UNFINISHED BUSINESS

Bill No: SB 1094
Author: Weber Pierson (D)
Amended: 8/19/26
Vote: 21

SENATE BUS., PROF. & ECON. DEV. COMMITTEE: 10-0, 4/6/26
AYES: Wahab, Choi, Archuleta, Arreguín, Caballero, Grayson, Menjivar, Niello, Strickland, Umberg
NO VOTE RECORDED: Smallwood-Cuevas

SENATE HEALTH COMMITTEE: 10-0, 4/22/26
AYES: Weber Pierson, Valladares, Caballero, Durazo, Gonzalez, Grove, Menjivar, Padilla, Pérez, Rubio
NO VOTE RECORDED: Smallwood-Cuevas

SENATE APPROPRIATIONS COMMITTEE: Senate Rule 28.8

SENATE FLOOR: 38-0, 5/18/26
AYES: Allen, Alvarado-Gil, Archuleta, Arreguín, Ashby, Becker, Blakespear, Cabaldon, Caballero, Cervantes, Choi, Cortese, Dahle, Durazo, Gonzalez, Grayson, Grove, Hurtado, Jones, Laird, Limón, McGuire, McNerney, Menjivar, Ochoa Bogh, Pérez, Reyes, Richardson, Rubio, Seyarto, Smallwood-Cuevas, Stern, Strickland, Umberg, Valladares, Wahab, Weber Pierson, Wiener
NO VOTE RECORDED: Niello, Padilla

ASSEMBLY FLOOR: Passed, 8/26/26

**SUBJECT:** Prescription drugs

**SOURCE:** Author

**DIGEST:** This bill requires a health plan or insurer to cover a lower-cost biosimilar if it covers a brand-name biological product. Authorizes health plans and insurers, upon 60 days' notice to enrollees, insureds, and prescribing providers,

to require enrollees/insureds currently prescribed a biological product to try a 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.

*Assembly Amendments* require plans and insurers to cover at least one lower-net-cost biosimilar if they cover a reference product, restrict the ability of a plan or insurer to require an enrollee or insured to try an alternative product in which the entity has a direct or indirect financial interest, and expand regulators' ability to implement plan and insurer reporting requirements. Assembly amendments also bolster and broaden plan and insurer notification requirements to include a detailed 60-day notice requirement before any requirement to try a biosimilar or interchangeable biological product, as specified, as well as a notice by January 15, 2027, of possible pharmacy substitutions based on current formularies.

**ANALYSIS:**

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 (Knox-Keene Act) and the California Department of Insurance (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. This does not preclude the prescriber from prescribing another covered drug that is medically appropriate or a generic substitution. This does not apply to off-label use of drugs. This 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) Establishes the Pharmacy Law which provides for the licensure and regulation of pharmacies, pharmacists, and dangerous drug or device wholesalers, and

establishes the Board of Pharmacy (the Board) to enforce the Pharmacy Law. [Business & Professions Code (BPC) §4000, et seq.]

4) 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]

5) 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 4) 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]

6) 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. [BPC §4073.5]

This bill:

1) Requires health care service plan contracts and health insurance plans that provide prescription drug benefits and maintain one or more drug formularies

that include a reference product to include at least one biosimilar or interchangeable biological product licensed for the same reference product on the formulary if the biosimilar has a lower net cost to the plan than the reference product.

2) Authorizes health plans and insurers to require enrollees who are currently on a prescribed name brand drug or reference biological product to try a therapeutically equivalent generic, biosimilar, or interchangeable biological product to the reference product unless the prescriber has not indicated "Do not substitute."

3) Restricts the authority to require patients try an alternative product to those biological products that have a lower net cost to the plan or insurer and have the same or lower cost-sharing for the enrollee/insured, which must be based on the net cost of the drug or biological product, as defined by CDI and DMHC. Prohibits a plan or insurer from requiring the patient to try a biological product in which the pharmacy benefit manager, health care service plan, insurer, or affiliated entity has a direct or indirect financial interest, if biosimilars not affiliated with these entities are also available.

4) Requires plans or insurers to provide at least 60 days' advance notice to the enrollee/insured and prescribing provider of a requirement to try an alternative product. Clarifies that enrollees/insureds may request exceptions via existing step therapy exceptions or nonformulary drug requests, that the prescription may be reissued by the prescribing provider with "do not substitute" to maintain current coverage without additional authorization, and that health plans or insurers are not issuing or altering prescriptions. Requires the notice to a prescribing provider to indicate the prescribers affected plan enrollees. Clarifies that a plan or insurer may fulfill this requirement through a formulary change notice.

5) Requires plans and insurers, by January 15 2027, to notify the plan's or insurer's prescribing providers of any reference biological product and any biosimilar or interchangeable biological product for that reference product that is already included on the plan formulary and notification that a pharmacist may substitute a biosimilar or interchangeable biological product for the prescribed reference product unless the prescriber indicates "Do not substitute." The notification shall identify any of the provider's enrollees or insureds whose prescribed reference biological product may be subject to that substitution.

6) Requires health plans and insurers, on or before October 1, 2027, as part of the data included in annual prescription drug price reporting, to provide DMHC or CDI with the proportion of prescription substitutions resulting from this bill that result in reduced cost-sharing, information about the factors affecting when an enrollee's or insured's cost-sharing is not reduced, the impact of these substitutions on premiums, and any other related information requested by the regulating department.

7) Amends Pharmacy Law to authorize a pharmacist to select an alternative biological product if the alternative product is biosimilar to or interchangeable with a prescribed reference product.

8) Requires the Board of Pharmacy to maintain a link to the Food and Drug Administration (FDA)'s Database of Licensed Biological Products (the "Purple Book") on its website.

**Background**

According to the author of this bill:

> 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. Biologics are particularly expensive: though only 5% of prescriptions, they account for about half of all drug spending. Expanding the use of lower-cost alternatives, like biosimilars, could help reduce pharmaceutical spending and lower insurance premiums. This bill promotes biosimilar adoption by requiring health plans and insurers to include at least one lower-cost biosimilar on the formulary if they cover a reference product, allowing pharmacists to substitute a biologic with a biosimilar unless otherwise indicated, and allowing health plans to require enrollees to try a generic or biosimilar when available at the same or lower cost unless otherwise indicated. It also requires insurers to report the proportion of substitutions that reduce cost-sharing and the impact on premium growth.

*California Health Benefits Review Program (CHBRP) analysis. Coverage impacts and enrollees covered*. *Medical effectiveness.* There is very strong evidence of no differences in safety or efficacy between biosimilars and their reference biologic, based on FDA regulatory standards. There is also very strong evidence that there is no difference in safety or side effects when switching between reference biologics

and their biosimilar based on 31 randomized control trials and over 15 years of extensive pharmacovigilance data, derived from continuous monitoring of biosimilars after being made available to the public.

a) *Utilization*. CHBRP estimates that 24,700 Californians would be switched from a brand name reference product to a lower-cost biosimilar, and that the impact of small molecule drug switches would be negligible due to high rates of switching already.
b) *Medi-Cal.* Although Medi-Cal pharmacy benefits are carved out through Medi-CalRx, this bill still impacts nearly 9 million Medi-Cal enrollees through DMHC-regulated Medi-Cal managed care medical benefits. Medi-Cal premiums are expected to decrease by $1.5 million in a 50% market shift scenario ($0.01 per member per month).
c) *Impact on expenditures*. CHBRP performed a sensitivity analysis of three different utilization scenarios: a 10%, 50%, or 90% switch from reference products to biosimilars or interchangeable biological products. All scenarios resulted in premium savings, ranging between $17.5 million (0.01%) for a 10% market shift scenario and $175 million (0.09%) for a 90% market shift scenario. In a 50% market shift scenario, premiums are expected to decrease by $87.7 million, with a $55.5 million reduction in employer or union premiums, a $14.6 million reduction in premiums for enrollees in group insurance, and a $16 million reduction in premiums for enrollees in the individual market. For those whose prescriptions are switched to a biosimilar by a pharmacist or who are required to try a biosimilar by their health plan, average savings are much greater, saving the enrollee between $92 and $310 annually in total cost-sharing, depending on their insurance market.

*Biological products and biosimilars.* Biological products, like monoclonal antibodies, insulin, vaccines, and allergenic products, are large, complex molecules made from living sources. Biological products are approved by the FDA under a standalone Biologics License Application (BLA) that contains all data necessary to demonstrate the product's safety and effectiveness, including both preclinical studies and clinical trials in humans. The BLA must be approved by the FDA before the product can be legally marketed in the U.S.

The Biologics Price Competition and Innovation Act (BPCIA) of 2009 defined a biosimilar as a biological product with active components that are highly similar to a reference product that demonstrates no clinically meaningful differences in terms of safety, purity, or potency. 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 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.

*Biosimilar cost savings.* 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. 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.

*Interchangeability.* Under the BPCIA, an interchangeable biosimilar may be substituted for its reference product without intervention from the prescribing health care provider. Manufacturers must apply for this designation, which historically required costly switching studies. In 2024, the FDA rescinded that requirement after a decade of evidence found no meaningful differences in safety or immunogenicity between patients who switched to biosimilars and those who did not. The FDA now states that biosimilars and interchangeable biosimilars meet the same high standards for biosimilarity, and that the comparative analytical data

supporting biosimilarity can also support interchangeability. The FDA has proposed eliminating the statutory distinction by deeming all approved biosimilars interchangeable, aligning the U.S. more closely with the E.U. The bipartisan Biosimilar Red Tape Elimination Act, which would do the same, has unanimously advanced through policy committees in both chambers of Congress.

**FISCAL EFFECT:** Appropriation: No Fiscal Com.: Yes Local: Yes

According to the Assembly Appropriations Committee:

- The California Health Benefits Review Program (CHBRP) estimates savings of $1.5 million to the Medi-Cal program (General Fund, federal funds).
- CHBRP estimates costs savings of $4.1 million in reduced premiums for DMHC-regulated health plans offered through the California Public Employees Retirement System (CalPERS). About one-half of CalPERS members are associated with state employment, and a portion of premiums are paid by members, so the state's share of the savings would be around $1.7 million (General Fund). In addition, there would be smaller cost reductions in CDI-regulated insurance policies offered through CalPERS.
- Minor and absorbable costs to the Board of Pharmacy, CDI, and DMHC.
- CHBRP estimates $87.7 million (0.05%) in reduced premiums paid by all payors, including employers, enrollees, and government.

**SUPPORT:** (Verified 8/26/26)

America's Health Insurance Plans
America's Physician Groups
American Federation of State, County and Municipal Employees
American GI Forum Education Foundation of Santa Maria, California
Association of California Life & Health Insurance Companies
Blue Shield of California
California Academy of Family Physicians
California African American Chamber of Commerce
California Association of Health Plans
California Association of Physician Groups
California Chamber of Commerce
California Pharmacists' Association
California Primary Care Association Advocates
California Senior Alliance
California State Council of Service Employees International Union
Coalition of Los Angeles Probation Unions
CVS Health

Hardesty, LLC.
Health Access California
Pharmaceutical Care Management Association
Santa Clara County Probation Peace Officer's Union
Sharp Healthcare
Several individuals

**OPPOSITION:** (Verified 8/26/26)

Alliance for Patient Access
Alliance for Safe Biologic Medicines
Amgen
Axis Advocates
Biocom California
Biotechnology Innovation Organization
California Chronic Care Coalition
California Health Collaborative
California Rheumatology Alliance
California Society of Dermatology & Dermatologic Surgery
Carrie's Touch
Infusion Access Foundation
International Cancer Advocacy Network
International Foundation for Autoimmune & Autoinflammatory Arthritis
Looms for Lupus
Lupus and Allied Diseases Association, Inc.
Lupus Los Angeles
Neuropathy Action Foundation
U.S. Pain Foundation

**ARGUMENTS IN SUPPORT:** The sponsor of the bill, the California Association of Health Plans (CAHP), states that this bill is a step towards addressing prescription drug prices, the fastest-growing driver of health plan premiums in California. CAHP writes that this bill modernizes outdated pharmacy substitution laws and permits health plans to make formulary changes that align with those already occurring in Medicare Part D plans, which can substitute coverage of a brand-name biologic with a biosimilar. Blue Shield of California and America's Physician Groups point out that the Office of Health Care Affordability places all health care industry players on a budget except pharmaceutical manufacturers, and this bill is a small but important step towards making the pharmaceutical industry part of the solution, injecting competition into drug pricing that will bring down costs to the system. CVS Health reports that they've transferred 93% of the

patients they serve to Hyrimoz, a Humira biosimilar, which has saved their members in California $33.2 million and has reduced total gross cost per prescription by almost $6,700 since 2023. CVS plans to continue transitioning patients to osteoporosis biosimilars that offer a 50% cost savings over brand-name alternatives. Sharp HealthCare saved more than $6.4 million last year through biosimilar conversions, which helped reduce overall healthcare costs and allowed Sharp to reinvest in expanded access to services, patient care programs, and critical clinical resources. California Primary Care Association (CPCA) Advocates emphasizes that the bill increases access to lower-cost biologic medication, which is critically important to the communities served by CPCA Advocates' member community health centers and clinics, who often serve as the only source of care for lower-to-middle-class families in many rural communities. Health Access California states that six in ten Californians are skipping or delaying health care due to costs, and one-third of Americans are cutting back on daily spending, even skipping meals, due to health care costs. Ensuring Californians have access to safe alternatives like biosimilars is an important method of reducing consumer costs without risks to quality of care.

*Support if amended.* The California Society of Health-System Pharmacists also supports the bill if amended to state that the law can't be construed to require a medical provider or pharmacy to stock, procure, dispense, or administer drugs from manufacturers or distributors that are not currently part of the pharmacy's existing contractual agreements.

**ARGUMENTS IN OPPOSITION:** The California Rheumatology Alliance, Osteopathic Physicians and Surgeons of California, and Lupus and Allied Diseases Association argue that biosimilars may have subtle differences in efficacy that may lead to unintended consequences for patients and insist that patients should not be switched to a different biological product without advance consultation with the prescribing physician unless the product has been deemed interchangeable by the FDA. They further argue that patients on biologics are living with complex medical conditions and have often tried multiple biologics before finding an effective therapy and oppose the ability of health plans to force a patient to try a biosimilar if they are stable on their existing therapy. The Lupus and Allied Diseases Association state that lupus is an unpredictable, individualized, heterogeneous, multi-system disease that requires access to the full array of treatments. Any disruption in continuity of care as a result of payer utilization management policies, formulary or dosage changes, or other cost containment measures has detrimental consequences on patients, possibly exacerbating the disease and augmenting costs. The Osteopathic Physicians and Surgeons of California emphasize that no other state allows substitution of biosimilars not

deemed interchangeable, claiming that this process is working for Californians and that it is not in the best interests of patients to allow a pharmacist to substitute a biosimilar.

*Oppose unless amended.* Amgen and Biocom oppose the bill unless amended to maintain the current pharmacy substitution law, which allows substitution only with interchangeable biosimilars. Biocom also proposes that the health and safety code changes be amended to preserve California's longstanding continuity-of-care protections by preventing mid-year, non-medical switching of patients who are stable on a prescribed therapy.

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