SENATE COMMITTEE ON HEALTH
Senator Caroline Menjivar, Chair

BILL NO: AB 554
AUTHOR: Mark González, Haney
VERSION: June 24, 2025
HEARING DATE: July 16, 2025
CONSULTANT: Teri Boughton

SUBJECT: Health care coverage: antiretroviral drugs, drug devices, and drug products

SUMMARY: Prohibits grandfathered (before the federal Affordable Care Act [ACA]) and nongrandfathered (after the ACA) health plans and insurance policies from imposing any cost-sharing for antiretroviral drugs, devices, or drug products that are either approved by the federal Food and Drug Administration (FDA) or recommended by the federal Centers for Disease Prevention and Control (CDC) for preexposure prophylaxis. Delays implementation in the individual and small group market until January 1, 2027. Requires coverage for self-administered antiretroviral drug products and those not self-administered that are approved by the FDA and recommended by the CDC for the prevention of HIV/AIDS, including supplying providers directly with a product that is not self-administered.

Existing law:

1) Establishes the Department of Managed Health Care (DMHC) to regulate health plans under the Knox-Keene Health Care Services Plan Act of 1975; the California Department of Insurance (CDI) to regulate health and other insurers; Covered California as California's health benefit exchange for individual and small business purchasers as authorized under the federal Patient Protection and Affordable Care Act (ACA); and, the Department of Health Care Services (DHCS) to administer the Medi-Cal program. [HSC §1340, et seq., INS §106, et seq., GOV §100500 -100522, and WIC §14000, et seq.]

2) Requires health plans and insurers, at a minimum, to provide coverage for and prohibits any cost-sharing requirements for several services including, but not limited to evidence-based items or services that have in effect a rating of "A" or "B" in the recommendations of the United State Preventive Services Task Force (USPSTF) and immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the CDC.
[HSC §1367.002 and INS §10112.2]

3) Prohibits health plans and insurers from subjecting antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP), to prior authorization or step therapy, except that if the FDA approves one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, in which case health plan and insurers are only required to cover at least one therapeutically equivalent version without prior authorization or step therapy. [HSC §1342.74(a) and INS §10123.1933(a)]

4) Prohibits health plans and insurers or their designated pharmacy benefit manager from prohibiting, a pharmacy provider from dispensing PrEP or PEP. [HSC §1342.74(b) and INS §10123.1933(b)]

5) Requires health plans and insurers to cover PrEP and PEP that has been furnished by a pharmacist, as authorized in the law, including the pharmacist's services and related testing ordered by the pharmacist. Requires plans and insurers to pay or reimburse, consistent with the law, for the service performed by a pharmacist at an in-network pharmacy or a pharmacist at an out-of-network pharmacy if the health plan has an out-of-network pharmacy benefit. [HSC §1342.74(c) and INS §10123.1933(c)]

6) Indicates that the law does not require health plans and insurers to cover PrEP and PEP furnished by a pharmacist at an out-of-network pharmacy, unless the health plan or insurer has an out-of-network pharmacy benefit. [HSC §1342.74(d) and INS §10123.1933(d)]

7) Exempts Medi-Cal managed care plans from 3) through 6) above to the extent that the services are excluded from coverage under the contract between the Medi-Cal managed care plans and DHCS. [HSC §1342.74(e)]

8) Requires a health plan contract that provides coverage for outpatient prescription drugs to cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with the Knox-Keene Act. [HSC §1342.71 and INS §10123.193]

9) Establishes a requirement, under federal regulations, that health plans and insurers have a process for review, upon request, of a decision that a drug is not covered by a plan. Requires notification of the determination within 72 hours of the request, or 24 hours based on exigent circumstances. Requires health plans and insurers to have a process for external review of denials of a standard exception, or for an expedited exception. [45 CFR §156.122]

10) Requires in state law an external exception request review process for a denial of a prior authorization or step therapy exception request. Requires an independent review organization's reversal of a health plan or insurer denial of a request for an exception, prior authorization, or step therapy exception to be binding and apply for the duration of the prescription, and refills. [HSC §1367.241 and INS §10123.191]

This bill:

1) Adds, to the exemption from prior authorization and step therapy for antiretroviral drugs for the prevention of HIV/AIDS, drug devices or drug products that are either approved by the FDA or recommended by the CDC. Prohibits a health plan or insurer from using any other protocol designed to delay this treatment. Removes the qualifier that these drugs, drug devices, or drug products are medically necessary.

2) Adds to the exclusion from the exemption described in 1) above a condition that the plan (in addition to at least one therapeutically equivalent) also provide coverage for a noncovered therapeutic equivalent antiretroviral drug, drug device, or drug product without cost-sharing pursuant to an exception request. States that a long-acting drug, drug device, or drug product is not therapeutically equivalent to a long-acting drug, device, or drug product with a different duration.

3) Requires a health plan or insurer to cover PrEP and PEP furnished by a pharmacist at an out-of-network pharmacy in the case of a medical emergency.

4) Requires a grandfathered and a nongrandfathered health plan contract or health insurance policy to provide coverage, without cost-sharing, for antiretroviral drugs, devices, or drug products that are either approved by the FDA or recommended by the CDC for PrEP. Applies this to the individual and small group health insurance markets beginning January 1, 2027.

5) Requires plans and insurers to provide coverage under the outpatient prescription drug benefit for antiretroviral drugs, drug devices, or drug products for the prevention of HIV/AIDS that are either FDA approved or CDC recommended, including by supplying providers directly with a drug, drug device, or drug product that is not self-administered.

6) Exempts specialized health plan contracts and insurance policies that cover only dental or vision benefits or a Medicare supplement contract.

7) Applies this bill and the law it amends to a antiretroviral drug, drug device, or drug product regardless of whether or not it is self-administered.

8) Requires a high deductible health plan (HDHP) under federal law to comply with cost-sharing requirements of this bill unless there is a conflict with federal requirements for HDHPs, in which case the cost-sharing exemption applies after deductible has been satisfied.

FISCAL EFFECT: According to the Assembly Committee on Appropriations:

1) Increases in premium costs to the California Public Employees Retirement System (CalPERS) system, likely in the low millions of dollars annually (General Fund), based on the CHBRP analysis of the introduced version of the bill, and assuming amendments reduce costs.

2) DMHC estimates costs of approximately $55,000 in fiscal year (FY) 2025-26 and $133,000 in FY 2026-27 and annually thereafter (Managed Care Fund).

3) CDI estimates costs of $13,000 in FY 2025-26, $25,000 in FY 2026-27, and $2,000 in FY 2027-28 and ongoing (Insurance Fund).

4) Costs would likely be offset to some extent by reduced costs of care due to a reduction in new HIV cases.

PRIOR VOTES:

Assembly Floor:	68 - 1
Assembly Appropriations Committee:	11 - 0
Assembly Health Committee:	14 - 0

COMMENTS:

1) *Author's statement.* According to the author, amid the chaos and attacks on healthcare access from the federal administration, California must take bold steps to safeguard and expand lifesaving HIV prevention. The HIV epidemic continues to disproportionately affect historically disadvantaged communities, yet cost and access remain major barriers to effective treatment. This bill ensures that all health insurance policies cover HIV PrEP without cost-sharing, eliminating out-of-pocket costs for one million Californians. Additionally, current laws exclude certain FDA-approved long-lasting injectable medications, further limiting patient choice and disproportionately impacting Latino and Black/African American communities, which face the highest rates of new HIV diagnoses. By

mandating full coverage for safe and effective prevention methods and allowing local clinics to receive reimbursement, this bill protects patient and provider choice while reducing the risk of HIV/AIDS in marginalized communities. California must lead where the federal government fails—ensuring equitable *access to HIV prevention for those who need it most.*

2) *USPSTF recommendation.* The current USPSTF recommendation (Grade A) for adults and adolescents weighing at least 77 pounds at increased risk of HIV acquisition is to prescribe PrEP with effective antiretroviral therapy* to decrease the risk of acquiring HIV. *Effective formulations of PrEP with current FDA approval include:
   a) Oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) and injectable cabotegravir are approved for use in at-risk adults and adolescents weighing at least 35 kg (77 lb) to reduce the risk of sexually acquired HIV.
   b) Oral TAF/FTC is approved for use in at-risk adults and adolescents weighing at least 35 kg (77 lb) to reduce the risk of sexually acquired HIV, excluding individuals at risk from receptive vaginal sex.
   c) No PrEP medications have FDA approval for the indication of reducing the risk of acquiring HIV via injection drug use, but Centers for Disease Control and Prevention (CDC) guidelines note that persons who inject drugs are likely to benefit from PrEP with any FDA-approved PrEP medication.
   d) It is important that persons taking PrEP receive counseling about medication adherence and safer sex including condom use, regular testing for HIV, and other necessary testing.

   In August of 2023, the USPSTF updated its 2019 recommendation, which recommended that clinicians offer PrEP with effective antiretroviral therapy to persons at high risk of HIV acquisition. For the updated recommendation, the USPSTF reviewed additional evidence on new formulations of PrEP and recommends that clinicians prescribe PrEP using effective antiretroviral therapy to persons at increased risk of HIV acquisition, after the clinician and patient have discussed PrEP and the patient agrees.

3) *California Health Benefits Review Program (CHBRP) report.* AB 1996 (Thomson, Chapter 795, Statutes of 2002) requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996, and reviewed this bill. Key findings of the March 3, 2025 version of this bill (which included a prohibition on utilization review) follows below. *Some of CHBRPs expenditure estimates may be lower than the March 3, 2025 version of this bill because of subsequent amendments which may be interpreted to limit the bill's coverage requirements*:
   a) *Antiretroviral drugs:* There are more than 30 FDA-approved antiretroviral drugs from eight drug classes that may be used to prevent initial HIV infection (PrEP or PEP); or treat HIV infection, prevent HIV transmission to other people, and prevent progression to AIDS. PrEP is indicated for all routes of sexual exposure. PrEP can be administered in oral or injection form. At present, there are two FDA-approved oral medications for use as PrEP, one FDA-approved injectable medication for use as PrEP, and another injectable medication recently approved by the FDA. PEP is a short-term, daily therapy similar to PrEP. 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 after a needle stick injury), men who have sex with men, people who inject drugs, as well for the prevention of perinatal HIV transmission in infants. This regimen must be started within 72 hours of

(suspected) HIV exposure and is only taken for 28 days. Treatment of HIV can reduce viral load to undetectable levels and reduce the risk of transmission. Treatment of HIV also reduces the progression of the virus to AIDS and reduces mortality and morbidity of AIDS. While most antiretroviral drugs are covered under the pharmacy benefit, long-acting injectable antiretroviral drugs such as cabotegravir and lenacapavir are covered under the medical benefit.

b) *HIV Prevalence in California.* From 2018 to 2022, the number of new HIV diagnoses remained relatively steady in California. New diagnoses increased by 0.4%, from 4,863 in 2018 to 4,882 in 2022, while the rate of new diagnoses per 100,000 population declined by approximately 0.8%, from 12.3 to 12.2. During the same four-year period (2018 to 2022), the number of persons living with HIV increased in California from approximately 136,100 to more than 142,700 — indicating the effectiveness of initiating and sustaining antiretroviral use.

c) *Race and ethnicity.* CHBRP found literature identifying disparities in antiretroviral drug uptake, adherence, and viral suppression by race/ethnicity, gender identity/sexual orientation, and age. Black people in California are disproportionately affected by new HIV diagnoses with rates 4.4 times higher among men and nearly 5.7 times higher among women than for White people. Similarly, Latino people in California are disproportionately affected by new HIV diagnoses with rates 2.7 times higher among men and 1.7 times higher among women than for White people. CHBRP found several studies indicating racial/ethnic disparities in antiretroviral use and viral suppression among Black people in California.

d) *Gender Identity or Sexual Orientation.* The subpopulations at highest risk for HIV, are men who have sex with men inclusive of gay, heterosexual, and bisexual men, who experience disproportionate rates of HIV. In 2022, men who had sex with men accounted for 66% of the population living with HIV, and 55% of all new HIV diagnoses. Disparities among Black and Latino men who have sex with men newly diagnosed with HIV have increased between 2018 and 2022, primarily due to a decrease in rates among White men who have sex with men. In 2022, Black men who have sex with men were 4.8 times more likely to be diagnosed with HIV compared to White men who have sex with men. Similarly, Latino men who have sex with men were approximately 3.3 times as likely to be diagnosed with HIV compared to White men who have sex with men. Moreover, Black men who have sex with men were found to have lower linkages to HIV care within one month of diagnosis and lower viral suppression within six months of HIV diagnosis compared to other race/ethnicities.

e) *Coverage impacts and enrollees covered*. CHBRP indicates in 2026, of the 22.2 million Californians enrolled in state-regulated health insurance, 9.2 million would have insurance subject to this bill in Year one. In Year two, this total would increase to 13.6 million enrollees. In Year one, 95.5% of health plans and policies are fully in compliance with this bill. In Year two, when an individual and small group is required to comply with this bill 4.98% of the enrollee population would gain coverage for the use of antiretroviral drugs without cost-sharing.

f) *Utilization*. In year one, CHBRP assumes a one percent increase in utilization, driven primarily because of new benefit coverage in grandfathered large-group plans. In year two, when the individual and small group plans are required to comply CHBRP assumed a one percent increase driven by the elimination of cost-sharing. CHBRP also anticipates an increase in utilization depending upon when new, longer acting antiretroviral drugs are approved. CHBRP assumed an increase in utilization due to the new medication. The FDA recently approved lenacapavir for use as PrEP in June 2025. CHBRP anticipates that uptake of lenacapavir will increase overall utilization of antiretroviral drugs in Year

two because of interest in a PrEP regimen that requires a lower frequency of doses to maintain. Since FDA-approval occurred earlier than anticipated in 2025, fiscal impacts could be higher in Year two. Changes in the drug's time to market would also impact fiscal estimates. Following Year two, utilization may be similar to that of other long-acting injectables during the first years they were available on the market.

g) *Impact on expenditures*. For large-group commercial/CalPERS DMHC-regulated plans and CDI-regulated policies, this bill would increase total premiums paid by employers and enrollees for newly covered benefits by $73,592,000 in Year one. Enrollee expenses for covered and/or noncovered benefits would decrease by $43,126,000 as a result of the prohibition on cost-sharing. This would result in an increase of total net annual expenditures of $30,466,000 (0.02%) for enrollees with large-group commercial/CalPERS DMHC-regulated plans and CDI-regulated policies. Total premium impact for employer-sponsored coverage would increase by .08% or over $52 million. Enrollee premiums would increase by $15 million. In Year two there would be an increase in total premiums paid by employers and enrollees for newly covered benefits by $135,988,000. Enrollee expenses for covered and/or noncovered benefits would decrease by $98,901,000 (0.48%) as a result of the prohibition on cost-sharing. This would result in an increase of total net annual expenditures of $37,087,000 (0.02%) for enrollees with DMHC-regulated plans and CDI-regulated policies. In Year two total premiums paid by employers would increase .10% by over $74 million. Enrollee premiums would increase by almost $24 million in group market and almost $32 million for individuals buying their own coverage.

4) *Prior legislation.* SB 427 (Portantino of 2024) was substantially similar to this bill. *SB 427 was held in the Assembly at the request of the author.*

5) *Support.* Equality California, one of the cosponsors of this bill, writes despite groundbreaking advancements in HIV prevention—including the approval of multiple oral and long-acting injectable PrEP medications—barriers to access persist, particularly for Black and Latino Californians. According to the CDC, recent estimates suggest 94% of white people who could benefit from PrEP have been prescribed it, but only 13% of Black and 24% of Latino people who could benefit have been prescribed PrEP. Insurance Commissioner Lara, another cosponsor, writes no one should have to jump through hoops or face financial burdens to access FDA-approved and CDC-recommended treatments that can prevent the spread of HIV/AIDS. Commissioner Lara says by eliminating cost-sharing for these essential medications, we are taking a significant step toward health equity—especially for communities disproportionately impacted by the HIV epidemic.

6) *Opposition.* The California Association of Health Plans and the Association of Life and Health Insurance Companies write with concerns regarding this bill's financial implications on the healthcare system, specifically the CHBRP estimates that this bill would increase total premiums paid by employers and enrollees by almost $136 million following full implantation in Year two, and enrollees in the Covered California individual market plan would see an increase in premiums of almost $11 million in Year two.

7) *Policy comment.* Existing federal and state law already require coverage of PrEP without cost-sharing, and make at least one therapeutically equivalent antiretroviral drug, device, or product for the prevention of AIDS/HIV, including PrEP and PEP available without prior authorization or step therapy requirements. The author indicates that several oral and injectable PrEP drugs are covered without cost-sharing but the current policy allows too

much flexibility with what is "medically necessary" and "therapeutically equivalent." The author intends this bill to ensure coverage for a new twice-yearly injectable PrEP medication that has recently been approved by the FDA, and both the one-month and six-month injectables to be covered once they are approved. Additionally, the author is intending clinics to bill health plans and insurers under the pharmacy benefit, rather than under medical benefits for injectable PrEP.

8) *Amendments.* Some amendments may be necessary to clarify intent, such as:
   a) Dental, vision, *and mental health* specialized plans and policies should be excluded from this bill.
   b) The requirements around prior authorization and step therapy need revision to address intent, specifically:
      i) (a)(2) If the FDA has approved one or more therapeutic equivalents of a drug, drug device, or drug product for the prevention of HIV/AIDS, this section does not require a health care service plan to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy ~~and the plan provides coverage for a noncovered therapeutic equivalent antiretroviral drug, drug device, or drug product without cost sharing pursuant to an exception request~~. For purposes of this section, a long-acting drug, drug device, or drug product is not therapeutically equivalent to a long-acting drug, drug device, or drug product with a different duration.
      ii) New (e)(3) <u>If a health care service plan covers a noncovered therapeutic equivalent antiretroviral drug, drug device, or drug product pursuant to an exception request, and the covered therapeutic equivalent antiretroviral drug, drug device, or drug product is not subject to cost-sharing, than the nonformulary therapeutic equivalent antiretroviral drug, drug device, or drug product shall not be subject to cost-sharing.</u>
      iii) The committee may wish to require the antiretroviral drug, drug device, or drug product be medically necessary, as required under existing law.

<u>SUPPORT AND OPPOSITION</u>:

Support: APLA Health (co-sponsor)
Equality California (co-sponsor)
Insurance Commissioner Ricardo Lara / California Department of Insurance (co-sponsor)
Los Angeles LGBT Center (co-sponsor)
San Francisco AIDS Foundation (co-sponsor)
AIDS Healthcare Foundation
AltaMed Health Services Corporation
American College of Obstetricians & Gynecologists - District Ix
API Equality-LA
Asian Americans Advancing Justice -- Southern California
Beyond AIDS Foundation
Biocom California
Black Women for Wellness Action Project
Buen Vecino
California Academy of Preventive Medicine
California Community Foundation
California Federation of Teachers
California Legislative LGBTQ Caucus

California LGBTQ Health and Human Services Network
California Life Sciences Association
California Nurses Association
California Pharmacists Association
California Physicians Alliance
California School-Based Alliance
California Society of Health-System Pharmacists
City of Long Beach
City of San Jose
City of West Hollywood
Clinica Monseñor Oscar A. Romero
Coachman Moore & Associates, Inc.
Community Clinic Association of Los Angeles County
County Health Executives Association of California
County of Santa Clara
Courage California
El/la Para Translatinas
End the Epidemics: Californians Mobilizing to End HIV, Viral Hepatitis, STIs, and Overdose
Essential Access Health
GLIDE
Health Access California
LGBTQ+ Inclusivity, Visibility, and Empowerment
Long Beach Forward
Northeast Valley Health Corporation
PFLAG Los Angeles
PFLAG San Jose/Peninsula
Pride At the Pier
Rainbow Families Action Bay Area
Sacramento LGBT Community Center
Sunburst Projects
The San Diego LGBT Community Center
The Translatin@ Coalition
The Wall Las Memorias Project
TransFamilies of Silicon Valley
Venice Family Clinic
Viet Voices
Viiv Healthcare
Youth Leadership Institute
One individual

Oppose: Association of California Life & Health Insurance Companies
California Association of Health Plans

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