SENATE COMMITTEE ON HEALTH
Senator Dr. Akilah Weber Pierson, Chair

BILL NO: SB 1023
AUTHOR: Laird
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SUBJECT: Health care coverage: antiretroviral drugs, drug devices, and drug products

SUMMARY: Adds, to an existing health plan and insurer prohibition on prior authorization and step therapy for medically necessary HIV/AIDS antiretroviral drugs, drug devices or drug products. Requires coverage of preexposure prophylaxis or postexposure prophylaxis provided by an out-of-network pharmacy in the case of an emergency; and, requires a health plan or insurer that covers non-self-administered antiretroviral drugs, drug devices, or drug products that are approved by the federal Food and Drug Administration for the prevention of HIV/AIDS as a medical benefit to also include those same drugs, devices, and products as an outpatient prescription drug benefit.

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; and the Department of Health Care Services (DHCS) to administer the Medi-Cal program. [HSC §1340, et seq., INS §106, et seq., 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 preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP, to prior authorization or step therapy, except that if the federal Food and Drug Administration (FDA) approves one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, health plans 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)]

3) 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)]

4) 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, 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)]

5) Exempts health plans and insurers from covering 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)]

6) Exempts Medi-Cal managed care plans from 2) through 5) 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)]

7) Establishes the California Department of Public Health (CDPH) to administer a variety of public health programs (HSC §131000, et Seq.)

This bill:
1) Adds drug devices, or drug products to an existing prohibition on plans and insurers from requiring prior authorization or step therapy under specified circumstances.

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

3) Requires a health plan contract or insurance policy issued, amended, or renewed on or after January 1, 2027, that covers non-self-administered antiretroviral drugs, drug devices, or drug products approved by the FDA for the prevention of HIV/AIDS as a medical benefit, to also include those non-self-administered antiretroviral drugs, drug devices, or drug products that are approved by the FDA for the prevention of HIV/AIDS as an outpatient prescription drug benefit.

4) Exempts specialized health plan contracts or insurance policies that cover only dental, mental health, or vision benefits, and Medicare supplement contracts and policies.

5) Applies the law regardless of whether an antiretroviral drug, drug device, or drug product is self-administered.

6) Authorizes CDI to exercise the authority provided in law and the Administrative Procedures Act (APA) as specified, to implement and enforce this bill and the law it amends. Permits a hearing requested by an insurer when a penalty is assessed to be conducted by an administrative law judge or the administrative hearing bureau of CDI under specified procedures. States that this does not impair or restrict the CDI Commissioner's authority pursuant to another provision of the law or the APA.

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

COMMENTS:
1) *Author's statement.* According to the author, this bill increases access to HIV PrEP by requiring health plans that already cover the medication to offer reimbursement through their outpatient prescription drug benefit pathway. PrEP is a highly effective clinical strategy that uses antiretroviral medication to prevent HIV-negative individuals from acquiring the virus. Currently, plans may restrict reimbursement for PrEP to the medical benefit pathway. Medical benefit billing is often unsustainable for smaller healthcare providers due to administrative and financial barriers. This bill allows healthcare providers to secure timely reimbursement, increasing access to HIV PrEP for patients who receive care at small local clinics. Given the current volatility of federal grants, structural adjustments to the reimbursement process are necessary to ensure California's public health infrastructure supports HIV prevention efforts.

2) *California Health Benefits Review Program (CHBRP) report.* CHBRP was created in response to AB 1996 (Thomson, Chapter 795, Statutes of 2002) requests the University of California to assess legislation proposing a mandated health insurance benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plans and health insurance benefit mandate legislation. CHBRP published a report last year for a similar but more expansive bill (AB 554, Mark González of 2025). Findings that are relevant to this bill are summarized below.
   a) *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 people living with HIV increased in California from approximately 136,100 to more than 142,700 — indicating the effectiveness of initiating and sustaining antiretroviral use.
   b) *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.
   c) *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.
   d) *Other relevant background.* Under the Affordable Care Act (ACA) and California law, nongrandfathered health plans are required to cover preventive services, without cost-sharing, that have been graded A and B from the United States Preventive Services Task Force (USPSTF). USPSTF currently has a Grade A recommendation for the prescription of PrEP with effective antiretroviral therapy to decrease the risk of acquiring HIV in adolescents and adults who do not have HIV and are at increased risk of contracting the virus. There is also a PrEP Assistance Program in CDPH, Office of AIDS which provides services at no cost, including antiretroviral drugs (PrEP and PEP), testing for HIV, and PrEP-related office visits. There is also an AIDS Drug Assistance Program which provides free FDA-approved medications for the treatment and suppression of HIV/AIDS and HIV/AIDS-related infections, and health insurance premium assistance. There are eligibility requirements for these state programs.
   e) *HIV/AIDS.* HIV attacks cells in the body that are integral to the body's immune function and if undiagnosed and untreated, HIV leads to opportunistic infections, cancers and

death. HIV can progress to acute HIV diseases, chronic HIV infection, and AIDS. There is no cure for HIV/AIDS but with routine care and proper treatment, HIV-related morbidity and mortality can be prevented through antiretroviral therapy.

f) *Antiretroviral therapy:* 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. Sustained HIV treatment reduces a person's viral load, or the amount of HIV in their blood. It is possible for HIV treatment to make the viral load so low that it is undetectable. People with an undetectable viral load will not transmit HIV to others through sex. Furthermore, undetectable viral loads reduce the risk of HIV transmission through sharing drug injection equipment, and during pregnancy, labor, and delivery.
   i) PrEP is a long-term regimen, 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.
   ii) PEP is a short-term, daily therapy 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 also reduces the progression of the virus to AIDS and reduces mortality and morbidity of AIDS.
   iii) The average annual cost of antiretrovirals is $19,318.

g) *Medical vs. Pharmacy*. In general, drugs that are physician-ordered and administered under the supervision of a physician (generally in a hospital, a provider's office, infusion center, or similar medical facility), along with the hospital stay or office visit, are generally covered through the medical benefit. Pharmacy benefits typically cover outpatient prescription drugs by covering prescriptions that are generally filled at a retail pharmacy, a mail-order pharmacy, or a specialty pharmacy. The majority of antiretroviral drugs are covered under the pharmacy benefit. However, long-acting injectable antiretroviral drugs, such as cabotegravir and lenacapavir, are typically covered under the medical benefit.

2) *Medi-Cal.* Long-acting PrEP injectables (both cabotegravir and lenacapavir) are covered under both the fee-for-service pharmacy benefit (Medi-Cal Rx) and medical benefit directly through the Department's Medi-Cal Fiscal Intermediary, the California Medicaid Management Information System (CA-MMIS), because as of January 1, 2021, HIV/AIDS drugs are carved-out of all Medi-Cal managed care plans.

3) *Prior legislation.* AB 554 (Mark González of 2025) would have prohibited nongrandfathered (established by the ACA) health plans and insurance policies from imposing any cost-sharing for antiretroviral drugs, devices, or drug products that are approved by the federal FDA for PrEP, and would have applied this bill and the law it amends to an antiretroviral drug, drug device, or drug product regardless of whether it is self-administered. *AB 554 was vetoed by the Governor, who wrote: I wholeheartedly support efforts to ensure affordable and accessible prevention and treatment of HIV/AIDS, and I share the author's desire to address politically motivated changes to long-standing preventive services requirements by the current hostile federal administration. This year's budget specifically codified the January 1, 2025, recommendations made by the USPSTF for*

no-cost share preventive services - ensuring the prior federal administration's guidelines are a matter of state law. As a result, CDPH now has the explicit authority to modify or supplement these baseline guidelines based on recommendations and guidance from medical and scientific organizations.

However, certain components of this measure raise concerns about affordability. By exceeding the cost-sharing provisions under the ACA, this bill would result in increased costs to health plans, which would then be passed on to consumers. At a time when individuals are facing double-digit rate increases in their health care premiums across the nation, the state must weigh the potential benefits of all new mandates against the comprehensive costs to the entire health care delivery system.

AB 144 (Committee on Budget, Chapter 105, Statutes of 2025) establishes a list of immunizations, items, and services recommended by the USPSTF, the Advisory Committee on Immunization Practices, and the Health Resources and Services Administration, in effect on January 1, 2025, as baseline recommendations for California, and gives CDPH authority to modify or supplement those baseline recommendations in consultation with medical and scientific organizations, including the American Academy of Pediatrics, the American College of Obstetricians and Gynecologists, and the American Academy of Family Physicians.

SB 427 (Portantino of 2024) was similar to AB 554 but did not include therapeutic equivalence of long-acting injectable drugs. *SB 427 was held in the Assembly at the request of the author.*

4) *Support.* The Los Angeles LGBT Center, one of this bill's cosponsors and a Federally Qualified Health Center specializing in HIV/AIDS specialty care, cites statistics indicating that uptake of HIV prevention among Black and Latine gay, bisexual, and same gender loving cisgender men and transgender women remains low despite innovations in treatment. According to this cosponsor, "commercial health plans and insurance policies cover PrEP through two pathways: the "medical benefit" and the "pharmacy benefit," also known as the "outpatient prescription drug benefit." For the purposes of provider reimbursement, the medical benefit typically requires providers to purchase drugs upfront, administer them to a covered patient, and then seek reimbursement after the fact. In contrast, the pharmacy benefit is adjudicated at the point of sale—coverage and reimbursement are calculated near instantaneously, and reimbursement is typically paid faster than claims made under the medical benefit. When injectable PrEP is only covered under the medical benefit, many providers are unable to offer it—particularly those that lack the resources to purchase medications upfront and seek reimbursement. As a result, patients are left with fewer options to access the modality that works best for them." The San Francisco AIDS Foundation, also a cosponsor, writes supporting providers by enabling them to choose the best billing pathway for their operations, and patients' needs, can help reduce these disparities in HIV diagnoses and inequities in health care delivery. Cosponsors believe this bill will remove one more barrier to PrEP access. California Life Sciences believes this bill expands protections beyond antiretroviral drugs to also cover devices and drug products used for HIV prevention, ensuring that emerging treatment modalities are not excluded on a technicality, and it blocks pharmacy benefit managers from blocking pharmacists from dispensing PrEP or PEP.

5) *Support if amended.* The California Pharmacists Association (CPhA) writes that pharmacy benefit managers frequently reimburse pharmacies below their cost of acquisition,

particularly for high-cost therapies, and ensuring fair and sustainable reimbursement is fundamental to achieving the goals of this bill. CPhA requests the author consider amendments that ensure pharmacies are reimbursed at or above their cost of acquisition for these medications.

6) *Opposition.* The California Association of Health Plans (CAHP) and the Association of Life & Health Insurance Companies (ACLHIC) indicate that they are already required to cover antiretroviral drugs for the prevention of HIV/AIDS without step therapy or prior authorization, as required under state law. They write this bill establishes a troubling precedent by directing how health plans and insurers structure their benefit designs, an area that has traditionally been within their purview based on clinical care guidelines, actuarial considerations, and regulatory standards. According to CAHP/ACLHIC, this bill requires plans and insurers to categorize certain provider-administered drugs as outpatient prescription drug benefits, despite that they are not self-administered and are delivered in clinical settings, and reclassifying these drugs in this manner is inconsistent with long industry standards and could create operational and administrative challenges.

7) *Policy comments.*
   a) Background provided by the author indicates that a break-through long-acting PrEP injectable taken twice-yearly was recently approved by the FDA and additional formulations are expected to reach the market in coming years. The author indicates these products are promising for patients facing barriers to accessing treatment due to stigma, housing instability, or treatment fatigue. The author also states that these typically physician-administered products are expensive and create inventory issues for smaller community-based providers which is why this bill is requiring plans and insurers to cover these products under a pharmacy benefit where the patient can obtain the injectable through a specialty pharmacy or as a medical benefit through their clinic or providers' office, if available.

   b) While the author has indicated this bill is not intended to be a new coverage mandate or require health plans or insurers to create a new pharmacy benefit where one does not already exist, **c**overage of PrEP for out-of-network pharmacy in the case of a medical emergency is likely an expansion as PEP is clearly considered an emergency treatment, but PrEP is not. Furthermore, it may be unnecessary and redundant to include PEP as plans are already required to cover out-of-network emergency treatment.

SUPPORT AND OPPOSITION:

Support: APLA Health (cosponsor)
California Insurance Commissioner Ricardo Lara (cosponsor)
Equality California (cosponsor)
Los Angeles LGBT Center (cosponsor)
San Francisco AIDS Foundation (cosponsor)
Access Reproductive Justice
Access Support Network
Bienestar Human Services
California Legislative LGBTQ Caucus
California LGBTQ+ Health and Human Services Network
California Life Sciences
California Medical Association
Casita Feliz Latine LGBTQ+ Center

Courage California
El/La Para Translatinas
Essential Access Health
Gender Affirming Professionals
Gender Alchemy
GLIDE
Health Access California
HealthRIGHT 360
Lyon-Martin Community Health Services
National Health Law Program
Rainbow Families Action Bay Area
Somos Familia Valle
Sunburst Projects
The TransLatin@Coalition
ViiV Healthcare Company
Four individuals

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

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