollees in full-scope Medi-Cal in 2020. Although not shown in Table 1, CHBRP estimates that utilization of PrEP will increase from 9000 baseline to 9,180 postmandate (2% utilization increase). The increase in utilization is estimated to increase state Medi-Cal expenditures \$1,256,539. CHBRP is unable to estimate utilization changes of PEP due to lack of data. Impacts in 2021 would be similar to the impacts projected in 2020.

(a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.<sup>48</sup>

(b) Health insurance that has no OPD benefit or has an OPD benefit not regulated by DMHC or CDI is considered compliant.<sup>49</sup>

(c) Occupational PEP may be covered through worker’s comp and therefore would not appear in this claims data. As a result, utilization of PEP may be higher on a per-person basis due to the nature of non-occupational exposure and the likelihood of repeat exposure.

(d) Approximately 56.17% of CalPERS enrollees in DMHC-regulated plans are state retirees, state employees, or their dependents. About one in five (20.5%) of these enrollees has a pharmacy benefit not subject to DMHC.<sup>50</sup> 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) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care.

(f) Includes only those expenses that are paid directly by enrollees to providers for services related to the mandated benefit that are not currently covered by insurance. In addition, this only includes those expenses that will 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; DMHC = Department of Managed Health Care; HMO = Health Maintenance Organizations; OPD = Outpatient Prescription Drug; PEP = post-exposure prophylaxis; PrEP = pre-exposure prophylaxis.

<sup>48</sup> For more detail, see *Estimates of Sources of Health Insurance in California*, available at [http://chbrp.com/analysis\\_methodology/cost\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/cost_impact_analysis.php).

<sup>49</sup> For more detail, see *Estimates of Pharmacy Benefit Coverage*, available at [http://chbrp.com/analysis\\_methodology/cost\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/cost_impact_analysis.php).

<sup>50</sup> For more detail, see *Estimates of Pharmacy Benefit Coverage*, available at [http://chbrp.com/analysis\\_methodology/cost\\_impact\\_analysis.php](http://chbrp.com/analysis_methodology/cost_impact_analysis.php).

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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 an actuarial firm, **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

**Janet Coffman, MA, MPP, PhD**, *Vice Chair for Medical Effectiveness*, University of California, San Francisco

**Sylvia Guendelman, PhD, LCSW**, University of California, Berkeley

**Gerald Kominski, PhD**, University of California, Los Angeles

**Sara McMenamin, PhD**, *Vice Chair for Medical Effectiveness and Public Health*, University of California, San Diego

**Joy Melnikow, MD, MPH**, *Vice Chair for Public Health*, University of California, Davis

**Jack Needleman, PhD**, University of California, Los Angeles

**Ninez Ponce, PhD**, University of California, Los Angeles

**Nadereh Pourat, PhD**, *Vice Chair for Cost*, University of California, Los Angeles

**Marilyn Stebbins, PharmD**, University of California, San Francisco

**Ed Yelin, PhD**, Professor Emeritus, University of California, San Francisco

### Task Force Contributors

**Danielle Casteel, MA**, University of California, San Diego

**Shana Charles, PhD, MPP**, University of California, Los Angeles, and California State University, Fullerton

**Shauna Durbin, MPH**, University of California, Davis

**Margaret Fix, MPH**, University of California, San Francisco

**Sarah Hiller, MA**, University of California, San Diego

**Naomi Hillery, MPH**, University of California, San Diego

**Jeffrey Hoch, PhD**, University of California, Davis

**Michelle Ko, MD, PhD**, University of California, Davis

**Connie Kwong**, University of California, San Francisco

**Kevin Lee, PhD Candidate**, University of California, Berkeley

**Elizabeth Magnan, MD, PhD**, University of California, Davis

**Ying-Ying Meng, PhD**, University of California, Los Angeles

**Jacqueline Miller**, University of California, San Francisco

**Dominique Ritley, MPH**, University of California, Davis  
**Dylan Roby, PhD**, University of California, Los Angeles, and University of Maryland, College Park  
**Riti Shimkhada, PhD**, University of California, Los Angeles  
**Meghan Soulsby Weyrich, MPH**, University of California, Davis  
**Steven Tally, PhD**, University of California, San Diego  
**Christopher Toretsky, MPH**, University of California, San Francisco  
**Sara Yoeun**, University of California, San Diego

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**Lauren LeRoy, PhD**, Strategic Advisor, L. LeRoy Strategies, *Chair*  
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**Marilyn Moon, PhD**, Vice President and Director, Health Program, American Institutes for Research, Silver Spring, MD  
**Carolyn Pare**, President and CEO, Minnesota Health Action Group, Bloomington, MN  
**Richard Roberts, MD, JD**, Professor 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  
**Karen Shore**, Contractor\*  
**Karla Wood**, Project Analyst  
**Ana Ashby**, Health Policy Graduate Assistant

**California Health Benefits Review Program**  
**MC 3116**  
**Berkeley, CA 94720-3116**  
[info@chbrp.org](mailto:info@chbrp.org)  
[www.chbrp.org](http://www.chbrp.org)  
(510) 664-5306

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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](http://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](mailto:info@chbrp.org) or [www.chbrp.org](http://www.chbrp.org)