SENATE THIRD READING
SB 1094 (Weber Pierson)
As Amended August 19, 2026
Majority vote

## SUMMARY

Expands the authority for a pharmacist to substitute a biosimilar *or interchangeable biological product in place of* a prescribed biological product and authorizes health plans and insurers to require their enrollees to try a biosimilar or interchangeable biological product of a reference product *that is subject to continuing coverage by the plan* under specified conditions.

**Major Provisions**

1) 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 determined to be interchangeable by the FDA.

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

3) 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.

4) Amends provisions of law that prohibit a health care service plan contract or health insurance policy from limiting or excluding coverage for an enrollee's or insured's previously covered drug to allow for a provider to prescribe another drug covered by a plan or insurer that is medically appropriate for the enrollee or insured and allows for biosimilar drug substitutions.

5) Authorizes a health care service plan or insurer to require an enrollee or insured to try a biosimilar or interchangeable biological product *in place of* a reference product *that is subject to continuing 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 *alternative biosimilar or interchangeable biological product is lower than the reference product.*

    c) An enrollee's or insured's cost sharing is based on the net cost of the *proposed biosimilar or interchangeable biological product alternative.*

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

    e) The plan or insurer provides at least 60 days' advance notice to the enrollee or insured and prescribing provider of a *requirement* to try an alternative *biosimilar or interchangeable biological product,* with specific information required to be provided.

6) Provides that an enrollee or insured who is required to try an alternative or the *plan's* prescribing provider may request an exception.

7) *No later than October 1, 2027, in a manner prescribed by the DMHC in coordination with the Department of Insurance***,** requires a plan or insurer to provide information related to the proportion of prescriptions filled for an alternative product 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 the new authority on premiums.

8) No later than January **15**, 2027, requires a plan or insurer to notify prescribing *plan* providers *who are appropriately licensed to prescribe prescription drugs* of the following:

   a) Any reference biological product and any biosimilar or interchangeable biological product for that reference product that is already included on the plan formulary.

   b) That a pharmacist dispensing a prescribed biological product may substitute a biosimilar or interchangeable biological product for the prescribed reference product unless the prescriber indicates "Do not substitute," or words of similar meaning.

   c) Any of the prescribing provider's enrollees whose prescribed reference biological product may be subject to that substitution.

9) Prohibits a pharmacy benefit manager, health care service plan, health insurer, or affiliated entity from requiring utilization of only a biosimilar product in which the pharmacy benefit manager, health care service plan, or affiliated entity has a direct or indirect financial interest if biosimilars not affiliated with these entities may also be available.

10) *Requires a health care service plan contract issued, amended, or renewed on or after January 1, 2027, that provides prescription drug benefits and maintains one or more drug formularies that include a reference product to also include, on the relevant plan formulary, at least one biosimilar or interchangeable biological product licensed for the same reference product if the biosimilar has a lower net cost to the plan than the reference product.*

## COMMENTS

*Pharmacist Scope of Practice.* California has long faced significant gaps and inequities in its health care workforce. There has historically been a persistent shortage of accessible health care providers overall, which disproportionately impacts communities with concentrated populations of immigrant families and people of color. A recent study found that between 2010 and 2019, the number of primary care physicians in proportion to population remained largely unchanged nationally. Meanwhile, counties with a higher proportion of minorities saw a decline during that period.

In response to these challenges, policymakers have repeatedly turned to pharmacists to help fill the provider gap in parts of the state where primary care providers can be inaccessible but local pharmacies are more readily available. Data cited by the BOP indicates that while 20 percent of Californians live in areas designated as primary care health professional shortage areas, only 6 percent of Californians live in areas designated as pharmacy deserts. Exercising their training and judgment, pharmacists are often relied upon to administer vaccines, furnish time-sensitive medication, and ensure that there is no delay in care. In 2013, the Legislature enacted SB 493

(Hernandez), which established an advanced practice pharmacist license and expanded the scope of practice for pharmacists to include additional acts, including independently furnishing specified nicotine replacement products, prescription medications for travel, and hormonal contraceptives.

During the BOP's prior sunset review in 2020-2021, the Committees discussed whether there should be consideration of the BOP transitioning to a standard of care model for pharmacy practice. The BOP established a Standard of Care Ad Hoc Committee, which convened seven meetings and subsequently submitted a report to the Legislature with its findings and recommendations. The BOP concluded that California patients would benefit from pharmacists gaining additional independent authority to provide patient care services, not limited to the traditional dispensing tasks performed at licensed facilities, consistent with their respective education, training, and experience.

The BOP further recommended revisions to certain provisions detailing a pharmacist's authorized scope of practice for specified clinical patient care services and transition to a standard of care model for specified patient care services, where sufficient safeguards are in place to ensure pharmacists retain autonomy to utilize professional judgment in making patient care decisions. Under those conditions, the BOP argued that transitioning to greater use of a standard of care model in the provision of specified patient care services could benefit patients by providing expanded and timely access to patient care. The BOP's Licensing Committee developed a legislative proposal to transition many provisions of pharmacist practice to a standard of care model in lieu of the existing prescriptive model.

Much of the BOP's proposed language was ultimately enacted through AB 1503 (Berman), the BOP's sunset bill, in 2025. The bill defined "accepted standard of care" for purposes of the Pharmacy Law. Consistent with that standard, current law now provides pharmacists with broader authority to engage in activities and services that they believe are in the best interest of a patient, including furnishing specified medications without a prescription, ordering and interpreting laboratory tests, and initiating and administering immunizations.

*Biologics and Biosimilars.* Biological products, often referred to as biologics, are therapeutic medications derived from living organisms or their components, such as proteins, cells, tissues, or microorganisms. While traditional small molecule drugs are synthesized through chemical processes, biologics are produced using complex biological systems and are often used to treat chronic, serious, or life-threatening conditions such as cancer, rheumatoid arthritis, inflammatory bowel disease, diabetes, and multiple sclerosis. Common examples include monoclonal antibodies such as Humira (adalimumab), Keytruda (pembrolizumab), and insulin products. Because biologics are manufactured from living sources, they are generally more complex and difficult to reproduce than conventional pharmaceuticals. The FDA defines biologics as products made from natural and living sources and notes that their complexity often requires specialized manufacturing and regulatory oversight.

A biosimilar is a biologic product that is highly similar to an original FDA-approved biologic, commonly referred to as the reference product. According to the FDA, "it is both normal and expected for both biosimilars and original biologics to have minor differences between batches of the same medication. This means that biologics cannot be copied exactly, and that is why biosimilars are not identical to their original biologic." The FDA further explains that "biosimilars must have no clinically meaningful differences from their original biologic, and as a

result, "biosimilars provide the same treatment benefits and have the same risks as the original biologic." The FDA states that biosimilars are just as safe and effective as their reference product.

While all biosimilars are rigorously and thoroughly evaluated by the FDA to confirm that they are as safe and effective as their original biologic, some biosimilars may go through an additional process to be designated by the FDA as "interchangeable." The federal Biologics Price Competition and Innovation Act, enacted in 2010 as part of the federal Patient Protection and Affordable Care Act, authorizes the FDA to designate certain biosimilars as "interchangeable" if they meet additional statutory requirements demonstrating that it can be expected to produce the same clinical result as the reference product in any given patient and, when administered more than once, that switching between the biosimilar and reference product does not create additional risk. A company must specifically request that the FDA approve its biosimilar as interchangeable; the FDA states that in some cases, companies do not make this request for various business reasons.

*Pharmacist Substitution of Biologics.* The Biologics Price Competition and Innovation Act included language stating that the interchangeability designation for biosimilars was intended to mean "that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product." Legislation has since been enacted in all 50 states to allow for this manner of substitution. In 2013, AB 1139 (Lowenthal) and SB 598 (Hill) were introduced to authorize California pharmacists to substitute an interchangeable biosimilar when filling a prescription for a prescribed biologic; while SB 598 was passed by the Legislature, it was vetoed by Governor Jerry Brown.

Governor Brown's veto message declared his support for amending the Pharmacy Law to allow interchangeable biosimilars to be substituted for biologic drugs, once these interchangeable drugs are approved by the FDA. However, the Governor appeared hesitant to support language in the bill requiring pharmacists to notify prescribers when a biosimilar has been substituting, noting that "this requirement, which on its face looks reasonable, is for some reason highly controversial" and that while doctors supported the notification requirement, "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." Governor Brown further argued that physician notification was premature given that the FDA had not yet established its standards for biosimilars to be designated as interchangeable.

In 2015, SB 671 (Hill) was introduced to authorize a pharmacist to substitute an interchangeable biosimilar when filling a prescription for a prescribed biologic. The bill expressly prohibited substitution when the prescriber indicated "do not substitute" or words to that effect on the prescription, and required information regarding the substitution to be entered into an electronic records system product within five days. The bill also required the BOP to maintain a link on its website to the list of interchangeable biological products recognized by the FDA.

SB 671 was supported by pharmaceutical manufacturers and medical specialists for its notification requirements and limited authority for substitution. However, the bill was opposed by health plans, insurers, and pharmacy benefit managers, who argued that the bill "creates doubt about the safety of biosimilar drugs by placing notification requirements on drugs that have been available in international markets for over a decade." The opposition believed that restricting the authority to substitute biosimilars and placing new administrative burdens on pharmacists would

impede cost savings, discourage substitution, and cause patients to question the effectiveness and safety of biosimilars. Despite this opposition, SB 671 was signed into law.

The market for biologics and biosimilars has grown substantially in the years following the enactment of SB 671 in 2015, at which time one biosimilar had been approved by the FDA. In March 2024, the FDA announced that it had approved 50 biosimilars for 15 different biologics. Two years later, that number has grown to over 80 biosimilars approved by the FDA for use in the United States. The FDA has publicly supported efforts to increase the development and use of biosimilars as a way to reduce treatment costs and promote competition, citing statistics that biologics represent five percent of prescriptions but 51 percent of drug spending.

The FDA has issued new draft guidance intended to streamline the approval process for biosimilars. Additionally, public statements issued by the FDA have minimized the distinction between interchangeable biosimilars and biosimilars without that designation. The director of the FDA's Office of Therapeutic Biologics and Biosimilars has stated: "Both biosimilars and interchangeable biosimilars meet the same high standard of biosimilarity for FDA approval and both are as safe and effective as the reference product."

When the BOP submitted its proposed language to establish a standard of care practice model for pharmacists as part of its sunset review in 2025, it included language to expand the authority of a pharmacist to "perform therapeutic interchanges." Earlier iterations of AB 1503 would have repealed the biosimilar substitution provisions of the Pharmacy Law enacted through SB 671 and instead more broadly authorized interchanges including, but not limited to, "use of biosimilars, different dosage forms, drugs within the same drug classification, and generic substitutions intended to optimize patient care." The bill would have required patient consent and would have prohibited a pharmacist from performing a therapeutic interchange when the prescriber had indicated "do not substitute" on the prescription or when medical literature does not support the change.

The therapeutic interchange language in AB 1503 was opposed by organizations representing physicians and pharmaceutical manufacturers. Letters of opposition specifically opposed the expansion of biosimilar substitutions and the repeal of the language enacted through SB 671, arguing that "it would be a grave mistake to replace those carefully vetted and negotiated provisions with the broad language currently contained in AB 1503." The language authorizing pharmacists to perform therapeutic interchange was subsequently removed from the BOP's sunset bill in the Senate.

This bill would similarly expand the authority of a pharmacist to select an alternative biological product when filling a prescription for a prescribed biologic by removing the requirement that the biologic being substituted be designated as interchangeable by the FDA. The bill would not repeal or substantially amend the language enacted through SB 671, including provisions providing for prescriber notification. The bill would additionally update the requirement that the BOP post a link on its website to the FDA's list of approved interchangeable biosimilars to require a link to be posted to the FDA's Purple Book Database of Licensed Biological Products.

*Health Plans and Insurers.* In addition to the section of this bill amending the Pharmacy Law, this bill would amend the Knox-Keene Health Care Service Plan Act of 1975 and provisions of the Insurance Code related to health insurers. Existing law prohibits a health plan or insurer from limiting or excluding coverage for a previously approved drug. This bill would authorize

health plans and insurers to require an enrollee or insured to try a biosimilar or interchangeable biological product of a reference product that was previously approved for coverage by the plan.

Certain conditions must be met for a health plan or insurer to require substitution of a drug; for example, the prescriber would retain the express authority to indicate "do not substitute" on the prescription. The bill would also require that the net cost to the plan or insurer of the substitute be lower than the brand name or reference product and would specify cost sharing. A health plan or insurer would additionally be required to provide at least 60 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. Health plans and insurers would also be required to notify prescribing providers that a pharmacist dispensing a prescribed biological product may substitute a biosimilar or interchangeable biological product for the prescribed reference product unless the prescriber indicates "Do not substitute." This bill would also require health plans and insurers to submit information relating to the proportion of prescription substitutions resulting from the bill that resulted in reduced cost sharing as well as information about the factors affecting when an enrollee's cost sharing is not reduced, along with information regarding the impact on premiums.

**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. 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. 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. 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."

**Arguments in Support**
The *California Association of Health Plans* (CAHP) is the sponsor of this bill. CAHP writes: "SB 1094 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. Without this legislative change, Californians will remain locked into higher-priced brand-name products, even when safe, lower-cost alternatives are available."

**Arguments in Opposition**
*Amgen* opposes this bill, writing: "For complex biologics, a default opt-out standard does not provide the same patient protections as affirmative prescriber involvement. When a prescriber determines that continuity, device familiarity, training, or patient-specific considerations matter, the law should not place the burden on that prescriber to preemptively block automatic

substitution across all cases. Patient protection is stronger when substitution without prescriber intervention is limited to products that FDA has designated interchangeable."

## FISCAL COMMENTS

According to the Assembly Committee on Appropriations, the California Health Benefits Review Program (CHBRP) estimates savings of $1.5 million to the Medi-Cal program, with estimated costs savings of $4.1 million in reduced premiums for DMHC-regulated health plans offered through the California Public Employees Retirement System (CalPERS); minor and absorbable costs to the BOP, CDI, and DMHC; CHBRP estimates $87.7 million (0.05%) in reduced premiums paid by all payors, including employers, enrollees, and government.

## VOTES

**SENATE FLOOR: 38-0-2**
**YES:** 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
**ABS, ABST OR NV:** Niello, Padilla

**ASM BUSINESS AND PROFESSIONS: 19-0-0**
**YES:** Berman, Addis, Ahrens, Alanis, Bains, Bauer-Kahan, Caloza, Chen, Elhawary, Hadwick, Haney, Hart, Irwin, Jackson, Patterson, Lowenthal, Macedo, Nguyen, Pellerin

**ASM HEALTH: 14-0-2**
**YES:** Bonta, Sanchez, Addis, Ahrens, Caloza, Carrillo, Jeff Gonzalez, Mark González, Johnson, Patel, Patterson, Schiavo, Sharp-Collins, Stefani
**ABS, ABST OR NV:** Aguiar-Curry, Celeste Rodriguez

**ASM APPROPRIATIONS: 15-0-0**
**YES:** Wicks, Hoover, Arambula, Calderon, Caloza, Dixon, Fong, Mark González, Krell, Pacheco, Pellerin, Sharp-Collins, Solache, Ta, Tangipa

## UPDATED

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