Date of Hearing: June 30, 2026

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
SB 1094 (Weber Pierson) – As Amended April 8, 2026

SENATE VOTE: 38-0

SUBJECT: Prescription drugs.

SUMMARY: Authorizes health plans and insurers, upon 30 days' notice to enrollees, insureds, and prescribing providers, to require enrollees/insureds currently prescribed a drug or biological product to try a generic or biosimilar when available at the same or lower cost-sharing unless the prescribing provider indicates not to substitute. Authorizes a pharmacist to substitute a reference product with a biosimilar when available to the patient at the same or lower cost-sharing unless the prescribing provider indicates not to substitute. Specifically, **this bill**:

1) Authorizes a health plan or insurer to require an enrollee or insured to try an AB-rated generic equivalent of a brand name drug, a biosimilar, or interchangeable biological product of a reference product that was previously approved for coverage by the plan if all of the following conditions are met:

    a) The prescriber has not personally indicated "Do not substitute," or words of similar meaning.

    b) The net cost to the plan or insurer of the substitute is lower than the brand name or reference product.

    c) An enrollee's or insured's cost-sharing is based on the net cost of the drug or biological product.

    d) An enrollee's or insured's cost-sharing is the same or less than the cost-sharing of the brand name drug or reference product.

    e) The plan or insurer provides at least 30 days' advance notice to the enrollee or insured and prescribing provider of a substitution requirement prior to requiring an enrollee or insured to try a substitute.

2) Provides that an enrollee or insured who is required to try a substitute or the enrollee's prescribing provider may request an exception pursuant to existing law.

3) Requires a plan or insurer to provide the Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) with information related to the proportion of prescription substitutions that resulted in reduced cost-sharing as well as information about the factors affecting when an enrollee's or insured's cost-sharing is not reduced and the impact of substitutions resulting from that authority on premiums.

4) Defines "AB-rated generic equivalent" to mean a drug product rated with an AB code in the Approved Drug Products with Therapeutic Equivalence Evaluations published by the United States Food and Drug Administration (FDA).

5) Defines "biosimilar," "biological product," "interchangeable biological product," and "reference product" as having the same meaning as those terms are used in federal law.

6) Authorizes a pharmacist filling a prescription order for a prescribed biological product to select an alternative biological product that is biosimilar to the prescribed reference product that has not been determined to be interchangeable by the FDA.

7) Updates the requirement that the Board of Pharmacy (BOP) post a link on its website to the current list of biological products determined by the FDA to be interchangeable to require a link to the FDA's Purple Book Database of Licensed Biological Products.

EXISTING LAW:

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

2) Prohibits a health plan contract from limiting or excluding coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's condition. Does not preclude the prescriber from prescribing another covered drug that is medically appropriate or a generic substitution. Does not apply to off-label use of drugs. Does not prohibit a health plan from charging a subscriber or enrollee a copayment or a deductible for prescription drug benefits or from setting forth, by contract, limitations on maximum coverage of prescription drug benefits. [HSC § 1367.22]

3) Requires health plans to maintain an expeditious process by which the prescribing provider may obtain authorization for a medically necessary nonformulary prescription drug, except the process is not required for nonformulary drugs that have been prescribed pursuant to 2) above. [HSC § 1367.24 and INS § 110123.193]

4) Requires, if a health plan or health insurer that provides coverage for prescription drugs fails to respond to a prior authorization or step therapy exception request, as specified, within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist, upon the receipt of a completed form, the request to be deemed granted. [HSC § 1367.241 and INS § 10123.191]

5) Requires a health plan or insurer to expeditiously grant a request for a step therapy exception within the applicable time limit described in 4) above 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'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]

6) 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 utilization management process. [HSC § 1367.206 and INS § 10123.201]

7) Indicates for purposes of 5) and 6) above, a health plan or insurer or utilization review organization is not prohibited from requiring an enrollee or insured to try an AB-rated generic equivalent, biosimilar or interchangeable biological product before providing coverage for the equivalent branded prescription. This does not prohibit or supersede a step therapy exception request. [HSC § 1367.206 and INS § 10123.201]

8) Requires health plans and insurers to report rate information to DMHC and CDI to also report specified information related to prescription drug pricing. Requires DMHC and CDI to compile specified information into a report that demonstrates the overall impact of drug costs on health care premiums. [HSC § 1367.243 and INS § 10123.205]

9) Establishes the Pharmacy Law which provides for the licensure and regulation of pharmacies, pharmacists, and dangerous drug or device wholesalers, and establishes BOP to enforce the Pharmacy Law. [Business and Professions Code (BPC) § 4000, *et seq.*]

10) Authorizes a pharmacist filling a prescription for a drug product to select a different form of medication with the same active ingredients of equivalent strength and duration of therapy as the prescribed drug when the change will improve the ability of the patient to comply with

the prescribed drug therapy unless the prescriber indicates "Do not substitute." Specifies that the pharmacist assumes the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product using the prescribed form of medication and specifies that there is no liability on the prescriber pursuant to this authority. Requires the patient to be informed that a different form of medication was used and requires the prescription label to include the name of the dispensed drug product. Prohibits substitution between long-acting and short-acting forms of a medication with the same chemical ingredients or between one drug product and two or more drug products with the same chemical ingredients. [BPC § 4052.5]

11) Authorizes a pharmacist, when filling a prescription for a drug product prescribed by its trade or brand name, to select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name. Outlines the same "Do not substitute" specifications, pharmacist discretion specifications, prescriber liability specifications, patient communication specifications, and prescription label specifications in 10) above. Prohibits a pharmacist from substituting if the drug selected substitution costs the patient the same or more than the prescribed drug, including any professional fee charged by the pharmacist. [BPC § 4073]

12) Authorizes a pharmacist filling a prescription for a prescribed biological product to select an alternative biological product if the alternative biological product is interchangeable and if the prescriber does not indicate "Do not substitute" or words of similar meaning. Requires a dispensing pharmacist or their designee to make an entry of the specific biological product provided to the patient within five days of dispensing it, including the name of the biological product and the manufacturer. Requires an entry that can be electronically accessed by the prescriber through various electronic records systems and specifies that entering the information into an electronic records system is presumed to provide notice to the prescriber. Outlines the same "Do not substitute" specifications, pharmacist discretion specifications, prescriber liability specifications, patient communication specifications, and prescription label specifications in 10) above. Outlines the same cost specifications in 11) above. Clarifies that the biological product substitution authority above does not prohibit a disability insurer or health care service plan from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological product. [BPC § 4073.5]

13) Requires BOP to maintain a link on its public internet website to a list of the biological products that the FDA has determined are interchangeable. [BPC § 4073.5]

FISCAL EFFECT: According to the Senate Appropriations Committee, pursuant to Senate Rule 28.8, negligible state costs.

COMMENTS:

1) **PURPOSE OF THIS BILL**. According to the author, a majority of Californians report health care costs rising faster than their income, causing many to delay or avoid care. One driver of rising health insurance premiums is prescription drug spending, which has increased 72% since 2017. Biological products are particularly expensive: though only 5% of prescriptions, they account for about half of all drug spending. The author argues that expanding the use of lower-cost alternatives, like generics and biosimilars, could help reduce pharmaceutical spending and lower insurance premiums. Despite no clinically meaningful differences in safety, purity, or potency, biosimilars are often significantly cheaper than their

reference biologic. Furthermore, competition between biosimilars and brand-name biologics helps drive prices down overall. Despite their potential savings, biosimilars remain underused. The author states that this bill encourages the use of lower cost biosimilars when available by: (1) allowing pharmacists to substitute a reference biologic with a biosimilar unless the prescribing provider indicates otherwise; and (2) allowing health plans to require patients currently using brand-name products to try therapeutically equivalent generics or biosimilars when those alternatives are available at the same or lower cost and the prescriber has not indicated otherwise. The author concludes that as Californians face a health care affordability crisis, addressing underlying cost drivers such as the high price of prescription drugs is an important step toward reducing overall health care costs.

2) **BACKGROUND**. Most pharmaceutical products can be broadly categorized as either small-molecule drugs, which are made from chemicals and are relatively easy to copy, or biological (large-molecule) drugs, which are complex products derived from living organisms like yeast, bacteria, or animal cells. Biological products include monoclonal antibodies, insulin, vaccines, and allergenic products, and are most often used to treat chronic skin diseases, inflammatory bowel diseases, arthritis, kidney conditions, diabetes, and cancer.

   a) **Biosimilars.** Biosimilars are large-molecule biologics that are highly similar to an already approved biological reference product. Like generic drugs, biosimilars are approved through an abbreviated pathway that relies on the FDA's prior approval of a reference biologic. To gain approval as a biosimilar, manufacturers must perform rigorous comparative analysis of the physicochemical and biological functional characteristics of a biosimilar to the reference product and an assessment of immunogenicity (the immune response in the body). The proposed biosimilar product must be shown to have the same mechanism of action as the reference product, the same route of administration, dosage form, and strength as the reference product, and may be licensed only for conditions that have been previously licensed for the reference product. The FDA maintains an online database of all reference products and approved biosimilars, called the Purple Book.

   b) **Interchangeable biologics.** Interchangeable biological products are biosimilars that meet additional FDA criteria such as lack of substantial immunologic adverse reactions or no changes in therapeutic effect from repeated switching. There are currently over 90 biosimilar products approved by the FDA, of which less than half have been approved as interchangeable biological products. According to the FDA, both biosimilars and interchangeable biosimilars meet the same high standard of biosimilarity for approval and are equally as safe and effective as the reference product. Manufacturers must apply for the interchangeable designation, which originally required costly and lengthy clinical "switching studies" to demonstrate that alternating between the biosimilar and the reference product posed no greater risk to safety or efficacy than continued use of the reference product alone. The requirement for switching studies was rescinded in a 2024 draft guidance when the FDA found—through a decade of experience and a 2023 systematic review and meta-analysis—no difference in the safety profiles or immunogenicity rates in patients who were switched between the biosimilar and reference product and those who were not. The FDA states that "the same comparative analytical data that supports a demonstration of biosimilarity can support a demonstration of interchangeability." Additionally, the FDA has advanced legislative proposals for fiscal years 2025, 2026, and 2027 to eliminate the statutory distinction between

biosimilars and interchangeable biosimilars by deeming all approved biosimilars interchangeable. The FDA contends this would better align the U.S.'s licensing approach with other regulatory jurisdictions like the E.U., which does not have an interchangeable designation.

c) **Cost savings from biosimilars.** According to a Department of Health and Human Services (HHS) fact sheet, biologics are a significant driver of prescription drug costs in the U.S., accounting for over half of total U.S. drug spending in 2024 despite comprising just 5% of prescriptions. According to a *KFF* report, retail prescription drug prices are the fastest growing cost in national healthcare expenditures. DMHC reports that prescription drug costs paid by California health plans have increased by 72%, or $6.2 billion, since 2017. One of the primary drivers of these increases is the rising cost of specialty drugs, which in 2024 accounted for 63% of prescription drug spending but make up less than 2% of the total number of drugs dispensed in the state. When drug prices increase, these costs get passed on to employers and health plan enrollees via increased premiums. The 2025 California Health Benefits Survey reports that 36% of large California companies (over 200 employees) report that prescription drug prices contributed "a great deal" to higher premiums, including 63% of companies with 5,000 or more workers.

   Because biosimilars are approved through an abbreviated pathway that avoids the need for as many costly and lengthy clinical trials as the reference product, biosimilars offer considerable cost savings. Since their introduction to the market, biosimilars have generated savings totaling $56.2 billion for both patients and the healthcare system, according to the Association of Accessible Medicines (AAM). Recognizing the potential for cost savings for payors, the Center for Medicare and Medicaid Services' May 2024 Final Rule for Medicare Part D plans authorized Part D sponsors to substitute, upon 30 days' notice, a biosimilar biological product for its reference product on their formularies. This bill aims to adopt the same standard in California.

d) **The California Health Benefits Review Program (CHBRP).** CHBRP was created in response to AB 1996 (Thomson), Chapter 795, Statutes of 2002, which 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. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on essential health benefits (EHBs), and legislation that impacts health insurance benefit designs, cost-sharing, premiums, and other health insurance topics to CHBRP's purview. CHBRP reviewed this bill and included the following impact estimates in their analysis:

   i) **Significant cost savings:** CHBRP estimates SB 1094 would result in approximately 27,400 enrollees being switched from a brand-name reference product to a lower-cost biosimilar, and a $87.7 million reduction in total annual premiums paid by employers and enrollees. Cost-sharing and premiums for individuals switched from a reference product would decrease between $92 and $310 per year depending on market segment.

   ii) **No negative impact on health outcomes:** CHBRP estimates that this bill would have no short-term public health impact because the evidence suggests that the switching of patients to biosimilar prescription drugs does not negatively impact health

outcomes. For this reason, CHBRP concludes that this bill would also have no impact on disparities in health outcomes by gender, race/ethnicity, age, or other determinants. Despite no change in health status, there could be decreased financial burden on enrollees due to a decrease in out-of-pocket costs of prescription drugs.

iii) **Long-term cost savings:** CHBRP anticipates increased competition among biosimilar manufacturers, which may lead to a reduction in net prices for prescription drugs and substitution of lower-cost drugs may become the norm. This could lead to a decrease in prescription drug spending over the long-term and may help alleviate the financial burden on enrollees, especially those with chronic conditions treated with high-cost biologics.

3) **SUPPORT**. The California Association of Health Plans (CAHP) is sponsoring this bill, stating that as the Office of Health Care Affordability moves to enforce a 3.5% spending growth target, it is imperative that we find common sense ways to curb unsustainable costs, while ensuring that patients maintain the highest quality of care. CAHP continues that biosimilars are FDA-approved, safe, and effective alternatives to brand-name biologic drugs, often offering the same clinical results at a fraction of the cost. Current California law, however, restricts the ability of health plans and pharmacists to substitute brand-name biologic drugs with lower cost biosimilars. CAHP argues that this framework was enacted over 25 years ago, long before the current biosimilar market matured, and no longer aligns with federal regulatory standards or modern clinical reality. CAHP notes that in June of 2024 the FDA declared that all biosimilar products and interchangeable biosimilar products meet its rigorous standards for approval for the indications described in product labeling. CAHP concludes that this bill will remove existing barriers by allowing health plans and pharmacies to substitute lower-cost biosimilars for high-cost brand-name biologics, regardless of the "interchangeable" designation. Furthermore, the bill ensures transparency by requiring health plans to provide data to the DMHC demonstrating the resulting consumer affordability benefits.

4) **SUPPORT IF AMENDED.** The California Society of Health System Pharmacists (CSHP) appreciate the intent to broaden access to biosimilars, however this bill, as currently written, risks destabilizing the pharmacy supply chain and undermining patient access. CSHP requests amendments that: (1) protect pharmacies' ability to align dispensing with their contracted acquisition pathways and from being forced to procure products off contract at higher acquisition costs; (2) prevent health plans and pharmacy benefit managers from mandating specific biosimilar National Drug Codes that conflict with pharmacy purchasing contracts; (3) address inventory burden and financial sustainability risks; and, (4) safeguard against anti-competitive effects of vertical integration. CSHP argues that absent these considerations, the bill may inadvertently accelerate pharmacy closures and reduce access to care for the very patients it seeks to protect.

5) **OPPOSITION**. The California Chronic Care Coalition (CCCC) is opposed to this bill, citing concerns about non-medical switching. CCCC notes that when a patient is moved off a stable therapy based on cost, formulary preference, or administrative convenience rather than clinical judgment, the consequences can be dangerous. Even when a replacement product is safe and effective for many patients, CCCC argues that a forced switch can still create delays in care, complications in monitoring, and uncertainty for patients whose conditions require consistency and close physician supervision. CCCC raises a fundamental fairness concern in

the relationship between patients and their health plans. CCCC continues that patients enroll in coverage, pay premiums, satisfy deductibles, and rely on plan approval decisions with the understanding that a treatment that has been approved and is working will remain available absent a true clinical reason to change course. CCCC argues that when state law allows a plan to approve a drug on paper but later redirect the patient to a different product for non-clinical reasons, the practical value of that coverage promise is diminished. CCCC states that in effect, the contract benefit begins to resemble an illusory clause: the patient pays for the security of stable access to a medically necessary therapy, while the plan retains expanded discretion to withhold the very treatment the patient reasonably believed had been secured. CCCC continues that prescribers are in the best position to evaluate whether a patient can safely transition from one product to another, taking into account diagnosis, treatment history, comorbidities, prior adverse events, adherence issues, and the patient's own experience with therapy. CCCC concludes that state policy that makes substitution easier outside that clinical relationship reduces transparency and weakens accountability when problems arise.

6) **OPPOSED UNLESS AMENDED.** The California Rheumatology Alliance (CRA) is opposed to this bill unless it is amended. CRA states that this bill allows insurers to demand that patients switch to a biosimilar or interchangeable product as a condition of coverage, even if they have been stable on a reference product. CRA argues that this switching ignores individual patient history and mandates that physicians spend valuable time navigating prior authorizations to maintain the treatment plan that works. CRA requests amendments that: make pharmacists liable for adverse outcomes when switching occurs, require a 30-day notification from pharmacists to the patient and prescriber when switching medication, only allow for one switch for a patient, and require health plans and insurers to direct 100% of all cost savings to reduce premiums.

7) **DOUBLE REFERRAL.** This bill was heard in the Assembly Business and Professions Committee on June 23, 2026 and passed with a 19-0 vote.

8) **PREVIOUS LEGISLATION**.

   a) SB 621 (Caballero) Chapter 495, Statutes of 2023, authorizes a health plan, health insurer, or utilization review organization to require an enrollee or insured to try a biosimilar drug, as defined, before providing coverage for the branded prescription drug. The bill also clarifies that a requirement to try a biosimilar, generic, or interchangeable drug does not prohibit or supersede a step therapy exception request.

   b) SB 671 (Hill) Chapter 545, Statutes of 2015, authorizes a pharmacist to select an alternative biological product when filling a prescription order for a prescribed biological product if the alternative biological product is interchangeable, costs the same or less than the cost of the prescribed biological product, and the prescriber does not personally indicate "Do not substitute." The pharmacist must notify the patient of any substitution and record the specific biological product provided within 5 days of being dispensed in a manner accessible to the prescriber.

   c) SB 598 (Hill) of 2013 would have authorized pharmacists to substitute an interchangeable biosimilar for a biologic if the prescriber did not indicate "Do not substitute," including a requirement that notification of the substitution be provided. SB 598 was vetoed by Governor Brown, who wrote:

"Senate Bill 598 would effect two changes to our state's pharmacy law. First, it would allow interchangeable "biosimilar" drugs to be substituted for biologic drugs, once these interchangeable drugs are approved by the federal Food and Drug Administration (FDA). This is a policy I strongly support. Second, it requires pharmacists to send notifications back to prescribers about which drug was dispensed. This requirement, which on its face looks reasonable, is for some reason highly controversial. Doctors with whom I have spoken would welcome this information. CalPERS and other large purchasers warn that the requirement itself would cast doubt on the safety and desirability of more cost-effective alternatives to biologics. The FDA, which has jurisdiction for approving all drugs, has not yet determined what standards will be required for biosimilars to meet the higher threshold for "interchangeability." Given this fact, to require physician notification at this point strikes me as premature."

d) AB 1139 (Lowenthal) of 2013 would have authorized a pharmacist to substitute a biosimilar for a biological product if the product is deemed by the FDA to be interchangeable with the biological product. AB 1139 was held in the Assembly Business and Professions Committee.

9) AMENDMENTS. The author committed to take the following amendments in the Business and Professions Committee:

a) Expand the timeline for plans to notify patients and providers of formulary changes from 30 to 60 days. Detail required information to be provided in in patient and provider notifications. Add new reporting to providers on biologics, biosimilars, and interchangeable biosimilars on the formulary.

b) Prohibit a pharmacy benefit manager, health plan, or affiliated entity from requiring utilization of a biosimilar in which they have a financial interest, if there are biosimilars not affiliated with the entity also available.

The author is additionally proposing the following amendments for the committee's consideration:

a) Remove the inclusion of AB-rated generics in the HSC and INS code changes.

b) Add a severability clause.

REGISTERED SUPPORT / OPPOSITION:

Support

California Association of Health Plans (sponsor)
American Federation of State, County and Municipal Employees, AFL-CIO
American GI Forum Education Foundation of Santa Maria, CA
American Muslims for Sustainability
Association of California Life & Health Insurance Companies
Blue Shield of California
California African American Chamber of Commerce
California Hispanic Chambers of Commerce
Clergy & Laity United for Economic Justice

Coalition of LA Probation Unions
Community Church (Oakland)
Corinthian Baptist Church
CVS/Caremark Corporation
Ephesian Baptist Church (Oakland)
First Union Baptist Church
Good News Missionary Baptist Church
Hardesty LLC
Health Access California
Los Angeles Civil Rights Association
Parchester First Baptist Church
Pharmaceutical Care Management Association
Santa Clara County Probation Officers - Local 1587
SEIU California
Shalom International Outreach
The Sperantia Foundation
West Oakland Job Resource Center
Several individuals

Opposition

California Chronic Care Coalition
Osteopathic Physicians and Surgeons of California
U.S. Pain Foundation

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