SENATE COMMITTEE ON BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT

Senator Dr. Aisha Wahab, Chair
2025 - 2026 Regular

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Author:	Weber Pierson		
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Consultant:	Sarah Mason		

Subject: Prescription drugs

SUMMARY: 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.

NOTE: This bill is double-referred to the Senate Committee on Health, second.

Existing federal law:

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

2) The Public Health Service Act (PHSA) prohibits 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)

4) The Biologics Price Competition and Innovation Act of 2009 (BPCIA) establishes an abbreviated licensure pathway for biosimilar and interchangeable biological products. (42 U.S.C. § 262(k))

5) Requires a biosimilar application to include analytical, animal, and clinical data, as appropriate, sufficient to demonstrate biosimilarity under a "totality of the evidence" standard. (42 U.S.C. § 262(k)(2))

6) Clarifies that a product is biosimilar to a reference product under the BPCIA if it is highly similar to the reference product, notwithstanding minor differences in clinically inactive components and has no clinically meaningful differences in safety, purity, and potency. (42 U.S.C. § 262(i)(2)(A) and (B))

7) Provides that new drugs may not be introduced into interstate commerce unless the application is approved, including:

   a) A full report of investigations to be filed with an application to the Secretary of Health and Human Services and which have been made to show:

      i) Whether or not the drug is safe and effective for use.

      ii) A full list of the components and composition of the drug.

      iii) A full description of the methods used in, and the facilities and controls used for the manufacturing, processing, and packing of the drug.

      iv) Samples of the drug and of the articles used as components, as the Secretary may require.

      v) Specimens of the labelling proposed to be used for the drug.

      vi) Any assessments required under Section 355c. (21 U.S.C § 355(b))

   b) An abbreviated application of a new drug to be filed with the Secretary and which must contain:

      i) Information to show that the conditions of use prescribed, recommended or suggested in the labeling proposed for the new drug have been previously approved.

      ii) Information to show that the new drug has the same active ingredient(s) as the listed drug referred to.

      iii) Information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to.

      iv) Information to show that the new drug is bioequivalent to the listed drug, except as specified.

      v) Information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to unless the new drug and listed drug are produced or distributed by different manufacturers. (21 U.S.C § 355(j))

8) Defines a biological product to include, among other things, viruses, vaccines, blood products, and proteins. (42 U.S.C. § 262(i)(1))

9) Regulates insulin as a biological product under section 351 of PHSA, including the statutory definition of ‘biological product’ (42 U.S.C. § 262(i)) and the biologics licensure and biosimilar approval framework (42 U.S.C. § 262(a), (k))

10) Provides that certain drugs must be dispensed only upon prescription where they are not safe for use without practitioner supervision. (21 U.S.C.§ 353(b))

Existing California law:

1) 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.)

2) Authorizes a pharmacist filling a prescription for a drug product to select a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product when the change will improve the ability of the patient to comply with the prescribed drug therapy, unless the prescriber indicates either orally or in their own handwriting, "Do not substitute" or words of similar meaning. Authorizes a prescriber to check a box on a prescription marked "Do not substitute" if the prescriber personally initials the box or checkmark. Specifies that selection of a different form of medication is within the discretion of the pharmacist and that they assume 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. Specifies that there is no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this authority. In the event of substitution, requires the patient to be informed that a different form of medication is 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.)

3) Further authorizes a pharmacist, when filling a prescription for a drug product prescribed by its trade 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 as determined by the United States Adopted Names (USAN) and accepted by the federal FDA, of those drug products having the same active chemical ingredients. Outlines the same "Do not substitute" specifications, pharmacist discretion specifications, prescriber liability specifications, patient communication specifications, and prescription label specifications in 2) above. Prohibits a pharmacist from substituting unless the drug product the pharmacist selects costs the patient less than the prescribed drug product. Clarifies that cost includes any professional fee charged by the pharmacist. Specifies that these requirements apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program. (BPC § 4073)

4) Authorizes a pharmacist filling a prescription for a prescribed biological product (as defined by federal law) 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, within five days following the dispensing of a biological product, a dispensing pharmacist or their designee to make an entry of the specific biological product provided to the patient, 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. In the event a pharmacist does not have access to any of the various electronic records systems, authorizes the pharmacist or their designee to communicate the name of the biological product via fax, telephone, electronic transmission, or other means but the communication is not required if there is no FDA approved interchangeable biological product or if the refill is not changed from the product dispensed on the prior filling. Outlines the same "Do not substitute" specifications, pharmacist discretion specifications, prescriber liability specifications, patient communication specifications, and prescription label specifications in 2) above. Outlines the same cost specifications in 3) above. (BPC § 4073.5)

5) Requires the Board to maintain a link to the current list of biological products the FDA has determined are interchangeable. (*Id.*)

6) Defines interchangeable as a biological product that FDA has determined meets specified standards in federal law or a biological product that has been deemed therapeutically equivalent by the federal FDA as set forth in the latest addition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations. (*Id.*)

7) 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. (*Id.*)

8) Establishes the Food and Drug Branch (FDB) within the California Department of Public Health (CDPH) to assure that foods, drugs, medical devices, cosmetics and certain other consumer products are safe and are not adulterated, misbranded nor falsely advertised; and that drugs and medical devices are effective.

9) Defines biologics as human whole blood, human whole blood derivatives specified by regulations, serum, vaccine, live vaccine, killed vaccine, tissue vaccine, autogenous vaccine, live virus, killed virus, live bacterial culture, killed bacterial culture, bacterin, hormone, tissue extract, gland extract, gland preparation, insulin, and similar products made from human or animal tissues or micro-organisms. (Health and Safety Code (HSC) § 1600.1)

10) Requires health plans to cover a patient's drug if they previously covered it and the drug continues to be medically necessary for the patient. (HSC §1367.22)

11) Allows health plans to require step therapy if there is more than one clinically appropriate drug, including requiring an enrollee to try an AB-rated generic equivalent, biosimilar, or interchangeable biological product before providing coverage for the equivalent branded prescription drug. Patients can request an exception. (HSC §1367.206)

12) Requires health plans to cover at least one FDA-approved medication in several categories of opioid use disorder treatment without step therapy, prior authorization, or utilization review, and allows for these to be AB-rated generic equivalents, biosimilars, or interchangeable biological products. (HSC §1342.75)

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.

FISCAL EFFECT: Unknown. This bill is keyed fiscal by Legislative Counsel.

COMMENTS:

1. **Purpose.** This bill is sponsored by the California Association of Health Plans. According to the Author, "A majority of Californians say their health care costs have risen faster than their income over the past year, causing many to delay, avoid, or modify care. One major driver of rising costs is prescription drugs. Prescription drug prices for California health plans have increased by 72% since 2017. Biologic drugs play a disproportionate role in these costs: although they make up only 5% of prescriptions, they account for about half of all drug spending.

   Encouraging the use of lower-cost alternatives such as generics and biosimilars could help reduce pharmaceutical spending and health insurance premiums. Biosimilars are FDA-approved medications that are highly similar to existing biologic drugs with no clinically meaningful differences in safety, purity, or potency, but they are often significantly cheaper. For instance, the rheumatoid arthritis and Crohn's disease drug Humira costs nearly $7,000 for a one-month supply, while biosimilars may provide savings of up to 85%. Competition between biosimilars and brand-name biologics can also help drive prices down overall.

   Despite their potential savings, biosimilars remain underused. This bill promotes their adoption by: 1) allowing pharmacists to substitute a biologic with a biosimilar

unless the prescribing provider indicates "Do Not Substitute," and 2) allowing health plans to switch enrollees from brand-name drugs or biologics to generics or biosimilars when available at the same or lower cost. It also requires insurers to report the share of substitutions that reduce cost-sharing and their impact on premium growth to encourage cost-saving substitutions for consumers."

The Author notes that "In the U.S., one of the barriers to biosimilar uptake is the category of 'interchangeable' biosimilars, a legal designation manufacturers must apply for that does not exist in other regulatory jurisdictions like the E.U. In California, pharmacists may not substitute prescriptions for reference biologics for a biosimilar unless the biosimilar is designated 'interchangeable,' even though both biosimilars and interchangeable biosimilars are considered as safe and effective as the reference product. Therefore, this bill authorizes pharmacists to substitute a reference biologic with any of its biosimilars, whether or not they have been designated 'interchangeable.'"

According to the Author, "current California law (HSC §1367.22) also does not allow health plans to switch patients who are currently on prescriptions for a previously-covered brand-name product to a generic or biosimilar—a drug must be covered for a patient as long as it continues to be appropriately prescribed and is considered safe and effective. This bill amends this code section to allow health care service plans or utilization review organizations to require that patients try a generic equivalent, biosimilar, or interchangeable biological product when covered by the plan at equal or lower cost-sharing to the patient. Lastly, the Health & Safety Code section discussed above does not exist in the Insurance Code. This bill adds the same section to the insurance code to harmonize current law between DMHC- and DOI-regulated plans."

2. **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. Biologics represent a significant and growing share of drug spending in the United States, accounting for a disproportionate percentage of total prescription drug expenditures despite representing a smaller share of total prescriptions.

Both the FDA’s Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research have regulatory responsibility for therapeutic biological products, including premarket review and oversight. Following initial laboratory and animal testing that show the use of a particular biological product in humans is reasonably safe, biological products (like other drugs), can be studied in clinical trials in humans under an investigational new drug application. If trials and studies demonstrate that a product is safe and effective for its intended use, the FDA may then approve the market of a biologic by granting a biologics license. There are some individuals who are not good candidates for use of therapeutic biological products, such as those who are immunocompromised. Individuals can also have or develop allergic or other adverse reactions to biological products.

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. Biosimilars have been defined by the World Health Organization as "a biotherapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product," (World Health Organization, *Guidelines on Evaluation of Similar Biotherapeutic Products*, 2009) by the European Medicines Agency as "a biological medicine highly similar to another already approved biological medicine (the reference product), based on a comprehensive comparability exercise demonstrating similarity in quality, safety, and efficacy," (European Medicines Agency, *Biosimilars in the EU: Information Guide for Healthcare Professionals*, 2019) and by the FDA as a biological product which is "highly similar to the reference product notwithstanding minor differences in clinically inactive components" and for which there are "no clinically meaningful differences…in terms of safety, purity and potency." (42 U.S.C. § 262(i)(2); see also U.S. Food and Drug Administration, *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product*, 2015)

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 have to establish ongoing monitoring programs to ensure the safety of biosimilars.

A pathway for biosimilar regulation in the U.S. was established under the Biologics Price Competition and Innovation Act, enacted as part of the 2010 Patient Protection and Affordable Care Act. The FDA has issued a series of guidance documents since 2012 outlining the evidentiary standards for demonstrating biosimilarity and interchangeability. The guidance included which types of studies manufacturers should undertake in order to ensure product safety, potency and purity. In addition to the draft guidelines for biosimilars, the FDA has also compiled a list of biological products licensed by FDA under the Public Health Service Act, including reference products, biosimilar products, and interchangeable biological products. This list, known as the "Purple Book", includes the date a biological product was licensed under the PHSA and whether a biological product has been evaluated as a reference product, including applicable exclusivity information under section 351(k) of the PHSA. The Purple Book is analogous to the Orange Book for

small-molecule drugs. It is maintained as a searchable online database identifying licensed biological products, including biosimilar and interchangeable products, along with exclusivity information. Biosimilar and interchangeable biological products licensed under section 351(k) of the PHSA are listed under the reference product to which biosimilarity or interchangeability was demonstrated. These lists are updated on an ongoing basis as FDA licenses biological products and makes determinations regarding date of first licensure for a biological product licensed under the PHSA.

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. In support of the proposal, FDA stated:

> "The statutory distinction between biosimilars and interchangeable biosimilars has led to confusion and misunderstanding, including among patients and healthcare providers, about the safety and effectiveness of biosimilars and about whether interchangeable biosimilars are safer or more effective than other biosimilars. FDA is seeking to amend section 351 of the [PHSA] to no longer include a separate statutory standard for a determination of interchangeability and to deem all approved biosimilars to be interchangeable with their respective reference products. This proposal would make the U.S. biosimilar program more consistent with current scientific understanding as well as with the approach adopted by other major regulatory jurisdictions such as the European Union where biosimilars are interchangeable with their respective reference products upon approval. Further, this proposal is expected to increase uptake of biosimilars, with potential downstream effects of increasing competition, access, and affordability." (U.S. Department of Health and Human Services, *Fiscal Year 2025 Budget in Brief – FDA Legislative Proposals*.)

Prescription Drug Costs. According to a 2026 joint informational hearing background paper from the California State Senate Committee on Health and California State Assembly Committee on Health, affordability remains a central challenge in California's health care system, even after major coverage expansions, impacting "ability of Californians to obtain or maintain affordable coverage" in the face of rising costs across the system. Prescription drugs are a key cost driver affecting both coverage and access, particularly for patients managing chronic conditions or requiring high-cost therapies. Public Policy Institute of California reported in its 2024 statewide survey *Californians and Their Economic Well-Being* that a meaningful share of Californians report delaying or forgoing needed medical care, including prescription medications, due to cost. Prescription drug affordability can serve as a barrier to access, with implications for patient adherence to treatment plans, health outcomes, and overall system costs.

According to the California Department of Managed Health Care *Prescription Drug Cost Transparency Report, Measurement Year 2024*, health plan spending on prescription drugs reached approximately $14.9 billion in 2024, an increase of nearly $1.3 billion in a single year, with drug costs continuing to outpace growth in other areas of health care spending and premiums. The report further finds that prescription drugs account for more than 15% of total health plan premiums and that a small share of high-cost specialty drugs, 1.8% of prescriptions, drives approximately 63% of total spending. The report also showed high-cost specialty drugs account for a disproportionate share of total prescription drug spending, contributing to rising premiums and out-of-pocket costs for consumers

Nationally, biologics are a driver of prescription drug spending despite relatively low utilization. According to the U.S. Department of Health and Human Services 2025 *Fact Sheet: Bringing Lower-Cost Biosimilar Drugs to American Patients*, biologic medicines account for approximately 5% of prescriptions but represent about 51% of total drug spending as of 2024, reflecting their significantly higher per-patient costs. Studies also show that specialty drugs, including many biologics, constitute roughly half or more of total drug spending while representing a small share of prescriptions.

3. **Prior Related Legislation.** SB 671 (Hill, Chapter 545, Statutes of 2015) authorizes a pharmacist to substitute an alternative biological product when filling a prescription for a prescribed biological product if the alternative biological product is designated as interchangeable with the reference product, among other conditions, and communication is provided to the patient and physician that a substitution was made. It also requires the Board of Pharmacy to maintain a link on its Website to the list of biological products recognized as interchangeable by the federal Food and Drug Administration.

   SB 598 (Hill) of 2013 would have authorized pharmacists to substitute a biosimilar for a biologic under specified circumstances, including a requirement that notification of the substitution be provided, and defined "biological product," "biosimilar," and "interchangeable" according to their definitions within the PHSA. (Status: *The bill was vetoed by Governor Brown who noted that "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.")

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. (Status: *The bill was never heard in a policy committee of the Legislature.*)

4. **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."

   According to the California Chamber of Commerce, In June 2024, the Federal Food and Drug Administration (FDA) declared that all biosimilar products and interchangeable biosimilar products meet its rigorous standards for approval for the prescribed reasoning on the product labeling…California's employers are proud to provide their employees with health coverage. Employer-sponsored health care coverage is usually some of the most formidable expenses a business experiences. SB 1094 will support the state's efforts to make health care more affordability for Californians."

   The California Association of Health Plans writes that "Without this legislative change, Californians will remain locked into higher-priced brand-name products, even when safe, lower-cost alternatives are available." According to the group, "The FDA further states that patients and health care providers can be as confident in the safety and effectiveness of the biosimilar and interchangeable biosimilar as they can be for the reference product."

   According to Blue Shield of California, this bill "is a small, but important step toward making the pharmaceutical industry part of the solution, not just part of the problem. In short the measure will make access to lower cost, equally safe and effective biosimlar medications available to consumers right at the pharmacy, maintaining all existing consumer protections and the sanctity of the doctor-patient relationship… SB 1094 is a critical tool to insert competition into drug pricing that will bring down costs to the system by eliminating the market protections the industry so desperately wants to maintain. In California alone, SB 1094 will save the healthcare

system hundreds of millions of dollars that will go to offsetting member premiums without any impact on safety."

CPCA Advocates notes that this bill "promotes the use of lower-cost, equally effective treatments, encourages timely coverage of more affordable therapies, and protects continuity of care for patients."

Health Access California writes "With health care costs continuing to rise faster than wages and inflation, and losses in coverage and price hikes due to federal action, it's critical we pass legislation and support policies to rein in rising health care costs and restore coverage."

Sharp Healthcare states that it "saved more than $6.4 million last year through biosimilar conversions which helped reduce overall healthcare costs and allowing Sharp to reinvest in expanded access to services, patient care programs, and critical clinical resources. The use of biosimilars can also result in direct patient savings as biosimilars often have lower patient co-pays and outpatient costs. Additional savings—and patient benefits—remain unrealized due to outdated statutory barriers."

5. **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."

6. **Arguments in Opposition**. According to Amgen**, "**The FDA's assessment of therapeutic equivalence for generics, which is key to pharmacy substitution of generics in California, takes into account differences in dosage form and other characteristics. By expanding the standard for pharmacy substitution beyond designated interchangeable biosimilars to all biosimilars, California would effectively hold complex biologics to a less robust standard than even less complex AB-rated generic drugs." Amgen states that the "significant growth in biosimilar adoption has occurred in an environment in which all 50 states share California's current requirement that a biosimilar be deemed interchangeable to permit pharmacy substitution. Indeed, many biologics are administered in a clinical setting by healthcare professionals and are not dispensed at the pharmacy." According to Amgen, "…even as FDA reduces the circumstances in which it expects switching studies for an interchangeability designation, the federal interchangeability

determination is still the tool FDA uses to assess substitution without prescriber intervention. SB 1094 would erode that patient protection function." Amgen believes that this bill would weaken patient safeguards by authorizing pharmacy substitution of non-interchangeable biosimilars at a time when the FDA's approach has shifted towards granting interchangeability virtually by default except where it determines further evidence is needed to address areas of potential concern, and by creating a new statutory pathway for plans and insurers to require mid-course, nonmedical switches even when a patient is stable on a therapy that was previously approved for coverage."

Biocom writes that this bill "would undermine longstanding patient protections and create unnecessary risk of treatment disruption… Policies that weaken prescriber oversight and continuity-of-care protections are unnecessary and could ultimately undermine patient confidence in these therapies." Biocom requests that the bill maintain the current requirement that pharmacy substitution be limited to FDA-designated interchangeable biosimilars, or require explicit prescriber authorization for substitution of noninterchangeable products and prevent mid-year, nonmedical switching of patients who are stable on a prescribed therapy.

According to the California Rheumatology Alliance, "While biosimilars are 'highly similar' to their reference products, they are not identical. There may be some subtle differences leading to differences in efficacy or even reactions in individuals… When a patient is switched to a different biological product, it is crucial that the treating physician is consulted ahead of time and that the product is tracked for safety reasons. The substitution mechanisms in this bill could obscure these processes."

The Osteopathic Physicians and Surgeons of California states that the current "process is working for California patients and that it is not in the best interest of patients to remove the interchangeable standard and allow a pharmacist to substitute all biosimilars." The organization 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. "SB 1094, instead, gives health plans the ability to switch these patients with little to no notification, and without the intervention or approval of their treating physician."

7. **Proposed Author's Amendments.**

In response to ongoing discussions with stakeholders, the Author is proposing amendments to:

- Add the word "safe" to Legislative intent provisions.
- Clarify that substitution for an alternative biological product by a pharmacist is a biosimilar to or interchangeable with the prescribed reference product.
- Require the Board to maintain a link to the Purple Book rather a list of products FDA has determined are interchangeable.

- Define reference product as having the same meaning as federal law.

- Specify, for purposes of requiring an enrollee to try a therapeutically equivalent generic, biosimilar, or interchangeable biological product, that the plan must provide at least 30 days advance notice to the enrollee and their prescribing provider prior to substitution and authorizes the enrollee or their provider to request an exception to the requirement to try an alternative product.

- Specify that a plan is not authorized to alter or issue a prescription.

- Make various technical and conforming changes.

SUPPORT AND OPPOSITION:

Support:

American Muslims for Sustainability
Association of California Life and Health Insurance Companies
Blue Shield of California
California Association of Health Plans
California Chamber of Commerce
CPCA Advocates, Subsidiary of the California Primary Care Association
CVS Health
CVS/Caremark Corporation
Health Access California
Los Angeles Civil Rights Association
SEIU California
Shalom International Outreach
Sharp Healthcare
The Sperantia Foundation

Opposition:

Amgen
BIO
Biocom California
California Rheumatology Alliance
Osteopathic Physicians and Surgeons of California

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