Key Findings

Analysis of California Senate Bill 427
Antiretroviral Drugs, Devices, and Products

Summary to the 2023–2024 California State Legislature, April 21, 2023

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

AT A GLANCE

The version of California Senate Bill 427 analyzed by CHBRP would require health plans and health policies regulated by the Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) to cover all U.S. Food and Drug Administration (FDA)-approved or Centers for Disease Control and Prevention (CDC)-recommended antiretroviral drugs, products, and devices (ARVs) for HIV/AIDS with no cost sharing or utilization review requirements for enrollees in both grandfathered and nongrandfathered DMHC-regulated plans and CDI-regulated policies under the outpatient prescription drug benefit.

In 2024, 100% of the 22.8 million Californians enrolled in state-regulated health insurance would have insurance subject to SB 427.

Benefit Coverage: At baseline, 98.9% of enrollees in DMHC-regulated plans and CDI-regulated policies have coverage for ARVs, while only 38.6% of enrollees have coverage fully compliant with SB 427. Postmandate, 100% of enrollees with coverage subject to SB 427 would have coverage with ARVs without cost sharing. SB 427 would not be likely to exceed essential health benefits (EHBs).

Medical Effectiveness: CHBRP researched the effects of cost sharing and utilization management on ARV use and adherence for patients with HIV and those at risk of contracting HIV. CHBRP found:

- *Inconclusive evidence* on the effect of cost sharing for ARVs on long-term adherence and viral suppression for people living with HIV.
- *Insufficient evidence* on the effect of cost sharing for ARVs on health care utilization and health outcomes.
- *Insufficient evidence* on the effect of utilization management for ARVs on health care utilization and health outcomes.

Cost and Health Impacts[1]: In 2024, CHBRP estimates SB 427 would increase total net annual expenditures by $51,601,000 or 0.0352% for enrollees with DMHC-regulated health plans and CDI-regulated policies, excluding DMHC-regulated Medi-Cal. This is due to a $157,254,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a $105,653,000 decrease in enrollee expenses for covered and/or noncovered benefits.

SB 427 would result in an increase of 1,402 enrollees utilizing ARVs for a total utilization equal to 132,133 enrollees. This includes an increase in the number of individuals who do not seroconvert due to pre-exposure prophylaxis (47) and postexposure prophylaxis (22) access, an increase in the number of HIV-positive individuals who access ARVs and sustain linkages to care (1,332), and a subsequent decrease in both short- and long-term adverse health outcomes (including a reduction in the transmission of HIV to noninfected sexual partners).

The impacts of SB 427 on disparities are unknown because data are unavailable to estimate the impact of eliminating cost sharing and utilization management on ARV utilization among newly covered enrollees.

CONTEXT

Human immunodeficiency virus (HIV) attacks the body's CD4 and/or T-cells (i.e., a type of white blood cell), which are integral to the body's immune function.[2] Without initial treatment and routine adherence to treatment, HIV typically progresses through three stages of disease: (1) acute HIV infection; (2) chronic HIV infection; and (3) acquired immunodeficiency syndrome (AIDS). There is no cure for HIV/AIDS; however, with routine care and proper treatment, HIV-related morbidity and mortality can be prevented through the use of antiretroviral therapy—known for inhibiting viral replication and allowing for immune reconstitution. Given the availability of ARVs, it is possible for people living

[1] Similar cost and health impacts could be expected for the following year, though possible changes in medical science and other aspects of health make stability of impacts less certain as time goes by.

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

with HIV to achieve a life expectancy similar to that of the general population.

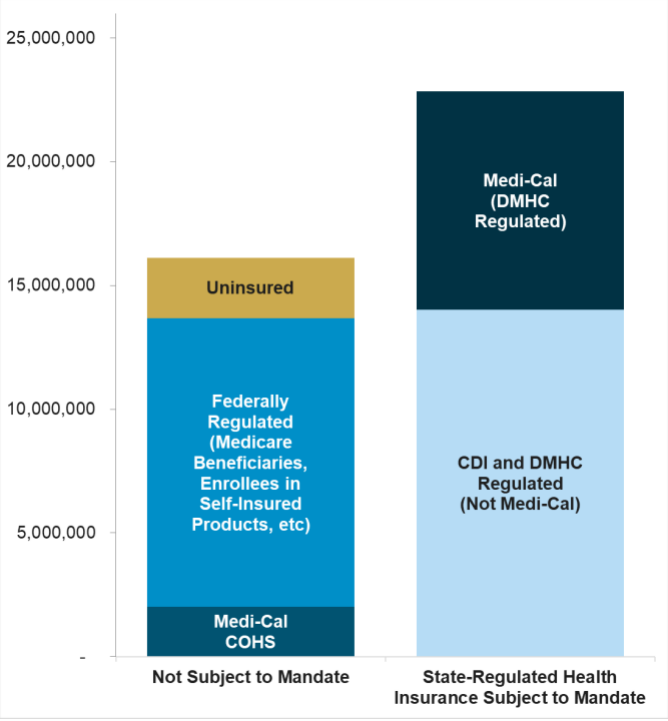
The U.S. Department of Health and Human Services recommends that the primary goal of ARVs is to prevent HIV-associated morbidity and mortality and to reduce the risk of HIV transmission to sexual partners and to infants born to persons with HIV. ARVs are widely accepted as effective treatment for the control of HIV as well as the prevention of transmission of HIV.

BILL SUMMARY

SB 427 would require Department of Managed Health Care (DMHC)-regulated health plans and California Department of Insurance (CDI)-regulated policies to cover all U.S. Food and Drug Administration (FDA)-approved or Centers for Disease Control and Prevention (CDC)-recommended ARVs with no cost sharing or utilization review requirements for enrollees in both grandfathered and nongrandfathered DMHC-regulated plans and CDI-regulated policies under the outpatient prescription drug benefit.

Figure A notes how many Californians have health insurance that would be subject to SB 427.

Figure A. Health Insurance in CA and SB 427



Source: California Health Benefits Review Program, 2023.

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

IMPACTS

Benefit Coverage, Utilization, and Cost

Benefit Coverage

At baseline, 100% (22,842,000) of enrollees with DMHC- or CDI-regulated health insurance plans/policies would have coverage subject to SB 427. Of these, 98.9% have coverage for ARVs. At baseline, 38.6% of enrollees have coverage for ARVs that is fully compliant with SB 427. Postmandate,100% of enrollees with coverage subject to SB 427 would have coverage for ARVs without cost sharing.

Although the benefit coverage for beneficiaries with DMHC-regulated Medi-Cal plans is subject to SB 427, their pharmacy benefit is carved out and administered under Medi-Cal Rx, and therefore, SB 427 would not impact their benefit coverage.

Utilization

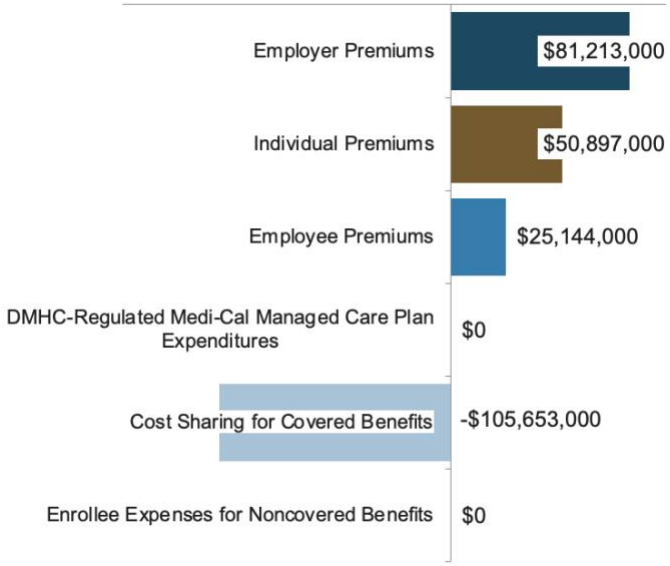
At baseline, CHBRP estimates that 130,731 enrollees per year in DMHC-regulated plans and CDI-regulated policies used ARVs with cost sharing. Among these, 49,257 enrollees per year used ARVs with cost sharing and 97,658 enrollees used ARVs with no cost sharing. It is important to note that these two groups had some overlap (16,184 enrollees), as some enrollees had cost sharing during the year until hitting their maximum out-of-pocket limit, and then had no cost sharing for the remainder of the year. On average, each enrollee with cost sharing had on average 7.6 prescriptions annually with cost sharing at baseline, with an average of 6.5 prescriptions for enrollees with no cost sharing.

Postmandate, CHBRP estimates an additional 1,402 enrollees will utilize ARVs (equal to 132,133 enrollees overall), representing a 1% increase in enrollees using ARVs overall. On average, enrollees who use ARVs would obtain 7.7 prescriptions without cost sharing annually, per person. This translates to an overall utilization of 1,016,959 ARV prescriptions without cost sharing, postmandate, representing a 1% increase in ARV prescriptions.

Expenditures

SB 427 would increase total net annual expenditures by $51,601,000 or 0.0352% for enrollees with DMHC-regulated plans and CDI-regulated policies, excluding DMHC-regulated Medi-Cal.

Figure B. Expenditure Impacts of SB 427



Source: California Health Benefits Review Program, 2023.

Medi-Cal

For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there is no impact.

CalPERS

For enrollees associated with CalPERS in DMHC-regulated plans, premiums would increase by 0.08% ($0.53 per member per month, or approximately $4.7 million total increase in expenditures).

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 427.

Medical Effectiveness

CHBRP reviewed findings from evidence on the effects of cost sharing and utilization management on ARVs (including pre-exposure prophylaxis [PrEP] and postexposure prophylaxis [PEP]) use and adherence for patients with HIV and those at risk of contracting HIV.

CHBRP did not review literature on the effectiveness of ARVs because all ARVs have been approved by the FDA, and the efficacy of ARVs is well-established.

CHBRP found:

- *Inconclusive evidence*[3] on the effect of cost sharing for ARVs (including PrEP and PEP) on long-term adherence and viral suppression for people living with HIV.
- *Insufficient evidence*[4] on the effect of cost sharing for ARVs (including PrEP and PEP) on health care utilization and health outcomes.
- *Insufficient evidence* on the effect of utilization management for ARVs (including PrEP and PEP) health care utilization and health outcomes.

Public Health

Measurable health outcomes relevant to SB 427 include adherence to prescribed ARVs regimens and viral suppression, health care utilization, and HIV-related complications or comorbidities.

In the first year postmandate, CHBRP estimates an additional 1,402 enrollees would seek ARVs overall for the prevention or treatment for HIV/AIDS. This includes an increase in the number of individuals who do not seroconvert due to PrEP (47) and PEP (22) access, an increase in the number of HIV-positive individuals who access ARVs and sustain linkages to care (1,332), and a subsequent decrease in both short- and long-term adverse health outcomes (including a reduction in the transmission of HIV to noninfected sexual partners).

The impacts of SB 427 on disparities related to race or ethnicity, gender, gender identity or sexual orientation, and age are unknown because data are unavailable to estimate the impact of eliminating cost sharing and utilization management on ARVs utilization among newly covered enrollees.

Long-Term Impacts

The utilization increases estimated in this report are not expected to be different over the long-term. However, over time, adherence to ARVs may improve as cost sharing will no longer be a barrier, which could lead to an increase in overall annual utilization. However, this

[3] *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.

[4] *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.

effect would be limited because adherence is also dependent on other factors, such as the severity of side effects and access to health care.

Cost impacts over the long term would be proportional to any increase in utilization and are not anticipated to change after the first year postmandate. Although additional use of and adherence to ARVs will prevent HIV infection and later AIDS-related diseases, the marginal impact of SB 427 over the existing use of ARVs cannot be quantified. Additionally, the vast array of AIDS-related diseases that could occur and would be prevented cannot be quantified; in general, prevention of these conditions and their associated costs would provide an offset to CHBRP's estimated premium increases due to SB 427.

The long-term public health impacts of SB 427 are likely to include a reduction in future HIV transmissions (i.e., reduction in HIV incidence among those using PrEP and PEP), increased uptake of and adherence to ARVs (leading to a subsequent reduction in the number of overall adverse health outcomes in the long-term), as well as a reduction in downstream effects such as impacts on premature death.

Essential Health Benefits and the Affordable Care Act

SB 427 does not exceed essential health benefits because the bill would specify terms and conditions of coverage for ARVs and not mandate coverage for new tests, treatments, or services for nongrandfathered health plans or policies.