SENATE COMMITTEE ON HEALTH
Senator Dr. Susan Talamantes Eggman, Chair

BILL NO: SB 427
AUTHOR: Portantino
VERSION: March 21, 2023
HEARING DATE: April 26, 2023
CONSULTANT: Melanie Moreno

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

SUMMARY: Prohibits nongrandfathered health plans and insurers from imposing any cost-sharing or utilization review requirements for antiretroviral drugs, devices, or products that are either approved by the federal Food and Drug Administration (FDA) or recommended by the Centers for Disease Control and Prevention (CDC) for the prevention of AIDS/HIV, including preexposure prophylaxis (PrEP) or postexposure prophylaxis (PEP). Requires grandfathered health plans and insurers to provide coverage, without any cost-sharing or utilization review requirements, for antiretroviral drugs, devices, or products that are either approved by the FDA or recommended by the CDC for the prevention of AIDS/HIV, including PrEP and PEP.

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) Prohibits health plans and insurers from subjecting antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including PrEP and PEP, to prior authorization or step therapy, except that if the United States Food and Drug Administration (FDA) approves one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, health plan and insurers are not required 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. [HSC §1342.74 (a) and INS §10123.1933(a)]

3) 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 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]

This bill:
1) Deletes the reference to "medically necessary" in existing law above and instead prohibits prior authorization or step therapy for devices or products approved by the FDA or recommended by the CDC for the prevention of AIDS/HIV.

2) Adds to the exception described in 2) of existing law above "and the plan provides coverage for a noncovered therapeutic equivalent antiretroviral drug, device, or product without cost-sharing pursuant to an exception request."

3) Prohibits nongrandfathered health plans and insurers from imposing any cost-sharing or utilization review requirements for antiretroviral drugs, devices, or products that are either approved by the FDA or recommended by the CDC for the prevention of AIDS/HIV, including PrEP and PEP.

4) Requires grandfathered health plans and insurers to provide coverage, without any cost-sharing or utilization review requirements, for antiretroviral drugs, devices, or products that are either approved by the FDA or recommended by the CDC for the prevention of AIDS/HIV, including PrEP and PEP.

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

6) Specifies that this bill does not apply to a specialized health plan contract or health insurance policy that does not cover an essential health benefit or a Medicare supplement policy.

7) Applies the requirements above to Medi-Cal managed care plans, and regardless of whether or not an antiretroviral drug, device, or product is self-administered.

FISCAL EFFECT: This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) *Author's statement.* According to the author, the HIV epidemic continues to disproportionately affect historically disadvantaged communities in California. Cost and access are two major barriers to lifesaving medications. The only way to end the HIV epidemic is by ensuring effective HIV prevention and treatment reaches all communities, but especially those disproportionately affected by HIV. HIV PrEP and PEP are important for the overall health of many at-risk and historically disadvantaged communities. Under this bill, all grandfathered health insurance policies and health plans would be required to cover both HIV PrEP and PEP without any cost sharing, and in doing so the bill would expand zero-dollar coverage of PrEP to one million Californians who must currently pay out-of-pocket for PrEP. In addition, nongrandfathered health insurance policies and health plans would be required to cover PEP without cost sharing.

2) *Background.* According to the California Department of Public Health (CDPH), from 2016 through 2020, the number of persons in California living with diagnosed HIV infection increased from approximately 133,126 to over 139,000. In 2020, the prevalence rate of diagnosed HIV infection was 348.1 per 100,000 population, compared to 338.7 in 2016 (an increase of 2.8%). From 2016 through 2020, the number of persons in California living with diagnosed HIV infection increased from approximately 133,126 to over 139,000. A June 2022 Health Disparities Report published by CDPH's Office of AIDS states that HIV continues to disproportionately affect many populations. For example, the rate of new HIV diagnoses among Black/African Americans is 4.3 times higher than Whites among men and 5.4 times higher among women. Latinos are also disproportionately affected by HIV with

rates of new diagnoses 2.2 times higher than Whites among men and 1.2 times higher among women. Male-to-male sexual contact (MMSC), including MMSC with injection drug use, accounted for 60% of new HIV diagnoses and 73% of all HIV cases in 2020. Although rates for transgender people are not available, evidence suggests that they are also disproportionately affected by HIV.

PrEP and PEP are effective HIV-prevention strategies. PrEP is a daily pill taken by individuals who do not have HIV to stay HIV negative. PEP is 28-day courses of medicine people take after potential exposure to HIV to prevent infection. PEP must be started within 72 hours after a possible exposure. According to the CDC, PrEP can reduce the risk of contracting HIV from injections by 74% and from sexual activity by up to 99%. It is also a key part of the federal government's plan to reduce new HIV transmissions by 90% by 2030.

3) *CHBRP analysis.* 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 relevant to this bill include:

   a) *Utilization.* At baseline, CHBRP estimates that 130,731 enrollees per year in DMHC-regulated plans and CDI-regulated policies used antiretroviral therapy (ART) with cost sharing. Among these, 49,257 enrollees per year used ART with cost sharing and 97,658 enrollees used ART 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 ART (equal to 132,133 enrollees overall), representing a 1% increase in enrollees using ART overall. On average, enrollees who use ART would obtain 7.7 prescriptions without cost sharing annually, per person. This translates to an overall utilization of 1,016,959 ART prescriptions without cost sharing, postmandate, representing a 1% increase in ART prescriptions.
   b) *Expenditures.* This bill would increase premiums for employers, employees, individuals and families by $157,254,000. Enrollees who will no longer have cost-sharing for the drugs, devices and products described in this bill will have decreased cost sharing of $105,653,000. This bill would increase total net annual expenditures by total net annual $51,601,000 or total net annual 0.0352% for enrollees with DMHC-regulated plans and CDI-regulated policies, excluding DMHC-regulated Medi-Cal. For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there is no impact.
   c) *Benefit Coverage.* At baseline, 100% of enrollees with DMHC- or CDI-regulated health insurance plans/policies would have coverage subject to this bill. Of these, 98.9% have coverage for ART. At baseline, 38.6% of enrollees have coverage for ART that is fully compliant with this bill. Postmandate, 100% of enrollees with coverage subject to this bill would have coverage for ART without cost sharing.
   d) *Medi-Cal.* As of January 1, 2022, outpatient prescription drugs are covered on a fee-for-service basis for all Medi-Cal beneficiaries under the California Department of Health Care Services' Medi-Cal Rx program. Their pharmacy benefit is "carved out" of the

coverage provided by Medi-Cal managed care plans, and therefore, this bill would not impact their benefit coverage.

e) *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).

f) *Covered California – Individually Purchased.* Premiums for enrollees in individual plans purchased through Covered California would increase by 0.0721%, or approximately $14,362,000, in annual expenditures.

g) *Medical Effectiveness.* CHBRP reviewed findings from evidence on the effects of cost sharing and utilization management on ART (including PrEP and PEP) use and adherence for patients with HIV and those at risk of contracting HIV. CHBRP did not review literature on the effectiveness of ART because all ART medications have been approved by the FDA, and the efficacy of ART is well-established. CHBRP found:
   i) Inconclusive evidence on the effect of cost sharing for ART on long-term adherence and viral suppression for people living with HIV; and,
   ii) Insufficient evidence on the effect of cost sharing for ART on health care utilization and health outcomes and on the effect of utilization management for ART health care utilization and health outcomes.

h) *Public Health.* Measurable health outcomes relevant to this bill include adherence to prescribed ART 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 ART 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 ART and sustain linkages to care (1,332), and a subsequent decrease in both short- and long-term adverse health outcomes. The impacts of this bill on disparities related to race or ethnicity, gender, gender identity or sexual orientation, and age are unknown.

i) *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 ART may improve as cost sharing will no longer be a barrier, which could lead to an increase in overall annual utilization. However, this 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 ART will prevent HIV infection and later AIDS-related diseases, the marginal impact of this bill over the existing use of ART cannot be quantified. Additionally, the vast array of AIDS-related diseases that could occur and would be prevented cannot be quantified, but in general, prevention of these conditions and their associated costs would provide an offset to CHBRP's estimated premium increases due to this bill. The long-term public health impacts of this bill are likely to include a reduction in future HIV transmissions, increased uptake and adherence to ART, as well as a reduction in downstream effects such as impacts on premature death.

j) *Essential Health Benefits.* This bill does not exceed essential health benefits.

4) *Covered California Standard Plan Designs.* Covered California is California's state based marketplace (or exchange), which was created as a result of the federal ACA. Covered California makes health insurance plans available to purchase for individuals (and families) and small employers. Qualified individuals can also get financial assistance when purchasing individual/family policies through Covered California. State and federal law require plans

sold in the individual and small group market to meet 90/80/70/60% actuarial value (AV) requirements. This means that a platinum plan with 90% AV requires the plan to pay on average 90% of the cost of covered benefits and the enrollee pays 10% in the form of cost-sharing. These tend to be higher cost premium plans with the lowest cost-sharing requirements. On the other end, a bronze plan has a 60% AV which means the plan pays on average 60% of costs of covered benefits and the enrollee pays 40% in the form of cost-sharing. Bronze are typically the lowest cost premium plans but have the highest enrollee cost-sharing. There is some room allowance, referred to as de minimis range, which allows designs to fall a little outside the AV ranges but beyond that the products that fall outside of the AV requirements cannot be sold.

Covered California indicates that legislation, such as this bill, that limits cost-sharing for specific drugs or medical services could impact Covered California's ability to set standard benefit designs, which also impact individual and small group products offered outside of Covered California. *Reducing the cost-sharing for one benefit could result in higher cost-sharing for other benefits.* To illustrate how this works using the Silver 70 AV product from 2023, when the exact same plan design was run through the 2024 AV calculator (a federal instrument that is updated annually to reflect medical, pharmacy, and other trends), Covered California, with the consultation of their plan management advisory committee, decided on the following cost-sharing requirements for 2024:

a) Increased medical deductible by $650 (from $4750 to $5400)
b) Increased drug deductibles by $65 (from $85 to $150)
c) Increased maximum out of pocket by $350 (from $8,750 to $9,100)
d) Increased emergency room copay by $50 (from $400 to $450)
e) Increased copays by $5 for the following services: primary care, mental health and substance use disorder services, speech therapy, occupational and physical therapy, and specialist visits
f) Increased Tier 1 generic drugs by $3 (from $16 to $19) with no deductible
g) Increased outpatient coinsurance to 30% for outpatient facility/physician fees

5) *Related legislation.* SB 339 (Weiner) requires health plans and insurers to cover HIV PrEP and PEP furnished by a pharmacist, including costs for the pharmacist's services and related testing ordered by the pharmacist. Permits a pharmacist to furnish up to a 90-day course of PrEP, or beyond 90-days if specified conditions are met. *SB 339 is set to be heard in this committee on April 26, 2023.*

6) *Prior legislation.* SB 159 (Wiener, Chapter 532, Statutes of 2019) permits pharmacists to furnish a 60-day supply of PrEP and PEP; prohibits health plans and insurers from requiring prior authorization or step therapy for PrEP or PEP; requires coverage of pharmacist-prescribed PrEP and PEP; and, permits Medi-Cal reimbursement for pharmacists prescribing PrEP and PEP.

7) *Support.* California Insurance Commissioner Ricardo Lara writes that on March 30, 2023, a federal judge in Texas struck down national protections for preventive care benefits under the federal Affordable Care Act in Braidwood Management Inc. v. Becerra. Although legal appeals are expected, under this bill, there will be no question that HIV PrEP and PEP and all the necessary care for delivering this life-saving medication will remain covered without cost sharing. The Insurance Commissioner states that as someone who has been committed to fighting for affordable health care and more equitable access to health services during his

time in the California State Legislature and now as Insurance Commissioner, we must ensure that California can continue to provide fair and equal access to preventive care for all, as potential continued changes by some federal courts may attempt to curtail access to these essential services.

8) *Opposition.* The California Association of Health Plans, the Association of California Life and Health Insurance Companies, and America's Health Insurance Plans submitted a joint letter expressing opposition to 23 health insurance mandate bills that are before the Legislature this year, stating that these bills include mandates for health plans and insurers to cover specific services, as well as bills that eliminate cost sharing and limit utilization management, which have similar cost impacts as coverage mandates. Moreover, they will increase costs, reduce choice and competition, and further incent some employers and individuals to avoid state regulation by seeking alternative coverage options.

9) *Policy Comment*. This is another Senate Bill with cost-sharing limitations that the committee will be hearing, and there are at least seven Assembly Bills. Each bill on its own may or may not impact AV issues but together, there most definitely is an impact. As Covered California indicates, there are tradeoffs that come with bills that impose cost-sharing restrictions. Specifically, other equally important services may have higher cost-sharing requirements applied to offset the impacts of these bills. Policymakers should understand and be comfortable with these tradeoffs as these bills are being evaluated.

SUPPORT AND OPPOSITION:

Support: California Insurance Commissioner Ricardo Lara (sponsor)
California Academy of Family Physicians
Hemophilia Council of California

Oppose: Association of California Life and Health Insurance Companies
America's Health Insurance Plans
California Association of Health Plans
California Chamber of Commerce

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