Office of Senate Floor Analyses
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THIRD READING

Bill No: SB 1094
Author: Weber Pierson (D)
Amended: 4/8/26
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 APPROPRIATIONS COMMITTEE: Senate Rule 28.8

**SUBJECT:** Prescription drugs

**SOURCE:** California Association of Health Plans

**DIGEST:** This bill updates Pharmacy Law to authorize a pharmacist to select an alternative biological product for a prescribed biological product if it is a biosimilar. Authorizes health plans and insurers to require enrollees to try a therapeutically equivalent generic, biosimilar, or interchangeable biological product if the prescriber has not indicated "Do not substitute" and when the generics or biosimilars are covered by the health plan or insurer and available to the enrollee at the same or lower cost.

**ANALYSIS:**

Existing federal law:

1) Prohibits, via the Federal Food, Drug, and Cosmetic Act (FDCA), introduction of a "new drug" into interstate commerce unless a Food and Drug Administration (FDA)-approved application is in effect. (21 United States Code (U.S.C.) § 355)

2) Prohibits, via the Public Health Service Act (PHSA), introduction of a biological product into interstate commerce without an approved biologics license. (42 U.S.C. § 262(a))

3) Establishes drug approval pathways but does not regulate pharmacy-level substitution, leaving the regulation of prescription drug substitution to state law. (21 U.S.C. § 355; 42 U.S.C. § 262)

Existing state law 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 (Board) to enforce the Pharmacy Law. (Business and Professions Code (BPC) §§ 4000 et seq.)

This bill:

1) States Legislative intent to promote the use of equally effective lower cost treatments to ensure access and affordability for Californians and to promote the coverage of equally effective lower cost products within three calendar months of national availability.

2) Updates Pharmacy Law to authorize a pharmacist to select an alternative biological product for a prescribed biological product if it is a biosimilar or interchangeable, rather than if the alternative biological product is interchangeable. Specifies that biosimilar has the same meaning as under BPCIA.

3) Authorizes health plans and insurers to require enrollees to try a therapeutically equivalent generic, biosimilar, or interchangeable biological product if the prescriber has not indicated "Do not substitute" and when the generics or biosimilars are covered by the health plan or insurer and available to the enrollee at the same or lower cost. Requires health plans and insurers to report to Department of Managed Health Care (DMHC) or Department of Insurance (DOI) the proportion of plan-required substitutions that result in reduced cost sharing for the enrollee, information about those substitutions that did not experience reduced cost sharing, and the impact of substitutions on premiums.

**Background**

*Pharmacists and Substitution for Generic Drugs.* The FDA defines a generic drug as the same as a brand-name drug in dosage, safety, strength, route of administration, quality, performance characteristics, and intended use. Before

approving a generic drug product, the FDA requires rigorous testing and review to ensure that the generic can be substituted for the brand-name drug. The FDA evaluates substitutability, or "therapeutic equivalence," based on scientific evidence. Generic drug products must contain the same active ingredient(s), strength, dosage form, and route of administration as the brand-name product. A drug determined to be therapeutically equivalent can be expected to have the same clinical effect and safety profile when substituted for the brand-name drug. The FDA publishes *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book," which identifies drug products approved on the basis of safety and effectiveness under federal law. The FDA also provides daily electronic updates to the Orange Book to reflect new generic drug approvals and maintain a current list of therapeutically equivalent products for substitution purposes.

A prescription that includes refills authorizes a pharmacist to dispense the prescribed drug at the time of each fill, including refills, consistent with substitution authority. Pursuant to BPC § 4073, when a drug product is prescribed by its trade name, a pharmacist may select an equivalent drug product with the same active ingredient, strength, and dosage form, unless the prescriber indicates "Do not substitute." This authority applies at the time of dispensing and permits the pharmacist, in their professional discretion, to select among therapeutically equivalent products, including substituting a generic drug for a brand-name drug or dispensing products from different manufacturers over time, provided that the substituted product complies with applicable equivalence, labeling, and cost requirements.

Pharmacies routinely dispense an FDA-approved equivalent product that is covered or preferred by a patient's health plan, which can result in patients receiving different generic versions across refills. The pharmacist is dispensing a therapeutically equivalent drug product rather than altering the prescription itself. Therapeutic equivalence is determined based on scientific evaluations reflected in the Orange Book. Pharmacists may not substitute a product with a different active ingredient or a therapeutic alternative without prescriber authorization. This allows pharmacists to adapt to changing coverage and supply conditions at the time of each dispensing, including refills, while maintaining the requirement that the medication dispensed remains pharmaceutically and therapeutically equivalent.

*Biologics*. Biologic medicines are complex therapies that typically treat very serious diseases and conditions, including blood conditions, cancers, immune disorders like Rheumatoid Arthritis, Psoriasis and Crohn's Disease, as well as

neurological disorders like Multiple Sclerosis. Biologics are often administered in clinical settings such as physician offices or infusion centers, though many are also dispensed through specialty pharmacies for self-administration. Biological products are generally derived from living material, human, animal, or microorganism and FDA regulations specify that biological products include blood-derived products, vaccines, in vivo diagnostic allergenic products, immunoglobulin products, products containing cells or microorganisms, and most protein products, as defined under the Public Health Service Act.

*Alternative Biological Products - Biosimilars.* Biologics, often referred to as originator biological products or reference biological products, when discussing interchangeability and therapeutic equivalence, are large, complex protein molecules used in the treatment, diagnosis or prevention of disease. These are quite different from small molecule drugs, pills, which are not as structurally complex and are instead relatively simple, organic substances produced by chemical methods. Biologic medicines, on the other hand, are made in living organisms to produce proteins by genetically modifying cell constructs or cell lines. Biologics are grown, cultivated, and purified and are typically administered as injectables.

Due to the inherent complexity of biologics, biosimilars are not identical to their reference products but must be demonstrated to be highly similar, with no clinically meaningful differences in safety, purity, or potency. The molecular structure and functional characteristics of a biosimilar are expected to closely resemble those of the reference biologic, and unlike generic drugs which require the active ingredient to be identical, the exact manufacturing process of an original biologic cannot be exactly duplicated.

In response to increases in an aging population and larger numbers of patients suffering from chronic disease, there has been a rise in use of biologics, and accordingly a rise in the production efforts of biosimilars. Biosimilars go through an extensive review process, and manufacturers are required to submit immense studies and data demonstrating a products' efficacy and ensuring it is safe for use by consumers. Manufacturers also must establish ongoing monitoring programs to ensure the safety of biosimilars.

*Interchangeability and Substitution.* FDA guidance on biosimilars and interchangeability addresses the evidentiary standards for product approval, not pharmacy-level substitution, which FDA has stated is outside the scope of its approval authority and instead governed by state pharmacy law. (U.S. Food and

Drug Administration, *Considerations in Demonstrating Interchangeability With a Reference Product* (2019); 42 U.S.C. § 262(k).)

Under a 2025 final rule, the Centers for Medicaid Services (CMS) expanded how Medicare Part D plans can manage biologic drugs on their formularies. Medicare Part D, which provides outpatient prescription drug coverage to tens of millions of seniors and people with disabilities, now allows plan sponsors to treat biosimilars as therapeutically equivalent options for formulary placement and coverage, without requiring that the biosimilar be designated as interchangeable. (Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs, 89 Fed. Reg. 30448 (Apr. 23, 2024); see also CMS Fact Sheet, Apr. 2024.) While this policy does not govern pharmacy-level substitution, it reflects a shift toward treating all biosimilars as clinically appropriate alternatives.

In 2025, FDA proposed, as part of its legislative priorities, to eliminate the statutory distinction between the approval standard for biosimilar and interchangeable biosimilar products to deem that approved biosimilars are interchangeable.

**Comments**

The California Pharmacists Association requests that the bill be amended to "ensure that pharmacies are reimbursed at or above their cost of acquisition, along with a reasonable dispensing fee." The group states that "this will help ensure that the intended savings for patients do not come at the expense of access."

The Pharmaceutical Care Management Association writes that if this bill is enacted, it "would drive savings from enhanced biosimilar and generic competition, and patients would directly benefit… SB 1094 helps patients access more affordable medicines while ensuring all existing safety and clinical safeguards are kept in place. Generic and biosimilar substitutions must follow strict FDA standards and doctors always have the final say. Nothing in the bill overrides their medical judgement." The organization notes that "As SB 1094 moves through the legislative process, PCMA would like to stress the importance of ensuring that the bill preserves the intended flexibility for substitution outlined in the original bill language."

The California Society of Health-System Pharmacists requests that the bill be amended to clarify that "the law can't be construed to require a medical provider or

pharmacy to stock, procure, dispense, or administer drug products from manufacturers or distributors that are not part of the provider or pharmacy's existing contractual agreements." The group states that as the bill is currently drafted could have unintended consequences if health plans mandated a "plan-designated" biosimilar that falls outside a pharmacy's existing contracts that could then "disrupt procurement operations, inadvertently shift costs from the health plan onto the health system, and potentially place pharmacies in breach of their existing supply agreements."

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

**SUPPORT:** (Verified 5/4/26)

California Association of Health Plans (sponsor)
America's Health Insurance Plans
America's Physician Groups
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
CA African American Chamber of Commerce
California Academy of Family Physicians
California Association of Health Plans
California Chamber of Commerce
California State Council of Service Employees International Union
Coalition of LA Probation Unions
Cpca Advocates, Subsidiary of the California Primary Care Association
Cvs Health
Cvs/caremark Corporation
Hardesty LLC
Health Access California
Los Angeles Civil Rights Association
Santa Clara County Probation Peace Officer's Union, Afscme Local 1587
Shalom International Outreach
Sharp Healthcare
The Sperantia Foundation

**OPPOSITION:** (Verified 5/4/26)

Alliance for Safe Biologic Medicines

Amgen
Biocom
Biocom California
Biotechnology Innovation Organization
California Rheumatology Alliance
Infusion Access Foundation
Lupus and Allied Diseases Association, INC
Osteopathic Physicians and Surgeons of California

**ARGUMENTS IN SUPPORT:**

Supporters write that "Biologics and biosimilars are designed to treat complex and serious conditions like autoimmune diseases and cancer. In addition to the emotional burden of being affected by these conditions, patients and their families are currently expected to pay top dollar for treatment. The Department of Health and Human Services reports that expensive biologic medications make up only 5% of prescriptions in the U.S. but account for 51% of total drug spending as of 2024. There has been an undue financial burden placed on a relatively small proportion of patients and families who are already working through unimaginable circumstances. SB 1094 provides an alternative, creating a pathway for patients to access lower-cost prescriptions that are still safe and effective." According to supporters, "Brand drug manufacturers have a history of employing anti-competitive strategies to limit the availability of generics and biosimilars — such as paying to delay their release — which is estimated to drive up drug costs by nearly $12 billion per year. Increased availability of more affordable prescriptions is essential in a climate where manufacturers continue to arbitrarily push prices higher, while patients fight daily to afford their medications."

**ARGUMENTS IN OPPOSITION:**

Opposition writes that, SB 1094 would inappropriately permit third-party pharmacy level substitution of non-interchangeable biosimilars" and "support for any biosimilar substitution from the medical societies and patient advocacy organizations for any biosimilar substitution has always been contingent on the assurance that ONLY interchangeable biosimilars may be substituted by someone other than the patient's physician." The groups claim that the bill would "expand the ability of third parties like insurance companies and pharmacy benefit managers to drive substitution decisions based on profitability and without adequate clinical justification (non-medical switching)." Opposition further states,

"that the bill would weaken patient safeguards and threaten patient wellbeing by overriding California's prohibition on non-medical switching to prohibit a previously approved drug that is protected under non-medical switching law by allowing a switch" and "substitution should only occur when the FDA has designated a biologic product as interchangeable and proper protections are upheld including Pharmacist-Patient communication to ensure complete transparency and pharmacovigilance." The opposition is also concerned with the health insurance provisions in this bill that give health insurance companies the authority to force a patient to try a biosimilar regardless of how stable they are on their existing therapy.

Prepared by: Sarah Mason /Anna Billy / B., P. & E.D. /
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