SENATE COMMITTEE ON HEALTH
Senator Dr. Akilah Weber Pierson, Chair

BILL NO: SB 1094
AUTHOR: Weber Pierson
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HEARING DATE: April 22, 2026
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SUBJECT: Prescription drugs

SUMMARY: Authorizes health plans and insurers, upon 30 days' notice to enrollees, insureds, and prescribing providers, to require enrollees/insureds currently prescribed a drug or biological product to try a generic or biosimilar when available at the same or lower cost-sharing unless the prescribing provider indicates not to substitute. Authorizes a pharmacist to substitute a reference product with a biosimilar when available to the patient at the same or lower cost-sharing unless the prescribing provider indicates not to substitute.

Existing law:
1) Establishes the Department of Managed Health Care (DMHC) to regulate health plans under the Knox-Keene Health Care Service Plan Act of 1975 (Knox-Keene Act) and the California Department of Insurance (CDI) to regulate health insurance. [HSC §1340, et seq. and INS §106, et seq.]

2) Prohibits a health plan contract from limiting or excluding coverage for a drug for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's condition. This does not preclude the prescriber from prescribing another covered drug that is medically appropriate or a generic substitution. This does not apply to off-label use of drugs. This does not prohibit a health plan from charging a subscriber or enrollee a copayment or a deductible for prescription drug benefits or from setting forth, by contract, limitations on maximum coverage of prescription drug benefits. [HSC §1367.22]

3) Requires health plans to maintain an expeditious process by which the prescribing provider may obtain authorization for a medically necessary nonformulary prescription drug, except the process is not required for nonformulary drugs that have been prescribed pursuant to 2) above. [HSC §1367.24 and INS §110123.193]

4) Requires, if a health plan or health insurer that provides coverage for prescription drugs fails to respond to a prior authorization or step therapy exception request, as specified, within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist, upon the receipt of a completed form, the request to be deemed granted. [HSC §1367.241 and INS §10123.191]

5) Requires a health plan or insurer to expeditiously grant a request for a step therapy exception within the applicable time limit described in 4) above if a prescribing provider submits necessary justification and supporting clinical documentation that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services, taking into consideration the enrollee's or insured's needs and medical

history. Permits the basis of the provider's determination to include, but not be limited to, any of the following criteria:

a) The prescription drug required by the plan or insurer is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm in comparison to the requested prescription drug;
b) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee or insured and the known characteristics and history of the enrollee's or insured's prescription drug regimen;
c) The enrollee or insured has tried the required prescription drug while covered by their current or previous health coverage or Medicaid, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction. Permits the plan or insurer to require the submission of documentation demonstrating that the enrollee or insured tried the required prescription drug before it was discontinued;
d) The required prescription drug is not clinically appropriate for the enrollee or insured because the required drug is expected to do any of the following, as determined by the prescribing provider:
    i) Worsen a comorbid condition;
    ii) Decrease the capacity to maintain a reasonable functional ability in performing daily activities; or,
    iii) Pose a significant barrier to adherence to, or compliance with, the enrollee's drug regimen or plan of care.
e) The enrollee or insured is stable on a prescription drug selected by the prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid. [HSC §1367.206 and INS §10123.201]

6) Authorizes a health care provider or prescribing provider, enrollee, insured, or their designee or guardian to appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request consistent with the plan's or insurer's current utilization management process. [HSC §1367.206 and INS §10123.201]

7) Indicates for purposes of 5) and 6) above, a health plan or insurer or utilization review organization is not prohibited from requiring an enrollee or insured to try an AB-rated generic equivalent, biosimilar or interchangeable biological product before providing coverage for the equivalent branded prescription. This does not prohibit or supersede a step therapy exception request. [HSC §1367.206 and INS §10123.201]

8) Requires health plans and insurers to report requires health plans and insurers that report rate information to DMHC and CDI to also report specified information related to prescription drug pricing. Requires DMHC and CDI to compile specified information into a report that demonstrates the overall impact of drug costs on health care premiums. [HSC §1367.243 and INS §10123.205]

9) Establishes the Pharmacy Law which provides for the licensure and regulation of pharmacies, pharmacists, and dangerous drug or device wholesalers, and establishes the Board of Pharmacy (the Board) to enforce the Pharmacy Law. [BPC §4000, et seq.]

10) Authorizes a pharmacist filling a prescription for a drug product to select a different form of medication with the same active ingredients of equivalent strength and duration of therapy as the prescribed drug when the change will improve the ability of the patient to comply with

the prescribed drug therapy unless the prescriber indicates "Do not substitute." Specifies that the pharmacist assumes the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product using the prescribed form of medication and specifies that there is no liability on the prescriber pursuant to this authority. Requires the patient to be informed that a different form of medication was used and requires the prescription label to include the name of the dispensed drug product. Prohibits substitution between long-acting and short-acting forms of a medication with the same chemical ingredients or between one drug product and two or more drug products with the same chemical ingredients. [BPC §4052.5]

11) Authorizes a pharmacist, when filling a prescription for a drug product prescribed by its trade or brand name, to select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name. Outlines the same "Do not substitute" specifications, pharmacist discretion specifications, prescriber liability specifications, patient communication specifications, and prescription label specifications in 10) above. Prohibits a pharmacist from substituting if the drug selected substitution costs the patient the same or more than the prescribed drug, including any professional fee charged by the pharmacist. [BPC §4073]

12) Authorizes a pharmacist filling a prescription for a prescribed biological product to select an alternative biological product if the alternative biological product is interchangeable and if the prescriber does not indicate "Do not substitute" or words of similar meaning. Requires a dispensing pharmacist or their designee to make an entry of the specific biological product provided to the patient within five days of dispensing it, including the name of the biological product and the manufacturer. 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. Outlines the same "Do not substitute" specifications, pharmacist discretion specifications, prescriber liability specifications, patient communication specifications, and prescription label specifications in 10) above. Outlines the same cost specifications in 11) above. 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 [BPC §4073.5]

13) Requires the Board to maintain a link to a list of the biological products that the U.S. Food and Drug Administration (FDA) has determined are interchangeable. [BPC §4073.5]

This bill:

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

2) Restricts the authority to request patients try an alternative product to those drugs or biological products that have a lower net cost to the plan or insurer and have the same or lower cost-sharing for the enrollee/insured, which must be based on the net cost of the drug or biological product. Requires plans or insurers to provide at least 30 days' advance notice to the enrollee/insured and prescribing provider of a request to try an alternative product. Clarifies that enrollees/insureds may request exceptions via existing step therapy exceptions

or nonformulary drug requests and clarifies that health plans or insurers are not issuing or altering prescriptions.

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

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

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

FISCAL EFFECT: This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) *Author's statement.* 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. Biologics are particularly expensive: though only 5% of prescriptions, they account for about half of all drug spending. Expanding the use of lower-cost alternatives, like 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. For example, switching from the rheumatoid arthritis and Crohn's disease drug Humira to one of its biosimilars can reduce wholesale acquisition costs by 85%. Furthermore, competition between biosimilars and brand-name biologics helps drive prices down overall. Despite their potential savings, biosimilars remain underused. This bill promotes their adoption by allowing pharmacists to substitute a biologic with a biosimilar unless otherwise indicated, and allowing health plans to require enrollees to try a generic or biosimilar when available at the same or lower cost unless otherwise indicated. It also requires insurers to report the proportion of substitutions that reduce cost-sharing and the impact on premium growth.

2) *California Health Benefits Review Program (CHBRP) analysis.* AB 1996 (Thomson, Chapter 795, Statutes of 2002) requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996 and reviewed this bill. Key findings include:
   a) *Coverage impacts and enrollees covered*. CHBRP estimates that 22.8 million Californians with state-regulated insurance (60% of the state) have plans that would be subject to this bill. All these individuals have coverage for biological products on the medical benefit and 57.6% have coverage for biological products on the pharmacy benefit. This difference is due to the Medi-Cal outpatient prescription benefit being carved out of Medi-Cal managed care and provided through Medi-CalRx as well as the 5% of CalPERS enrollees who do not have pharmacy benefit coverage in their plan.

b) *Medical effectiveness.* There is very strong evidence of no differences in safety or efficacy between biosimilars and their reference biologic, based on FDA regulatory standards. There is also very strong evidence that there is no difference in safety or side effects when switching between reference biologics and their biosimilar based on 31 randomized control trials and over 15 years of extensive pharmacovigilance data, derived from continuous monitoring of biosimilars after being made available to the public.
c) *Utilization*. CHBRP estimates that 24,700 Californians would be switched from a brand name reference product to a lower-cost biosimilar, and that the impact of small molecule drug switches would be negligible due to high rates of switching already.
d) *Medi-Cal.* Although Medi-Cal pharmacy benefits are carved out through Medi-CalRx, this bill still impacts nearly 9 million Medi-Cal enrollees through DMHC-regulated Medi-Cal managed care medical benefits. Medi-Cal premiums are expected to decrease by $1.5 million in a 50% market shift scenario ($0.01 per member per month).
e) *Impact on expenditures*. CHBRP performed a sensitivity analysis of three different utilization scenarios: a 10%, 50%, or 90% switch from reference products to biosimilars or interchangeable biological products. All scenarios resulted in premium savings, ranging between $17.5 million (0.01%) for a 10% market shift scenario and $175 million (0.09%) for a 90% market shift scenario. In a 50% market shift scenario, premiums are expected to decrease by $87.7 million, with a $55.5 million reduction in employer or union premiums, a $14.6 million reduction in premiums for enrollees in group insurance, and a $16 million reduction in premiums for enrollees in the individual market. For those whose prescriptions are switched to a biosimilar by a pharmacist or who are required to try a biosimilar by their health plan, average savings are much greater, saving the enrollee between $92 and $310 annually in total cost-sharing, depending on their insurance market.
f) *Public health.* Because the evidence suggests switching patients to biosimilar products does not negatively impact health outcomes, no short-term public health impact is predicted. Some enrollees, however, may experience less financial burden due to a decrease in out-of-pocket costs. Long-term impacts include decreased enrollee financial burden with the normalization of lower-cost drug substitutions and increased biosimilar competition that would drive a reduction in the net prices of biological products.

3) *Biological products.* Biological products are large, complex molecules made from living sources, like bacteria, yeast, or animal cells. Biological products include monoclonal antibodies, insulin, vaccines, and allergenic products, and are most often used to treat chronic skin diseases, inflammatory bowel diseases, arthritis, kidney conditions, diabetes, and cancer. Biological products are approved by the FDA under the Public Health Service Act's 351(a) pathway, which consists of a standalone Biologics License Application (BLA) that contains all data necessary to demonstrate the product's safety and effectiveness, including both preclinical studies and clinical trials in humans. The BLA must be approved by the FDA before the product can be legally marketed in the U.S.

4) *Biosimilars.* The Biologics Price Competition and Innovation Act (BPCIA) of 2009 defined a biosimilar as a biological product with active components that are highly similar to a reference product that demonstrates no clinically meaningful differences in terms of safety, purity, or potency. Like generic drugs, biosimilars are approved through an abbreviated pathway (the Public Health Service Act's 351(k) pathway) that relies on the FDA's prior approval of a reference biologic. To gain approval as a biosimilar, manufacturers must perform rigorous comparative analysis of the physicochemical and biological functional characteristics of a biosimilar to the reference product and an assessment of immunogenicity.

The proposed biosimilar product must be shown to have the same mechanism of action as the reference product, the same route of administration, dosage form, and strength as the reference product, and may be licensed only for conditions that have been previously licensed for the reference product. The FDA maintains an online database of all reference products and approved biosimilars, called the Purple Book.

5) *Biosimilar cost savings.* According to a Department of Health and Human Services (HHS) fact sheet, biologics are a significant driver of prescription drug costs in the U.S., accounting for over half of total U.S. drug spending in 2024 despite comprising just 5% of prescriptions. According to a KFF report, retail prescription drug prices are the fastest growing cost in national healthcare expenditures. DMHC reports that prescription drug costs paid by California health plans have increased by 72%, or $6.2 billion, since 2017. When drug prices increase, these costs get passed on to employers and health plan enrollees via increased premiums. The 2025 California Health Benefits Survey reports that 36% of large California companies (over 200 employees) report that prescription drug prices contributed "a great deal" to higher premiums, including 63% of companies with 5,000 or more workers.

   Because biosimilars are approved through an abbreviated pathway that avoids the need for as many costly and lengthy clinical trials as the reference product, biosimilars offer considerable cost savings. Since their introduction to the market, biosimilars have generated savings totaling $56.2 billion for both patients and the healthcare system, according to the Association of Accessible Medicines (AAM). Recognizing the potential for cost savings for payors, the Center for Medicare and Medicaid Services' May 2024 Final Rule for Medicare Part D plans authorized Part D sponsors to substitute, upon 30 days' notice, a biosimilar biological product for its reference product on their formularies.

6) *Barriers to biosimilar development and uptake*. According to the 2025 AAM report, the U.S. biosimilar market has not yet reached its full potential. A 2024 IQVIA analysis shows that 90% of the biologics with a patent expiring between 2025-2034 do not have a biosimilar in development, creating a "biosimilar void" that is estimated to cost the U.S. around $189 billion. A 2025 report from the Eastern Research Group to the Department of Health and Human Services states that patent thickets (overlapping groups of patents that extend intellectual property rights well beyond the initial expiry date) are substantial hurdles for the biosimilar development pipeline that would allow competition to drive lower-cost therapies. Beyond the research and development pipeline, limited knowledge or lack of acceptance among patients and providers may also slow uptake. Furthermore, the narrative that biosimilars are inferior to reference products has been perpetuated in name brand marketing, according to educational materials published by the FDA and Federal Trade Commission. Lastly, the AAM report also highlights that financial incentives like rebates for health plans and pharmacy benefit managers (PBMs) that favor reference product placement on formularies discourage the use of lower-cost biosimilars.

7) *Interchangeability.* The fact that some biosimilars (about 30%) are designated "interchangeable" is another source of confusion and misunderstanding among patients and clinicians that may be contributing to lagging biosimilar uptake, according to the FDA Commissioner in a recent *JAMA Network* publication. Interchangeability, as defined in the BPCIA, is a designation a biosimilar can acquire if the manufacturers show that the product does not carry any increased risk of diminished safety or efficacy when switching between the use of the biosimilar and the reference product and means that the biological product may

be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

According to the FDA, both biosimilars and interchangeable biosimilars meet the same high standard of biosimilarity for approval and are equally as safe and effective as the reference product. Manufacturers must apply for the interchangeable designation, which originally required costly and lengthy clinical "switching studies" to demonstrate that alternating between the biosimilar and the reference product posed no greater risk to safety or efficacy than continued use of the reference product alone. The requirement for switching studies was rescinded in a 2024 draft guidance when the FDA found—through a decade of experience and a 2023 systematic review and meta-analysis—no difference in the safety profiles or immunogenicity rates in patients who were switched between the biosimilar and reference product and those who were not. The FDA states that "the same comparative analytical data that supports a demonstration of biosimilarity can support a demonstration of interchangeability." Additionally, the FDA has advanced legislative proposals for fiscal years 2025, 2026, and 2027 to eliminate the statutory distinction between biosimilars and interchangeable biosimilars by deeming all approved biosimilars interchangeable. The FDA contends this would better align the U.S.'s licensing approach with other regulatory jurisdictions like the E.U., which does not have an interchangeable designation.

8) *Double referral.* This bill was heard in the Senate Business, Professions, and Economic Development Committee on April 6, 2026, and passed with a 10-0 vote.

9) *Related legislation.* AB 2000 (Aguiar-Curry) prohibits a health plan or insurer that provides prescription drug benefits and maintains one or more drug formularies from making changes to a formulary during a plan or policy year, except under specified circumstances such as to: 1) add an additional drug to the formulary; 2) replace a covered drug with another in the same drug class or a brand name drug with a generic of the same drug or drug class, if the enrollee's cost sharing is the same or lower; or, 3) add a biosimilar or interchangeable biologic product that is the same or similar to a previously covered drug or reference product if the net cost to the plan and the enrollee's cost sharing is the same or lower than the reference product. *AB 2000 is pending in the Assembly Appropriations Committee.*

10) *Prior legislation.* SB 621 (Caballero, Chapter 495, Statutes of 2023) authorizes a health plan, health insurer, or utilization review organization to require an enrollee or insured to try a biosimilar drug, as defined, before providing coverage for the branded prescription drug. The bill also clarifies that a requirement to try a biosimilar, generic, or interchangeable drug does not prohibit or supersede a step therapy exception request.

SB 671 (Hill, Chapter 545, Statutes of 2015) authorizes a pharmacist to select an alternative biological product when filling a prescription order for a prescribed biological product if the alternative biological product is interchangeable, costs the same or less than the cost of the prescribed biological product, and the prescriber does not personally indicate "Do not substitute." The pharmacist must notify the patient of any substitution and record the specific biological product provided within 5 days of being dispensed in a manner accessible to the prescriber.

SB 598 (Hill of 2013) would have authorized pharmacists to substitute an interchangeable biosimilar for a biologic if the prescriber did not indicate "Do not substitute," including a

requirement that notification of the substitution be provided. *SB 598 was vetoed by Governor Brown, who wrote:*

> *Senate Bill 598 would effect two changes to our state's pharmacy law. First, it would allow interchangeable "biosimilar" drugs to be substituted for biologic drugs, once these interchangeable drugs are approved by the federal Food and Drug Administration (FDA). This is a policy I strongly support.*
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> *Second, it requires pharmacists to send notifications back to prescribers about which drug was dispensed. This requirement, which on its face looks reasonable, is for some reason highly controversial. Doctors with whom I have spoken would welcome this information. 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.*
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> *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." Given this fact, to require physician notification at this point strikes me as premature.*

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. *AB 1139 was held in the Assembly Business and Professions Committee.*

11) *Support.* The sponsor of the bill, the California Association of Health Plans (CAHP), states that this bill is a step towards addressing prescription drug prices, the fastest-growing driver of health plan premiums in California. CAHP writes that this bill modernizes outdated pharmacy substitution laws and permits health plans to make formulary changes that align with those already occurring in Medicare Part D plans, which can substitute coverage of a brand-name biologic with a biosimilar. Blue Shield of California and America's Physician Groups point out that the Office of Health Care Affordability places all health care industry players on a budget except pharmaceutical manufacturers, and this bill is a small but important step towards making the pharmaceutical industry part of the solution, injecting competition into drug pricing that will bring down costs to the system. CVS Health reports that they've transferred 93% of the patients they serve to Hyrimoz, a Humira biosimilar, which has saved their members in California $33.2 million and has reduced total gross cost per prescription by almost $6,700 since 2023. CVS plans to continue transitioning patients to osteoporosis biosimilars that offer a 50% cost savings over brand-name alternatives. Sharp HealthCare saved more than $6.4 million last year through biosimilar conversions, which helped reduce overall healthcare costs and allowed Sharp to reinvest in expanded access to services, patient care programs, and critical clinical resources. California Primary Care Association (CPCA) Advocates emphasizes that the bill increases access to lower-cost biologic medication, which is critically important to the communities served by CPCA Advocates' member community health centers and clinics, who often serve as the only source of care for lower-to-middle-class families in many rural communities. The California Chamber of Commerce supports efforts to make employer-sponsored health care coverage more affordable, pointing out that health care expenses are among the most formidable expenses a business experience. SEIU California states that health care costs are top of mind when workers and unions sit down at the bargaining table to negotiate contracts. As the cost of care rises, employers are pitting a livable wage against maintaining employer-sponsored coverage, which impacts how workers spend their paychecks. Health Access California states that six in ten Californians are skipping or delaying health care due to costs, and one-third of Americans are cutting back on daily spending, even skipping meals, due to health care costs.

Ensuring Californians have access to safe alternatives like biosimilars is an important method of reducing consumer costs without risks to quality of care.

12) *Support if amended*. The California Pharmacists' Association states that there is a need to ensure that pharmacies will be adequately reimbursed for dispensing medications, as under current practices, PBMs frequently reimburse pharmacies at rates below the cost of acquisition, leading to instability in the pharmacy supply chain and accelerating pharmacy closures. The Association will support the bill if it is amended to include fair and adequate reimbursement at or above the cost of drug acquisition, along with a reasonable dispensing fee. The California Society of Health-System Pharmacists also supports the bill if amended to state that the law can't be construed to require a medical provider or pharmacy to stock, procure, dispense, or administer drugs from manufacturers or distributors that are not currently part of the pharmacy's existing contractual agreements. They point out that as currently drafted, SB 1094 could allow health plans to mandate a "plan-designated" biosimilar that falls outside a pharmacy's existing contracts and could disrupt procurement operations and potentially place pharmacies in breach of their existing supply agreements. They also note that where a reference product and a biosimilar occupy the same formulary tier, mandated substitution may not reduce the patient's out-of-pocket burden at all, which could undermine the bill's affordability promise.

13) *Oppose unless amended.* Amgen and Biocom oppose the bill unless amended to maintain the current pharmacy substitution law, which allows substitution only with interchangeable biosimilars. Biocom also proposes that the health and safety code changes be amended to preserve California's longstanding continuity-of-care protections by preventing mid-year, non-medical switching of patients who are stable on a prescribed therapy. Amgen additionally proposes a 60-day notice period before formulary or utilization management changes that would restrict coverage for a drug the patient is currently using, as well as a transition supply of the previously approved drug and coverage pending appeal or exception review. Amgen also suggests requiring that any required substitute results in verifiable, real-time patient cost sharing that is the same or lower at the pharmacy counter or administration site and shortening prescriber notification timing for biologic substitution at the pharmacy to no later than the next business day.

14) *Opposition.* The California Rheumatology Alliance, Osteopathic Physicians and Surgeons of California, and Lupus and Allied Diseases Association argue that biosimilars may have subtle differences in efficacy that may lead to unintended consequences for patients and insist that patients should not be switched to a different biological product without advance consultation with the prescribing physician unless the product has been deemed interchangeable by the FDA. They further argue that patients on biologics are living with complex medical conditions and have often tried multiple biologics before finding an effective therapy and oppose the ability of health plans to force a patient to try a biosimilar if they are stable on their existing therapy. The Lupus and Allied Diseases Association state that lupus is an unpredictable, individualized, heterogeneous, multi-system disease that requires access to the full array of treatments. Any disruption in continuity of care as a result of payer utilization management policies, formulary or dosage changes, or other cost containment measures has detrimental consequences on patients, possibly exacerbating the disease and augmenting costs. The determination of the most optimum and appropriate medical treatment is best accomplished by open and transparent communication between the patient and the healthcare provider, who is ethically obligated to the patient and not to an insurance cost-cutting mandate. The Osteopathic Physicians and Surgeons of California

emphasize that no other state allows substitution of biosimilars not deemed interchangeable, claiming that this process is working for Californians and that it is not in the best interests of patients to allow a pharmacist to substitute a biosimilar.

15) *Other.* The Pharmaceutical Care Management Association (PCMA) writes that this bill aligns with California's broader efforts to address rising drug costs. PCMA writes, "Competition in the pharmaceutical market exists when there are multiple brand drugs for the same conditions, and/or generic and biosimilar competition. More generics and biosimilars in the market will allow PBMs to push manufacturers and pharmacies to compete on pricing to deliver the lowest-cost products. By encouraging the appropriate use of generics and biosimilars, the bill strengthens market forces and discourages strategies that delay competition. This approach benefits not only individual patients, but also employers, labor unions, and government entities that are working to manage costs and expand access to affordable care."

SUPPORT AND OPPOSITION:

Support: California Association of Health Plans (sponsor)
America's Health Insurance Plans
America's Physician Groups
American GI Forum Education Foundation of Santa Maria
Association of California Life and Health Insurance Companies
Blue Shield California
California African American Chamber of Commerce
California Chamber of Commerce
California Primary Care Association Advocates
California State Council of Service Employees International Union
Coalition of Los Angeles Probation Unions
CVS Health
Hardesty LLC
Health Access California
Santa Clara County Probation Peace Officer's Union
SHARP Healthcare
Ten individuals

Oppose: Amgen (unless amended)
Biocom California (unless amended)
Biotechnology Innovation Organization (unless amended)
California Rheumatology Alliance
Lupus and Allied Disease Association, Inc.
Osteopathic Physicians and Surgeons of California

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