KEY FINDINGS

Abbreviated Analysis of California Assembly Bill 554:
Antiretroviral Drugs, Drug Devices, and Drug Products

Summary to the 2025-2026 California State Legislature, April 22, 2025

CHBRP

Summary

The version of California Assembly Bill (AB) 554 analyzed by California Health Benefits Review Program (CHBRP) would, in Year 1, require large-group health plans regulated by the Department of Managed Health Care (DMHC) and large-group policies regulated by the California Department of insurance (CDI) to cover U.S. Food and Drug Administration (FDA)–approved or Centers for Disease Control and Prevention (CDC)–recommended antiretroviral (ARV) drugs, devices, and products for the prevention of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), with no cost sharing, prior authorization, step therapy, or utilization review requirements. DMHC- and CDI-regulated small-group and individual health plans and policies would be required to abide by the same requirements in Year 2 postmandate.

In 2026, of the 22.2 million Californians enrolled in state-regulated health insurance, 9.2 million would have insurance subject to AB 554 in Year 1. In Year 2 this total would increase to 13.6 million enrollees.

Benefit Coverage

At baseline, CHBRP estimates approximately 95.5% of health plans and policies are fully compliant with AB 554. Postmandate, 100% of health plans and policies regulated by DMHC and CDI would be fully compliant. AB 554 would not exceed essential health benefits (EHBs).

Cost Impacts[1]

In Year 1 (2026), AB 554 would result in an additional 1,566 enrollees newly utilizing ARV drugs, and a total of 25,079 additional enrollees using ARV drugs without cost sharing. This would result in an additional $30.5 million in annual expenditures, including a $73.6 million increase in total premiums, and a decrease of $43 million in enrollee cost sharing.

In Year 2, CHBRP estimates AB 554 would result in a net annual expenditure of $37,087,000 (0.02%), including an increase in total premiums paid by employers and enrollees for newly covered benefits by $135,988,000, and a decrease in enrollee cost sharing by $98,901,000 (0.48%) compared to baseline.

CHBRP was unable to estimate additional cost offsets related to the number of HIV infections prevented due to increased use of ARV drugs. Furthermore, the vast array of AIDS-related diseases, hospitalizations, and other related health care costs that could occur and would be prevented cannot be quantified. However, in general, prevention of these conditions and their associated costs would provide an offset to estimated premium increases.

Context

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. If undiagnosed and left untreated, HIV invades and effectively destroys CD4 cells during the virus replication process, leading to opportunistic infections, opportunistic cancers, and death. Without initial treatment and routine adherence to treatment, HIV typically progresses through three stages of disease: (1) acute HIV infection;[2] (2) chronic HIV infection; and (3) AIDS. There is no cure for HIV/AIDS; however, with routine care and proper treatment, HIV-related morbidity and mortality can be prevented through ARV therapy.

ARV therapy is the use of HIV medicines — also referred to as an HIV regimen — to treat or prevent HIV. There are more than 30 FDA-approved ARV drugs from eight drug classes that may be used to:

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

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

- Prevent initial HIV infection (i.e., preexposure prophylaxis [PrEP] or postexposure prophylaxis [PEP]); or
- Treat HIV infection, prevent HIV transmission to other people, and prevent progression to AIDS.

Given the availability of ARV drugs, it is possible for people living with HIV to achieve a life expectancy similar to that of the general population.

Bill Summary

AB 554 would require DMHC-regulated plans and CDI-regulated policies to cover FDA-approved or CDC-recommended ARV drugs, devices, and products for the prevention of HIV/AIDS, with no cost sharing or utilization review requirements. In addition, the bill language specifies that ARV drugs, devices, or products must not be subject to prior authorization, step therapy, or any other protocol designed to delay treatment. Coverage for all therapeutically equivalent versions of ARV drugs without prior authorization or step therapy would not be required if at least one therapeutic equivalent version is covered without prior authorization, step therapy requirements, or cost sharing, pursuant to an exception request.

AB 554 would apply to grandfathered and nongrandfathered DMHC-regulated health plans and CDI-regulated policies in the large-group market in Year 1. In Year 2, the bill would extend to include small-group and individual market insurance. DMHC-regulated Medi-Cal plans are excluded. Figure A notes how many Californians have health insurance that would be subject to AB 554.

Impacts

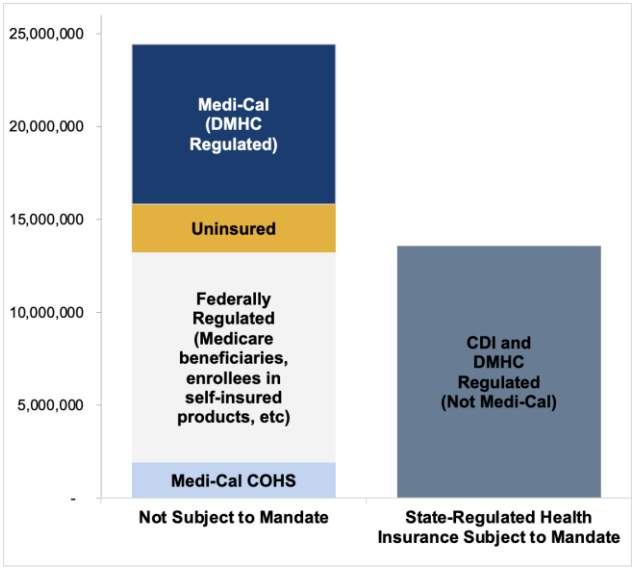
Benefit Coverage

CHBRP estimates that at baseline, 8,794,000 (95.5%) Californians with state-regulated insurance subject to the mandate are enrolled in plans or policies that are fully compliant with AB 554 and have coverage for ARV drugs without cost sharing. Approximately 2.1% of health plans and policies are in partial compliance (i.e., provide coverage but with cost sharing), and 2.4% are out of compliance (i.e., do not provide coverage). Postmandate, 100% of enrollees with health insurance subject to AB 554 would have coverage for ARV drugs without cost sharing.

Utilization

At baseline, CHBRP estimates 63,155 enrollees utilize ARV drugs each year, about half (53.5%) of whom also have cost sharing.

Figure A. Health Insurance in CA and AB 554



Source: California Health Benefits Review Program, 2025.
Key: CDI = California Department of Insurance; COHS = County Organized Health System; DMHC = Department of Managed Health Care.

CHBRP assumed that in Year 1 postmandate, there would be an increase in utilization, driven primarily by new benefit coverage in grandfathered large-group plans. CHBRP estimates an additional 25,079 enrollees would utilize ARV drugs without cost sharing in Year 1.

In Year 2 postmandate, when the mandate would apply to small-group and individual health plans and policies, in addition to the assumptions made for Year 1 utilization, CHBRP assumed further increases in utilization due to a new ARV drug. The FDA is expected to approve a long-acting injectable (lenacapavir) that requires two doses a year for use as PrEP in 2025. Based on historical data on the introduction of other long-acting injectable drugs to the market, CHBRP estimates that lenacapavir will not be readily available until 2027. CHBRP anticipates that uptake of lenacapavir will increase overall utilization of ARV drugs in Year 2 because of interest in a PrEP regimen that requires less frequent doses to maintain. Based on these assumptions, CHBRP estimates an additional 37,043 enrollees would utilize ARV drugs without cost sharing compared to baseline in Year 2.

Following Year 2, utilization may be similar to that of other long-acting injectables during the first years they were available on the market.

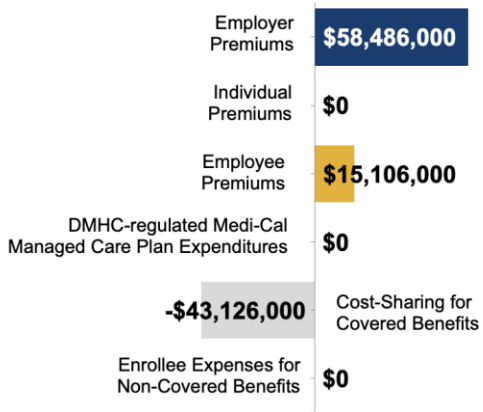
Expenditures

In the first year postmandate, AB 554 would result in an additional $30.5 million (0.02%) in net annual expenditures, including a $73.6 million increase in total premiums, and a decrease of $43 million (0.23%) in enrollee cost sharing for enrollees in large-group DMHC-regulated plans and CDI-regulated policies.

In Year 2, CHBRP estimates AB 554 would result in a net annual expenditure of $37,087,000 (0.02%), including an increase in total premiums paid by employers and enrollees for newly covered benefits by $135,988,000, and a decrease in enrollee cost sharing by $98,901,000 (0.48%) compared to baseline.

CHBRP was unable to estimate additional cost offsets related to the number of HIV infections prevented due to increased use of ARV drugs. Furthermore, the vast array of AIDS-related diseases, hospitalizations, and other related health care costs that could occur and would be prevented cannot be quantified. However, in general, prevention of these conditions and their associated costs would provide an offset to CHBRP's estimated premium increases due to AB 554.

Figure B. Expenditure Impacts of AB 554 (Year 1)



Source: California Health Benefits Review Program, 2025.
Key: DMHC = Department of Managed Health Care.

Medi-Cal

For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there would be no impact because these plans are excluded from the bill mandate.

CalPERS

For enrollees associated with the California Public Employees' Retirement System (CalPERS) in DMHC-regulated plans, CHBRP estimates premiums would increase by $0.64 per member per month (PMPM) for a total of approximately $5.9 million (0.08%) in Year 1 compared to baseline.

In Year 2, premiums would increase by $6,181,000 (0.07%) for enrollees associated with CalPERS in DMHC-regulated plans compared to baseline.

Covered California – Individually Purchased

In Year 1, AB 554 would not apply to any health plans or policies in the individual market.

In Year 2, premiums would increase by approximately $21.3 million (0.12%) for Covered California individual market plan enrollees, and mirror plans available to individuals outside of Covered California would see an increase in premiums of about $10.6 million (0.16%).

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 AB 554.

Long-Term Impacts

Cost impacts over the long term would be proportional to any increase in utilization. New ARV drugs, devices, and products that may be developed in the future could have additional impacts on utilization in the long-term. However, cost is not the only barrier to access to ARV therapy. Provider awareness, stigma, inequities in healthcare access, low perception of risk, and other factors also create challenges that impact ARV drug utilization and adherence, and ultimately the incidence and prevalence of HIV/AIDS.

Essential Health Benefits and the Affordable Care Act

Because ARV drugs are already covered under the EHB benchmark plan, AB 554 would not exceed the definition of EHBs in California.