Date of Hearing: June 23, 2026

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS
Marc Berman, Chair
SB 1094 (Weber Pierson) – As Amended April 8, 2026

NOTE: This bill is double referred and if passed by this Committee will be re-referred to the Assembly Committee on Health.

SENATE VOTE: 38-0

SUBJECT: Prescription drugs

SUMMARY: Expands the authority for a pharmacist to substitute a biosimilar for a prescribed biological product and authorizes health plans and insurers to require their enrollees to try an AB-rated generic equivalent, biosimilar, or interchangeable biological product of a reference product that was previously approved for coverage by the plan under specified conditions.

EXISTING LAW:

1) Establishes the Pharmacy Law. (Business and Professions Code (BPC) §§ 4000 *et seq.*)

2) Establishes the California State Board of Pharmacy (BOP) within the Department of Consumer Affairs to administer and enforce the Pharmacy Law. (BPC § 4001)

3) Provides that protection of the public shall be the highest priority for the BOP in exercising its licensing, regulatory, and disciplinary functions. (BPC § 4001.1)

4) Authorizes the BOP to adopt rules and regulations as may be necessary for the protection of the public. (BPC § 4005)

5) Defines "pharmacist" as a natural person to whom a license has been issued by the BOP which is required for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription; allows a pharmacist to authorize the initiation of a prescription consistent with the accepted standard of care. (BPC § 4036; § 4051)

6) Declares pharmacist practice to be a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of patient-care activities to optimize appropriate drug use, drug-related therapy, disease management and prevention, and communication for clinical and consultative purposes and that pharmacist practice is continually evolving to include more sophisticated and comprehensive patient care activities. (BPC § 4050)

7) Authorizes a pharmacist to perform specified functions and provide specified services as part of their scope of practice, including furnishing certain medications, performing certain procedures, administering drugs and biological products, ordering and interpreting tests, and providing consultation, training, and education to patients. (BPC § 4052)

8) Authorizes a pharmacist filling a prescription order for a drug product may 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. (BPC § 4052.5)

9) Prohibits the furnishing of any dangerous drug or device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor. (BPC § 4059)

10) Authorizes a pharmacist to refill a prescription for a dangerous drug or dangerous device without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being, subject to additional requirements. (BPC § 4064)

11) Authorizes a pharmacist filling a prescription order 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 as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients. (BPC § 4073)

12) Authorizes a pharmacist filling a prescription order for a prescribed biological product may select an alternative biological product only if all of the following:

    a) The alternative biological product is interchangeable.

    b) The prescriber does not personally indicate "Do not substitute," or words of similar meaning.

    (BPC § 4073.5(a))

13) Requires a pharmacist who is substituting an interchangeable biosimilar for a prescribed biological product to make an entry of the product provided to the patient, including the name of the biological product and the manufacturer, within five days. (BPC § 4073.5(b))

14) Prohibits a pharmacist from substituting an interchangeable biosimilar for a prescribed biological product if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. (BPC § 4073.5(e))

15) Provides that selection of an interchangeable biosimilar is within the discretion of the pharmacist and that the pharmacist shall assume the same responsibility for substituting the biological product as would be incurred in filling a prescription for a biological product prescribed by name. (BPC § 4073.5(f))

16) Defines "interchangeable" as a biological product that the FDA has determined meets certain standards, or has been deemed therapeutically equivalent by the FDA as set forth in the latest addition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations. (BPC § 4073.5(j))

THIS BILL:

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 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 generic or biosimilar drug substitutions.

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

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

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

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

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

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

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

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

FISCAL EFFECT: Pursuant to Senate Rule 28.8, negligible state costs.

COMMENTS:

Purpose. This bill is sponsored by the *California Association of Health Plans*. 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.

Background.

California State Board of Pharmacy. The BOP is the regulatory body responsible for overseeing pharmacies and pharmacist practice in California. As of 2025, the BOP is estimated to regulate over 50,700 pharmacists, 1,300 advanced practice pharmacists, 4,400 intern pharmacists, and 65,700 pharmacy technicians across 32 distinct licensing programs. In addition to regulating professionals, the BOP licenses and oversees pharmacies, clinics, wholesalers, third-party logistic providers, and automated drug delivery systems.

As one of approximately three dozen boards and bureaus under the Department of Consumer Affairs, the BOP plays an important role in the regulatory ecosystem that oversees the healing arts. In the face of persistent concerns such as the opioid crisis, the BOP is empowered to ensure that dangerous drugs and controlled substances are dispensed and furnished only under lawful circumstances. Under regulations enforced by the BOP, pharmacists are tasked with a corresponding responsibility for ensuring that the prescriptions they fill are legitimate and not for purposes of abuse.

Entrusted with administering and enforcing the state's Pharmacy Law, statute provides that "protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount."

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.[1]

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.

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[1] Liu M, Wadhera RK. *Primary Care Physician Supply by County-Level Characteristics*, 2010-2019.

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.[2]

A biosimilar is a biologic product that is highly similar to an original FDA-approved biologic, 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.[3]

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 Biologics Price Competition and Innovation Act, enacted in 2010 as part of the 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.[4]

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.

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[2] "Biosimilars Basics for Patients." *U.S. Food and Drug Administration*, https://www.fda.gov/drugs/biosimilars/biosimilars-basics-patients

[3] "Biosimilar and Interchangeable Biologics: More Treatment Choices." *U.S. Food and Drug Administration*, https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices

[4] "9 Things to Know About Biosimilars and Interchangeable Biosimilars." *U.S. Food and Drug Administration*, https://www.fda.gov/drugs/things-know-about/9-things-know-about-biosimilars-and-interchangeable-biosimilars

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.[5] 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.[6]

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."[7]

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[5] Woodcock, Janet, and Sarah Yim. "A Milestone in Facilitating Development of Safe and Effective Biosimilars." *FDA Voices*, *U.S. Food and Drug Administration*, July 2023.
[6] "FDA Proposes to Ease Testing Rules to Speed Up Biosimilar Drug Development." *Reuters*, March 2026.
[7] "FDA Updates Guidance on Interchangeability." *U.S. Food and Drug Administration*, https://www.fda.gov/drugs/drug-alerts-and-statements/fda-updates-guidance-interchangeability

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 an AB-rated generic equivalent of a brand name drug, a biosimilar, or interchangeable biological product of a reference product that was previously approved for coverage by the plan.

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 30 days' advance notice to the enrollee or insured and prescribing provider of a substitution requirement prior to requiring an enrollee or insured to try a substitute. Finally, this bill would 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.

Provisions in this bill relating to health plans and insurers are within the jurisdiction of the Committee on Health, which would be re-referred the bill upon passage by this Committee.

Prior Related Legislation. AB 1503 (Berman), Chapter 196, Statutes of 2025 extended the sunset date for the BOP and made additional changes to the Pharmacy Law.

SB 671 (Hill), Chapter 545, Statutes of 2015 authorized a pharmacist to substitute an alternative biological product when filling a prescription for a prescribed biological product if the biosimilar has been designated as interchangeable with the reference product by the FDA.

SB 598 (Hill) of 2023 would have authorized a pharmacist to substitute an FDA-approved interchangeable biosimilar for a prescribed biologic. *This bill was vetoed by the Governor.*

AB 1139 (Lowenthal) of 2013 would have authorized a pharmacist to substitute an FDA-approved interchangeable biosimilar for a prescribed biologic. *This bill did not receive a hearing in this committee.*

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.

Blue Shield of California supports this bill, writing:

> [Senate Bill 1094] will make access to lower cost, equally safe and effective biosimilar medications available to consumers right at the pharmacy, maintaining all existing consumer protections and the sanctity of the doctor-patient relationship. This is necessary because access to these medications is locked behind state law created intentionally to allow only certain types of so-called 'interchangeable' biosimilars to be substituted automatically, functionally creating a niche market without any benefit to consumers. The Food and Drug Administration (FDA) has repeatedly stated that there is no safety distinction between a biosimilar, an interchangeable biosimilar, or the reference (or branded) product – it's a distinction without a difference – except it costs multiple times more than the alternative AND patients have no choice on what they must buy.

Health Access California also supports this bill, writing:

> Prescription drugs are a significant driver of high health care costs for consumers. The Department of Managed Health Care recently reported that prescription drug expenses for large group health plans increased nearly 10 percent from 2024 to 2025. With prescription drug expenses making up nearly 18% of large group health care premiums, ensuring that consumers have access to more affordable prescription drugs is critical to their access to care, and controlling escalating health care premiums.

> That's why ensuring that consumers have access to safe alternatives like biosimilars is important. A biosimilar and its original biologic are made from the same types of sources and have the same treatment benefits and risks. They have no clinically meaningful differences. However, biosimilars can be made available at a lower cost than the original biologics or brand name drug.

ARGUMENTS IN OPPOSITION:

The *California Rheumatology Alliance* opposes this bill, writing:

> For many rheumatology patients, finding an effective biologic requires multiple failures of other treatments. Allowing pharmacists to make a medical decision to substitute biological products without the direct, proactive consent of the treating physician can lead to unintentional switches, increased immunogenicity, and loss of efficacy. SB 1094 would also allow insurers to demand that patients switch to a biosimilar or interchangeable product as a condition of coverage, even if they have been stable on a reference product. This switching ignores individual patient history and mandates that physicians spend valuable time navigating prior authorizations to maintain the treatment plan that works.

The *Biotechnology Innovation Organization* (BIO) opposes this bill unless amended to "allow automatic substitution of non-interchangeable biosimilars only upon the initial dispensing of a prescription, but not for patients on an established course of treatment." BIO further writes:

> It should also be clear that *this bill would not treat biosimilars more like generic drugs*. A common misconception exists that approval of a "traditional" or "small molecule" generic drug automatically means that the generic is substitutable without physician intervention at the pharmacy. That is not the case, and it conflates the standards for approval of a drug with the standard for dispensing it to patients. Even generic drugs are not substitutable by operation of law—FDA makes an assessment of therapeutic equivalence as a part of the approval process for a generic product. In fact, there are many generic drugs that were approved for marketing by the FDA without being substitutable at the pharmacy counter. To treat non-interchangeable biosimilars as interchangeable in California would be a big departure from the way FDA regulates small molecule drugs because, unlike for generic drugs, FDA would not have the flexibility to decide whether any given biosimilar should be substitutable at the pharmacy or not.

Amgen also 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.

POLICY ISSUES:

Disruption of Effective Treatments. As articulated in opposition comments from specialist physicians, patients who use biologic therapies often live with complex conditions that require long-term management and highly individualized treatment approaches, such as Crohn's disease, rheumatoid arthritis, and psoriasis. For these types of conditions, identifying a medication that can effectively and sustainably manage symptoms and slow disease progression can be challenging. Additionally, a biologic that works very well for one patient may not work for another patient with the same diagnosis. For example, two patients with rheumatoid arthritis may both be prescribed a TNF inhibitor such as Humira, but while one patient may experience improvement, the other may need a different biologic that targets another biological pathway.

This bill would authorize a pharmacist to substitute any biosimilar for a prescribed biologic even if the patient has been taking that prescribed biologic for a very long time and even if that biologic was prescribed after an extensive trial-and-adjustment process to identify a successful therapeutic solution for that patient. This could mean that a stable patient on a consistent treatment regimen could abruptly have their biologic switched out for a biosimilar that is less effective, or not effective at all. This interruption in therapy could have both short-term and long-term consequences; in some cases, the originally prescribed biologic may no longer be as effective even once the patient is switched back.

While there are cogent reasons to support allowing pharmacists to select an alternative biologic product for patients that would be more affordable or accessible, this conceivable benefit must be weighed against the potential impact on patients who are managing chronic conditions who could be destabilized by having their medication substituted. The author should consider amendments to ensure that prescribers are notified when a patient who is currently taking a biologic as part of an ongoing treatment regimen is subject to having that biologic substituted for a non-interchangeable biosimilar as a result of the expanded authority provided by this bill. This notification would enable those prescribers to indicate "do not substitute" on the patient's prescription if needed and if they have not already done so.

Potential for Actions against Prescribers. This bill would fully retain the authority of a physician or other prescriber to indicate "do not substitute" on a prescription for a biologic, which ostensibly protects patients who could suffer from a substitution. However, stakeholders have raised concerns that health plans and pharmacy benefit mangers could pressure those physicians through repeated requests for prior authorization, proof of adverse reactions or failure, or submissions of the clinical rationale for decisions, which could burden physicians and delay care. The author should consider amendments to ensure that prescribers who indicate "do not substitute" on prescriptions are not subject to inappropriate consequences.

REGISTERED SUPPORT:

California Association of Health Plans *(Sponsor)*
AFSCME District Council 36
American GI Forum Education Foundation of Santa Maria, CA
American Muslims for Sustainability
Blue Shield of California
California Academy of Family Physicians

California African American Chamber of Commerce
California Chamber of Commerce
California Hispanic Chambers of Commerce
Clergy and Laity United for Economic Justice
Coalition of LA Probation Unions
Community Church
Corinthian Baptist Church
CPCA Advocates, Subsidiary of the California Primary Care Association
CVS/Caremark Corporation
Ephesian Baptist Church
First Union Baptist Church
Good News Missionary Baptist Church
Hardesty LLC
Health Access California
Los Angeles Civil Rights Association
Mahoney Entertainment
Oakland Youth First Scotlan Youth & Family Center
Parchester First Baptist Church
Pharmaceutical Care Management Association
San Diego Regional Chamber of Commerce
Santa Clara County Probation Peace Officer's Union, AFSCME Local 1587
SEIU California
Shalom International Outreach
The Sperantia Foundation
West Oakland Job Resource Center
Three individuals

REGISTERED OPPOSITION:

Amgen
Biocom
Biotechnology Innovation Organization
California Dermatology Advocacy Network
California Rheumatology Alliance
California Society of Dermatology & Dermatologic Surgery
Osteopathic Physicians and Surgeons of California
U.S. Pain Foundation

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