Date of Hearing: July 11, 2023

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
SB 427 (Portantino) – As Amended June 13, 2023

SENATE VOTE: 33-1

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

SUMMARY: Prohibits a nongrandfathered or grandfathered health plan contract or health insurance policy from imposing any cost-sharing or utilization review (UR) requirements for antiretroviral drugs, devices, or products (ARVs) that are either approved by the United States Food and Drug Administration (FDA) or recommended by the federal Centers for Disease Control and Prevention (CDC) for the prevention of human immunodeficiency virus (HIV)/ acquired immunodeficiency syndrome (AIDS). Prohibits a health plan or health insurer from subjecting ARVs that are either approved by the FDA or recommended by the CDC for the prevention HIV/AIDS, to prior authorization or step therapy, but authorizes prior authorization or step therapy if at least one therapeutically equivalent version is covered without prior authorization or step therapy and the insurer provides coverage for a noncovered therapeutic equivalent antiretroviral drug, device, or product without cost sharing pursuant to an exception request. Specifically, **this bill**:

1) Prohibits a health plan or insurer from subjecting ARVs that are either approved by the FDA or CDC for HIV/AIDS prevention, including pre-exposure prophylaxis (PrEP) and postexposure prophylaxis (PEP), to prior authorization or step therapy, except as specified in 2) below.

2) Permits a health plan or insurer not 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 or insurer provides coverage for a noncovered therapeutic equivalent ARVs without cost sharing pursuant to an exception request.

3) Requires a nongrandfathered health plan contract or insurance policy to provide coverage for, and prohibits imposing any cost-sharing or UR requirements for, ARVs that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including PrEP or PEP.

4) Requires a plan contract or insurance policy that is a grandfathered health plan or insurer to provide coverage, and prohibits from imposing any cost-sharing or utilization review requirements, for ARVs that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including PrEP or PEP.

5) Requires a health plan or insurer to provide coverage under the outpatient prescription drug benefit for ARVs that are either approved by the FDA or recommended by the CDC for the prevention of HIV/AIDS, including by supplying providers directly with a drug, device, or product and is not self-administered, in addition to the coverage a health care service plan provides for prescription drugs that are not self-administered.

6) Exempts specialized health plan contracts or insurance policies that covers that covers only dental or vision benefits or a Medicare supplement contract from the provisions of this bill. Applies the provisions of this bill to Medi-Cal managed care plans that contracts with the Department of Health Care Services.

7) Applies the provisions of this bill regardless of whether or not an antiretroviral drug, device, or product is self-administered.

8) Authorizes the California Department of Insurance (CDI) and CDI Commissioner to implement and enforce this bill, as specified.

9) Requires a health plan contract or insurance policy that is a high deductible health plan (HDHP) under federal law to comply with the cost-sharing requirements of this bill unless the application conflicts with HDHP's federal requirements, and if so, applies the cost-sharing limits once a contract's deductible has been satisfied for the plan year.

EXISTING LAW:

1) Establishes the Department of Managed Health Care (DMHC) to regulate health plans under the Knox-Keene Health Care Service Plan Act of 1975 and CDI to regulate health insurers. [Health and Safety Code (HSC) §1340, *et seq*., and Insurance Code (INS) §106, *et seq*.]

2) Establishes as California's essential health benefits (EHBs) benchmark under the Patient Protection and Affordable Care Act (ACA), the Kaiser Small Group Health Maintenance Organization plan, existing California health insurance mandates, and the 10 ACA mandated benefits, including prescription drug coverage. [HSC §1367.005 and INS §10112.27]

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 States Preventive Services Taskforce 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]

4) Requires health plans and insurers to provide coverage for home test kits for sexually transmitted diseases (STDs), as defined, and the laboratory costs for processing those kits, that are deemed medically necessary or appropriate and ordered directly by a health care provider or furnished through a standing order for patient use based on clinical guidelines and individual patient health needs. [HSC §1367.34 and INS §10123.208]

5) Defines "basic health care services" as all of the following:
   a) Physician services, including consultation and referral;
   b) Hospital inpatient services and ambulatory care services;
   c) Diagnostic laboratory and therapeutic radiologic services;
   d) Home health services;
   e) Preventive health services;
   f) Emergency health care services, including ambulance and ambulance transport services and out-of-area coverage. Basic health care services includes ambulance and ambulance transport services provided through the 911 emergency response system; and,
   g) Hospice care, as specified. [HSC §1345]

6) Requires the criteria or guidelines used by health plans and insurers, or any entities with which plans or insurers contract for UR or utilization management (UM) functions, to determine whether to authorize, modify, or deny health care services to:
   a) Be developed with involvement from actively practicing health care providers;
   b) Be consistent with sound clinical principles and processes;
   c) Be evaluated, and updated if necessary, at least annually;
   d) If used as the basis of a decision to modify, delay, or deny services in a specified case under review, be disclosed to the provider and the enrollee or insured in that specified case; and,
   e) Be available to the public upon request. [HSC §1363.5 and INS §10123.135]

7) Authorizes a health plan or insurer that provides coverage for prescription drugs to require step therapy if there is more than one drug that is clinically appropriate for the treatment of a medical condition. [HSC §1367.206 and INS §10123.201]

8) Requires a health plan or insurer to expeditiously grant a request for a step therapy exception within the applicable time limit if a prescribing provider submits necessary justification and supporting clinical documentation that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services, taking into consideration the enrollee's or insured's needs and medical history. Permits the basis of the provider's determination to include, but not be limited to, any of the following criteria:

   a) The prescription drug required by the plan or insurer is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm in comparison to the requested prescription drug;
   b) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee or insured and the known characteristics and history of the enrollee's or insured's prescription drug regimen;
   c) The enrollee or insured has tried the required prescription drug while covered by their current or previous health coverage or Medicaid, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction. Permits the plan or insurer to require the submission of documentation demonstrating that the enrollee or insured tried the required prescription drug before it was discontinued;
   d) The required prescription drug is not clinically appropriate for the enrollee or insured because the required drug is expected to do any of the following, as determined by the prescribing provider:
      i) Worsen a comorbid condition;
      ii) Decrease the capacity to maintain a reasonable functional ability in performing daily activities; or,
      iii) Pose a significant barrier to adherence to, or compliance with, the enrollee or insured's drug regimen or plan of care.
   e) The enrollee or insured is stable on a prescription drug selected by the prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid. [HSC §1367.206 and INS §10123.201]

9) Authorizes a health care provider or prescribing provider, enrollee, insured, or their designee or guardian to appeal a denial of an exception request for coverage of a nonformulary drug,

prior authorization request, or step therapy exception request consistent with the plan's or insurer's current UM process. [HSC §1367.206 and INS §10123.201]

10) Prohibits a health plan or insurer from subjecting antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including PrEP or PEP, to prior authorization or step therapy. Permits a health plan or insurer not 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, if the FDA has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV. Limits coverage to a 60 day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber. [HSC §1342.74, INS §10123.1933]

FISCAL EFFECT: According to the Senate Appropriations Committee,

1) DMHC estimates minor and absorbable costs to administer the provisions;

2) CDI estimates no fiscal impact from administering the provisions; and,

3) The California Health Benefits Review Program (CHBRP) estimates an increase in CalPERS employer premiums of $4,664,000.

COMMENTS:

1) PURPOSE OF THIS BILL. 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. The author states that 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, this bill would expand zero-dollar coverage of PrEP to one million Californians who must currently pay out-of-pocket for PrEP. In addition, the author concludes that non-grandfathered health insurance policies and health plans would be required to cover PEP without cost sharing.

2) BACKGROUND. According to CHBRP, 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. HIV spreads via direct contact with certain bodily fluids of an individual with a detectable viral load. 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) 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 ARVs – known for inhibiting viral replication and allowing for immune reconstitution. Given the availability of ARVs, it is possible for people living with HIV to achieve a life expectancy similar to that of the general population.

a) Antiretrovirals for Prevention of HIV/AIDS. 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. PrEP and PEP are an essential part of the HIV prevention toolbox, which also includes education, needle exchanges, and condom programs. Both strategies involve using ARVs to abort the establishment of chronic HIV infection. 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 a larger HIV treatment regimen.

b) HIV Prevalence. Ongoing Department of Public Health (DPH) HIV surveillance over the years indicates promising progress in the reduction of new HIV infections as part of a broader nationwide initiative launched by the U.S. Department of Health and Human Services in 2019. California witnessed declines in both the annual number and rate of new HIV diagnoses over a four year period. From 2016 to 2020, the number of new HIV diagnoses declined by approximately 23% – from 5,140 in 2016 to 3,965 in 2020. Similarly, the rate of new diagnoses per 100,000 population declined by approximately 24%, from 13.1 to 9.9% during the same period. During the same 4-year period (2016 to 2020), the number of persons living with HIV increased in California – from approximately 133,000 to more than 139,000 – indicating the effectiveness of initiating and sustaining ARV use.

According to CHBRP, this bill requires health plans and insurers to provide coverage for FDA-approved ARVs. Health plans would not need to cover all therapeutically equivalent versions without prior authorization or step therapy (i.e. UM techniques) if they provide coverage for a noncovered therapeutic equivalent ARVs drug/device/product without cost sharing. For nongrandfathered and grandfathered plans, this bill prohibits cost sharing and UM for FDA-approved or CDC-recommended ARVs drugs, devices, or products. It should be noted that at the time of CHBRP's analysis, there are no FDA-approved or CDC-recommended antiretroviral devices or products. As such, CHBRP's analysis below focuses only on antiretroviral drugs.

c) 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. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on EHBs, and legislation that impacts health insurance benefit designs, cost sharing, premiums, and other health insurance topics. CHBRP states the following in its analysis:

- **i) Enrollees covered.** At baseline, 100% (22,842,000) 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 ARVs. At baseline, 38.6% of enrollees have coverage for ARVs that is fully compliant with this bill. Postmandate,100% of enrollees with coverage subject to this bill would have coverage for ARVs without cost sharing. Although the benefit coverage for beneficiaries with DMHC-regulated Medi-Cal plans is subject to this bill, their pharmacy benefit is carved out and administered under Medi-Cal Rx, and therefore, this bill would not impact their benefit coverage. 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.

ii) **Impact on expenditures.** This bill 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.
   (1) Medi-Cal. For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there is no impact.
   (2) 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).
   (3) Number of Uninsured in California. Since the change in average premiums does not exceed 1% for any market segment, CHBRP expects no measurable change in the number of uninsured persons due to this bill.

iii) **EHBs.** This bill does not exceed EHB's 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.

iv) **Medical effectiveness.** CHBRP reviewed findings from evidence on the effects of cost sharing and UM on ARVs (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 ARVs because all ARVs have been approved by the FDA, and the efficacy of ARVs is well-established. CHBRP found the following:
   (1) Inconclusive evidence on the effect of cost sharing for ARVs (including PrEP and PEP) on long-term adherence and viral suppression for people living with HIV.
   (2) Insufficient evidence on the effect of cost sharing for ARVs (including PrEP and PEP) on health care utilization and health outcomes; and,
   (3) Insufficient evidence on the effect of UM for ARVs (including PrEP and PEP) health care utilization and health outcomes.

v) **Public health.** Measurable health outcomes relevant to this bill 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. The impacts of this bill 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 UM on ARVs utilization among newly covered enrollees.

vi) **Long-term impacts**. According to CHBRP, the utilization increases estimated in this analysis 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. 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 this bill 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 this bill. The long-term public health impacts of this bill 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.

3) **SUPPORT**. CDI Commissioner Ricardo Lara, sponsor, writes that the HIV epidemic continues to disproportionately impact historically disadvantaged communities in California. In addition, cost and access are two major barriers to lifesaving medications. DPH's 2020 Health Disparities Report found the following: Black/African Americans are the most disproportionately affected by HIV making up 17% of California's HIV positive population, but only around 6% of California's total population; and, Latinx people make up the largest racial/ethnic group among new HIV diagnoses, accounting for 50% of all new HIV diagnoses, but only around 40% of California's population. Transmission by male-to-male sexual contact, including male-to-male sexual contact and injection drug use, make up the majority of the HIV positive population in California, accounting for 60% of new HIV diagnoses and 73% of all living HIV cases in 2020. In California, rates of HIV infection among transgender people are unknown, but transgender women are among the groups most affected by HIV. Nationally, HIV prevalence among transgender people is around 9.2%. Prevention efforts have been frustrated by, in part, limited access to health coverage. Health coverage plays a major role in enabling people to access health care and protecting families from high medical costs. Persons of color have faced longstanding disparities in health coverage that contribute to disparities in health. Persons from racial and ethnic groups are more likely to be uninsured compared to non-Hispanic whites, limiting their access to health care. CDI concludes that other barriers to health care access include lack of transportation and childcare, inability to take time off work, experiences with housing instability or homelessness, communication and language barriers, racism, discrimination, and lack of trust in health care providers.

4) **OPPOSITION**. The California Association of Health Plans (CAHP), the Association of California Life and Health Insurance Companies (ACLHIC), and America's Health Insurance Plans (AHIP) write that state mandates increase costs of coverage – especially for families who buy coverage without subsidies, small business owners who cannot or do not wish to self-insure, and California taxpayers who foot the bill for the state's share of those mandates. When considering the forthcoming analyses from CHBPR on these bills, CAHP, ACLHIC, and AHIP urge legislators to also consider the cumulative impacts that these mandates may have on premiums and access to coverage. All of these bills will increase costs and limit flexibility for employers. Faced with higher costs, employers must make difficult decisions about whether to absorb premium increases or seek alternative coverage options.

5) RELATED LEGISLATION.

a) SB 339 (Wiener) requires a health plan and health insurer to cover PrEP and PEP furnished by a pharmacist, including costs for the pharmacist's services and related testing ordered by the pharmacist. Includes PrEP furnished by a pharmacist as pharmacist services on the Medi-Cal schedule of benefits. Authorizes a pharmacist to furnish up to a 90 day course of PrEP, or beyond a 90 day course (existing law allows for a 60 day supply), if specified conditions are met. SB 339 is pending in Assembly Committee on Business and Professions.

b) AB 317 (Weber) requires a health plan and disability insurers that offer coverage for a service that is within the scope of practice of a duly licensed pharmacist to pay or reimburse the cost of services performed by a pharmacist at an in-network pharmacy or by a pharmacist at an out-of-network pharmacy if the health care service plan or insurer has an out-of-network pharmacy benefit. AB 317 is pending in the Assembly Floor.

c) AB 1645 (Zbur) prohibits a group or individual health plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2024, from imposing a cost-sharing requirement for office visits for preventive care services and screenings and for items or services that are integral to their provision. Prohibits contracts and policies from imposing a cost-sharing requirement, UR, or other specified limits on a recommended sexually transmitted infections screening, and from imposing a cost-sharing requirement for any items and services integral to a sexually transmitted infections screening, as specified. AB 1645 is pending in Senate Health Committee.

6) PREVIOUS LEGISLATION.

a) SB 306 (Pan), Chapter 486, Statutes of 2021, permits pharmacists to dispense a drug, without the name of an individual for whom the drug is intended, when prescribed for the sexual partner of someone who has been diagnosed with a STD; prohibits health care providers who prescribe, dispense, or furnish such a drug from being subject to, civil, criminal, or administrative penalties, as specified; requires a syphilis blood test, during the third trimester of pregnancy and at delivery, as specified; requires public and commercial health coverage of home STD test kits; and adds rapid STD tests to existing law which permits HIV counselors to perform rapid HIV and hepatitis C tests.

b) SB 159 (Wiener), Chapter 532, Statutes of 2019, authorizes a pharmacist to initiate and furnish HIV PrEP and PEP, as specified.

7) AUTHOR AMENDMENT. To address concerns regarding implementation, the author wishes to amend this bill as follows: Paragraph (1) and (2) shall apply to individual and small group contracts issued, amended, delivered, or renewed on or after January 1, 2025.

REGISTERED SUPPORT / OPPOSITION:

Support

Insurance Commissioner Ricardo Lara (sponsor)

California Department of Insurance
American College of Obstetricians and Gynecologists District IX
Equality California
Health Access California
Los Angeles LGBT Center

Opposition

America's Health Insurance Plans
Association of California Life & Health Insurance Companies
California Association of Health Plans
California Chamber of Commerce

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