TECHNICAL BRIEF

SB 1094

Prescription Drugs

CHBRP

About the Technical Brief

This document provides details on the analytical foundation for CHBRP's analysis of SB 1094. While the main report synthesizes key findings for immediate policy consideration, this document is designed to support a deeper understanding of the background of the topic of the legislation and CHBRP's methodology and research in conducting its analysis. It contains the data sources, methods, assumptions, and other bill-specific considerations necessary for legislative staff, fiscal analysts, and other stakeholders to fully understand the scope and impact of the proposed measure.

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Acronyms and Terminology

Acronyms

AB – Assembly Bill

ACA – Affordable Care Act

CA – California

CalPERS – California Public Employees' Retirement System

CDC – Centers for Disease Control and Prevention

CDI – California Department of Insurance

CHBRP – California Health Benefits Review Program

COHS – County Organized Health System

DHCS – Department of Health Care Services

DMHC – Department of Managed Health Care

EHB – essential health benefits

FDA – U.S. Food and Drug Administration

PBM – pharmacy benefit manager

SB – Senate Bill

URO – utilization review organization

Terminology

CHBRP uses the following terminology for this analysis:

Small-molecule drugs: Chemicals with relatively simple, well-defined structures that can be copied, small-molecule drugs are typically first introduced as **brand-name products** protected by patents and regulatory exclusivity.

AB-rated generic drug: As defined in SB 1094 and federal law,[1] refers to a group of small-molecule drugs that have met specific U.S. Food and Drug Administration (FDA) requirements as both a pharmaceutical and therapeutic equivalent to the brand-name drug product (also called a **reference drug**).

Biological product: as defined in SB 1094 and federal law,[2] refers to a group of pharmaceutical products derived or developed from living organisms like yeast, bacteria, or animal cells.

Reference product: Refers to a brand-name biologic.

Biosimilar: Refers to a biological product that is highly similar to a reference product, with minor differences in inactive components, and no clinically meaningful differences in safety, purity, and potency of the product.

Interchangeable biological product: A biosimilar that has met additional standards set by the FDA so that it may be substituted for a reference product without the intervention of the health care provider who prescribed the reference product.

Prescription: As defined in SB 1094, this term, with respect to a biological product, means a prescription for a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act,[3] and may only be dispensed via a licensed practitioner's written order, a recorded oral order, or an authorized refill.

[1] 42 U.S. Code 262(i)(1).
[2] 42 U.S. Code 262(i)(1).
[3] 21 U.S. Code 353(b).

Legislative Text Analyzed

CHBRP was requested by the California Senate Committee on Health to analyze SB 1094 Prescription Drugs, as introduced on February 13, 2026. The bill was then amended on April 8, 2026. CHBRP has adjusted its analysis to accommodate the amendments as much as possible, given the time constraints. The text analyzed, as amends today's law as of April 8, 2026, is copied below.

As Amends the Law Today

SECTION 1. *It is the intent of the Legislature 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.*

SEC. 2. Section 4073.5 of the Business and Professions Code is amended to read:

4073.5. (a) A pharmacist filling a prescription order for a prescribed biological product may select an alternative biological product only if all of the following:

(1) The alternative biological product is ~~interchangeable~~ *biosimilar to, or interchangeable with, the prescribed reference product*.

(2) The prescriber does not personally indicate "Do not substitute," or words of similar meaning, in the manner provided in subdivision ~~(d)~~ *(e)*.

(b) Within five days following the dispensing of a biological product, a dispensing pharmacist or the pharmacists' designee shall make an entry of the specific biological product provided to the patient, including the name of the biological product and the manufacturer. The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through one or more of the following electronic records systems:

(1) An interoperable electronic medical records system.

(2) An electronic prescribing technology.

(3) A pharmacy benefit management system.

(4) A pharmacy record.

(c) Entry into an electronic records system as described in subdivision (b) is presumed to provide notice to the prescriber.

(d) If the pharmacy does not have access to one or more of the entry systems in subdivision (b), the pharmacist or the pharmacist's designee shall communicate the name of the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required in this instance to the prescriber when either of the following apply:

(1) There is no *biosimilar or* interchangeable biological product approved by the federal Food and Drug Administration for the product prescribed.

(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(e) ~~In no case shall a selection~~ *A selection shall not* be made pursuant to this section if the prescriber personally indicates, either orally or in ~~his or her~~ *the prescriber's* own handwriting, "Do not substitute," or words of similar meaning.

(1) This subdivision shall not prohibit a prescriber from checking a box on a prescription marked "Do not substitute," provided that the prescriber personally initials the box or checkmark.

(2) To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription, as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(f) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (e). A pharmacist who selects an alternative biological product to be dispensed pursuant to this section 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. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a biological product pursuant to this section. In no case shall the pharmacist select a biological product that meets the requirements of subdivision (a) unless the cost to the patient of the biological product selected is the same or less than the cost of the prescribed biological product. Cost, as used in this subdivision, includes any professional fee that may be charged by the pharmacist.

(g) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(h) When a selection is made pursuant to this section, the substitution of a biological product shall be communicated to the patient.

(i) The board shall maintain on its public ~~Internet Web site~~ *internet website* a link to the ~~current list, if available, of biological products determined by the federal~~ *United States* Food and Drug ~~Administration to be interchangeable~~ *Administration's Purple Book Database of Licensed Biological Products*.

(j) For purposes of this section, the following terms shall have the following meanings:

(1) "Biological product" has the same meaning that applies to that term under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262(i)).

(2) "Biosimilar" has the same meaning as defined in Section 262(i) of Title 42 of the United States Code.

~~(2)~~ *(3)* "Interchangeable" means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in Section 262(k)(4) of Title 42 of the United States Code, or has been deemed therapeutically equivalent by the federal Food and Drug Administration as set forth in the latest addition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

~~(3)~~ *(4)* "Prescription," with respect to a biological product, means a prescription for a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).

(k) This section shall not prohibit the administration of immunizations, as permitted in Sections 4052 and 4052.8.

(l) This section shall 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.

SEC. 3. Section 1367.22 of the Health and Safety Code is amended to read:

1367.22. (a) *(1)* A health care service plan contract, issued, amended, or renewed on or after July 1, 1999, that covers prescription drug benefits shall not limit or exclude 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~~ *enrollee'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 medical condition. ~~Nothing in this section shall preclude~~

(2) This section does not preclude the prescribing provider from prescribing another drug covered by the plan that is medically appropriate for the enrollee, and does not prohibit generic or biosimilar drug substitutions as authorized by Sections 4073 and 4073.5 of the Business and Professions Code. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4059 of the Business and Professions Code, to treat a medical condition of an enrollee.

(b) (1) A health care service plan or utilization review organization may require an enrollee 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 in the manner provided in subdivision (b) of Section 4073 or subdivision (e) of Section 4073.5 of the Business and Professions Code, as applicable.

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

(C) The enrollee's cost sharing is based on the net cost of the drug or product.

(D) An enrollee's cost sharing is the same or less than the cost sharing for the brand name drug or reference product.

(E) The plan provides at least 30 days' advance notice to the enrollee and prescribing provider of a substitution requirement pursuant to this paragraph prior to requiring an enrollee to try a substitute pursuant to this paragraph.

(2) An enrollee required to try a substitute pursuant to paragraph (1) or the enrollee's prescribing provider may request an exception pursuant to Section 1367.206 or 1367.24.

(3) The plan shall include with the information required to be provided to the department pursuant to Section 1367.243 both of the following information:

(A) The proportion of prescription substitutions made through this subdivision that resulted in reduced cost sharing as well as information about the factors affecting when an enrollee's cost sharing is not reduced.

(B) The impact of substitutions permitted under this subdivision on premiums.

(4) This subdivision does not authorize a health care service plan to alter or issue a prescription.

~~(b)~~ *(c)* This section does not apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration. Coverage for different-use drugs is subject to Section 1367.21.

~~(c)~~ *(d)* This section shall not be construed to restrict or impair the application of any other provision of this chapter, including, but not limited to, Section 1367, which includes among its requirements that plans furnish services in a manner providing continuity of care and demonstrate that medical decisions are rendered by qualified medical providers unhindered by fiscal and administrative management.

~~(d)~~ *(e)* This section does not prohibit a health care service 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, provided that the copayments, deductibles, or limitations are reported to, and held unobjectionable by, the director and set forth to the subscriber or enrollee pursuant to the disclosure provisions of Section 1363.

(f) For purposes of this section, the following definitions apply:

(1) "AB-rated generic equivalent" means a drug product rated with an AB code in the Approved Drug Products with Therapeutic Equivalence Evaluations published by the United States Food and Drug Administration.

(2) "Biological product" has the same meaning as defined in Section 262(i)(1) of Title 42 of the United States Code.

(3) "Biosimilar" has the same meaning as defined in Section 262(i)(2) of Title 42 of the United States Code.

(4) "Cost sharing" includes a copayment, coinsurance, deductible, or any other form of cost sharing.

(5) "Interchangeable biological product" has the same meaning as defined in Section 262(i)(3) of Title 42 of the United States Code.

(6) "Reference product" has the same meaning as defined in Section 262(i)(4) of Title 42 of the United States Code.

***SEC. 4.** Section 10123.190 is added to the Insurance Code, to read:*

10123.190.

(a) (1) A health insurance policy issued, amended, or renewed on or after January 1, 2027, that covers prescription drug benefits shall not limit or exclude coverage for a drug for an insured if the drug previously had been approved for coverage by the insurer for a medical condition of the insured and the insured's prescribing provider continues to prescribe the drug for the medical condition, if the drug is appropriately prescribed and is considered safe and effective for treating the insured's medical condition.

(2) This section does not preclude the prescribing provider from prescribing another drug covered by the insurer that is medically appropriate for the insured, and does not prohibit generic or biosimilar drug substitutions as authorized by Sections 4073 and 4073.5 of the Business and Professions Code. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription, pursuant to subdivision (a) of Section 4059 of the Business and Professions Code, to treat a medical condition of an insured.

(b) (1) A health insurer or utilization review organization may require an 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 insurer if all of the following conditions are met:

(A) The prescriber has not personally indicated "Do not substitute," or words of similar meaning in the manner provided in subdivision (b) of Section 4073 or subdivision (e) of Section 4073.5 of the Business and Professions Code, as applicable.

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

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

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

(E) The insurer provides at least 30 days' advance notice to the insured and prescribing provider of a substitution requirement pursuant to this paragraph prior to requiring an insured to try a substitute pursuant to this paragraph.

(2) An insured required to try a substitute pursuant to paragraph (1) or the insured's prescribing provider may request an exception pursuant to Section 10123.201 or 10123.191.

(3) The insurer shall include with the information required to be provided to the department pursuant to Section 10123.205 both of the following information:

(A) The proportion of prescription substitutions resulting from the authority provided in paragraph (1) of this subdivision that resulted in reduced cost sharing as well as information about the factors affecting when an insured's cost sharing is not reduced.

(B) The impact of substitutions resulting from the authority provided in paragraph (1) under this subdivision on premiums.

(4) This subdivision does not authorize a health insurer to alter or issue a prescription.

(c) This section does not apply to coverage for any drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the federal Food and Drug Administration. Coverage for different-use drugs is subject to Section 10123.195.

(d) This section shall not be construed to restrict or impair the application of any other provision of this article.

(e) This section does not prohibit a health insurer from charging an insured a copayment or a deductible for prescription drug benefits or from setting forth, by contract, limitations on maximum coverage of prescription drug benefits, if the copayments, deductibles, or limitations are reported to, and held unobjectionable by, the commissioner and disclosed to the insured.

(f) For purposes of this section, the following definitions apply:

(1) "AB-rated generic equivalent" means a drug product rated with an AB code in the Approved Drug Products with Therapeutic Equivalence Evaluations published by the United States Food and Drug Administration.

(2) "Biological product" has the same meaning as defined in Section 262(i)(1) of Title 42 of the United States Code.

(3) "Biosimilar" has the same meaning as defined in Section 262(i)(2) of Title 42 of the United States Code.

(4) "Cost sharing" includes a copayment, coinsurance, deductible, or any other form of cost sharing.

(5) "Interchangeable biological product" has the same meaning as defined in Section 262(i)(3) of Title 42 of the United States Code.

(6) "Reference product" has the same meaning as defined in Section 262(i)(4) of Title 42 of the United States Code.

***SEC. 5.** No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*

Policy Framework

This brief provides additional material to support the findings and recommendations presented in CHBRP's *Analysis of California Senate Bill 1094: Prescription Drugs*.[4] The following sections contain details on the federal landscape. While this information is essential to the completeness of the analysis, it has been placed in this separate brief to maintain the flow of the main report. Readers are encouraged to consult this material for deeper insights into existing laws and technical details that informed the analysis and conclusions of the main report.

Federal Policy Landscape

Congress enacted the Biologics Competition and Innovation Act (BPCIA) in 2009[5] to help make more biosimilar products available for lower prices. There are now over 90 biosimilar products on the U.S. market, of which 41 are approved interchangeable products as of January 2026. This has represented a significant increase in the number of biosimilar products in recent years, as older reference products lose market exclusivity (Canter et al., 2021). These biosimilar products are used to treat chronic medical conditions including diabetes (insulin biosimilars), immune-mediated conditions like psoriasis, inflammatory bowel diseases (Crohn's disease or ulcerative colitis), rheumatoid arthritis, asthma and food allergies, and products to treat blood disorders associated with cancer treatments and chronic kidney disease.

In 2018, the FDA released its Biosimilars Action Plan to encourage innovation and competition in the biological product market and facilitate the development of biosimilars and interchangeable biological products (FDA, 2024a). In 2024, based on 15 years of data, the FDA confirmed that substituting between reference products and their biosimilar versions is safe and effective, with no significant health risks (Herndon et al., 20243). The FDA is in the process of updating its guidance to industry to move towards recognizing that all biosimilars are effectively interchangeable, and streamlining biosimilar development (FDA, 2024b; FDA, 2026). This change requires additional legislation because current laws govern how long manufacturers of reference biologics may have exclusive rights to market the product in the United States, in consideration of the considerable costs of research, innovation, and manufacturing these products (FDA CDER, 2026b).

[4] Available in Completed Analyses on www.chbrp.org.
[5] Food and Drug Administration (FDA). (2010). Biologics Price Competition and Innovation Act of 2009. *Federal Register.* 75(235):76472-76473

Background on Substitution of Prescription Products

Most pharmaceutical drugs can be broadly categorized as either **small-molecule** or **biologic (large-molecule)**. A description of each and related terminology is included below.

- **Small-molecule drugs** are chemicals with relatively simple, well-defined structures that can be copied. Small-molecule drugs are typically first introduced as **brand-name products protected by patents and regulatory exclusivity**, and after these protections expire, other manufacturers may produce **lower-cost generic versions** that are chemically identical to the original drug.
    - **AB-rated generic drug:** This drug has met specific FDA requirements as both a pharmaceutical and therapeutic equivalent to the brand-name drug product (called a **reference drug**).
    - **Pharmaceutical equivalent:** A product with an identical active ingredient, in an identical amount to be delivered over the same dosing period by the same route.
    - **Therapeutic equivalent:** A drug must demonstrate **bioequivalence** to the reference drug (usually by clinical studies), which means it can be expected to have the same clinical effect and safety profile when administered to patients under conditions specified in the labeling.
    - Generic drugs also must meet standards of purity, strength, quality, and potency, but they can have differences in terms of shape, color, form, flavor, preservatives, packaging, or shelf-life (expiration date). The FDA makes this determination and publishes a listing regularly (FDA CDER, 2026a).
- **Biologics** (**large-molecule drugs**) are complex products derived from living organisms like yeast, bacteria, or animal cells.
    - **Biosimilar products:** Biosimilars are biologics that are highly similar to an already approved biological **reference product.** They may have small natural structural differences when compared to the reference product, but they have no clinically meaningful differences in terms of the safety or effectiveness for treating medical conditions (FDA, n.d.-a). This category also includes **"follow-on" biological products,** which were approved prior to 2020, before FDA harmonized their review processes for new biologic license applications. Follow-on products include Basaglar (insulin glargine), GlucaGen (glucagon injection), Omnitrope (somatropin for injection), and Fortical (calcitonin-salmon) (Fonseca et al., 2017).
    - **Interchangeable products:** A biosimilar product that meets additional FDA criteria such as lack of substantial immunologic adverse reactions or no changes in therapeutic effect (due to the development of anti-drug antibodies) from repeated switching.

The FDA has specific rules for approving products as biosimilars based on evidence from clinical studies and manufacturing process reviews to ensure consistent quality and reliable bioactivity (FDA, 2024b). Biosimilars are regulated by the Public Health Service Act, which sets out the requirements for manufacturers to apply for a license to market new biological products in section 350(k) as biosimilars or interchangeable products. (FDA, 2024b)

Reference biologics that now have biosimilar and interchangeable products available include Lantus and NovoLog (insulin glargine), Remicade (infliximab), Enbrel (etanercept), Humira (adalimumab), and Stelara (ustekinumab), which are self-administered and covered by some pharmacy benefit plans. There are over 90 biosimilar products available in the U.S. market, many of which have been approved in the last 3 years (FDA CDER, 2026b).

Switching Between Drugs

There are two main categories of switching occurring in health care settings:

- **Medical switching:** When a physician decides to switch a patient from the reference product to a biosimilar to optimize the benefits of treatment (typically to reduce issues with long-term tolerability like injection site reactions, frequency of dosing, administration device preferences, and storage requirements for the product). This can include avoiding irritating ingredients (e.g., citrates) or avoiding hypersensitivity (for example, latex-free needle shields). Other reasons for switching may include easier medication administration in pre-filled autoinjector "pens" or single dose pre-filled syringes rather than vials requiring measuring doses (Mysler et al., 2021).
- **Nonmedical switching:** When a patient who is stable on a biologic or brand-name drug and is switched to a biosimilar or generic, respectively, for the purpose of cost savings or continuing access to the same type of drug that is on formulary for a health plan or pharmacy benefit, or only available in a specific geographic area. Hospital or retail pharmacists may also have to substitute biosimilar products when there are unexpected supply-chain issues due to manufacturing shutdowns. Because of the different payment systems for retail vs. hospital pharmacies, there may be incentives to reduce out-of-pocket costs to the patient or work within fixed reimbursement fees by substituting biosimilars which have lower costs (Mysler et al., 2021). Incentives may include **rebates**, which are costs reimbursed to a health plan or pharmacy benefits manager by the manufacturer based on units of the pharmaceutical product sold, effectively discounts on brand-name products.[6]

For either category, the physician and pharmacist may also be influenced by decisions made by payers, vendors, and pharmacy benefit managers (PBMs) who determine the price and formulary status for each product, whether brand-name, generic or biosimilar product. In some cases, health plans/insurers and PBMs may decide whether more than one biosimilar product or generic product may be available on formulary, and the decision on which biosimilar products to include would optimally consider the needs of patients and prescribers (Mysler et al., 2021; Rodriguez et al., 2023).

Nonmedical switching (also called "pharmacy-level substitution" or "automatic substitution of pharmaceutical products") occurs in a retail pharmacy when a generic or biosimilar is substituted for a brand-name drug or reference product to save patients money, without consulting the prescriber (Canter et al., 2021). As discussed in the *Policy Context* section in CHBRP's Bill Analysis of SB 1094, California law allows pharmacists to conduct nonmedical switching to less expensive AB-rated generic drugs or interchangeable biological products for a new prescription for a brand-name or reference product, as long as the prescriber has not written "Do not substitute" on the prescription.[7] Health care service plans, health insurers, or utilization management review organizations are currently restricted from substituting any AB-rated generic product or biosimilar for a continuing prescription for a reference drug product that was previously approved for coverage, even if that substitution would lower costs to the patient. Substitution of biosimilars has been estimated to reduce direct spending on biological drugs in the United States by about $54 billion from 2017 to 2026, but actual savings for patients and health plans are contingent on changes to drug supply chain practices to enable competition. Biosimilars represent an opportunity for cost containment in prescription drug spending (Mulcahy et al., 2018)

Physicians may decide to switch patients from a reference product to a biosimilar or follow-on biologic because these products have similar clinical efficacy and safety but cost less. While the intention of the Biologics Competition and Innovation Act was to make it easier to substitute less expensive biosimilar products for the original reference products, there was slow uptake by pharmacies and prescribers because of uncertainty about the criteria for automatic substitution and how prescribers and pharmacists were supposed to coordinate patient care (Canter et al., 2021). There has also been a substantial body of research in Europe to examine the substitution of biosimilars via different mechanisms (physician-initiated, pharmacy-led, or systematic mandates for switching). By 2020, the total clinical experience in Europe with biosimilar switching accumulated more than 2 billion treatment days, and no biosimilar required market withdrawal or modification of its product labeling because of safety concerns (Mysler et al., 2021). Biosimilar cross-switching

[6] For more information, see CHBRP's explainer *An Overview of the Drug Supply Chain*.
[7] Business and Professions Code (BPC) 4073.

(substitution of one biosimilar for another biosimilar product) has been occurring for patients who receive chronic therapy over long periods of time (Mysler et al., 2021). The FDA has indicated that the accumulated scientific evidence available on the safety and effectiveness of biosimilar products over the last 15 years has confirmed that there is no clinically significant safety concerns when switching between biosimilars and the reference products, and several products have been approved as interchangeable products by the FDA without switching studies (FDA, 2024b; Herndon et al., 2023).

Current dispensing practices include the following:

- **Generics:** To control costs of prescription pharmaceutical products, California and other states have adopted laws and/or regulations that facilitate pharmacist-led substitution of generic prescription drug products, which are typically less expensive than brand-name drugs. The dispensing pharmacist is limited to only substitute products listed as AB-rated generics for the prescribed brand-name product.
- **Interchangeable biological products:** After the FDA approval of a biological product as interchangeable biological product, a prescription for the reference product may be filled by a pharmacist by dispensing an interchangeable biological product without first getting approval from the prescribing doctor (a process called “pharmacy-level substitution” or “nonmedical switching”) if the cost to the patient will be lower than the original reference product price. Each state determines its own pharmacy practices and the conditions for pharmacy-level substitutions.
- **Biosimilars:** The automatic (nonmedical) switching issue is relevant to biological products that are being dispensed by retail pharmacies and to be self-administered by patients or their caregivers as outpatient management of chronic medical conditions. The substitution of biosimilar products is not an issue for drugs that are administered under medical supervision in hospitals, infusion centers, or ambulatory clinic settings because the prescriber and pharmacists are typically in close communication for coordination of patient care, and physicians sign off on any decision to switch products. The key issue for pharmacy-level switching is how and when the substitution is communicated to the physician and patient (Canter et al., 2021). Current practice would be changed by the provisions of this bill to permit switching by the pharmacy or health plan. Pharmacy substitution and nonmedical switching has not been permitted for follow-on products, even though they are therapeutically equivalent and deemed biosimilars by the FDA (Fonseca et al., 2017). One example of this is Basaglar, a follow-on to Lantus (insulin glargine). If the prescriber writes a prescription for Lantus, a pharmacist currently could not substitute Basaglar without a specific order from the prescriber, even if it could save money for the patient.

Prevalence of Diseases Treated with Biologics and Biosimilars in California

Biological products and biosimilars treat a wide range of medical conditions. The prevalence of biologic use is dependent on the evidence-based clinical practices for the medical condition being treated. The major categories for which biologics and biosimilars are used include diabetes mellitus, immune-mediated diseases of the skin (psoriasis) and/or joints (rheumatoid arthritis, psoriatic arthritis, or ankylosing spondylitis), or inflammatory bowel diseases, such as ulcerative colitis and Crohn’s disease. Biological products are also used to treat certain cancers, such as Herceptin (trastuzumab) for breast cancer and Rituxan (rituximab) for chronic lymphocytic leukemia and non-Hodgkin’s lymphoma, and biosimilars are now available for these original reference products. Non-Hodgkin’s lymphoma occurs in 21.4 per 100,000 persons in California (Movsisyan et al., 2019). Breast cancers occur in 121.23 per 100,000 persons in California (CCR, 2017) Biosimilars are also used to support patients who are undergoing chemotherapy treatments for certain cancers, to prevent or treat low blood counts (anemia or neutropenia).

Diabetes affects about 12% of the adult population in California, but the proportion that need insulin as treatment is not known (CHIS, 2024). Rheumatoid arthritis and psoriatic arthritis, two forms of immune-mediated arthritis, affect approximately 10.6 and 1.0 million people in the United States, respectively (Foster et al., 2025). Psoriasis, an immune-mediated skin condition, affects over 7.5 million American adults over the age of 20 (Armstrong et al., 2021). Inflammatory bowel diseases affect approximately 3 million people in the United States (Dahlhamer, 2015). Exact prevalence data for California residents are not available for these conditions. The estimated proportion of adults in the United States reporting these diagnoses based on national chronic disease surveys is shown in Table 1 below. Numbers for California

are based on estimated prevalence among adults living in California using 2020 census data and national survey prevalence estimates.

Table 1. Prevalence of Diseases Potentially Treatable by Biosimilar Products, United States and California

Disease Prevalence (source)	Estimated Number (millions, US)	% of U.S. Population (95% CI)	Estimated Number (thousands, CA)*
Total Adults with IBD (NHIS, 2015) [Dahlhamer, 2015]	3.087	1.3 (1.13-1.44)	403.3
Psoriasis, Adults (NHANES, 2011-2014) [Armstrong et al., 2021]	7.55	3.0 (2.6-3.4)	930.6
Rheumatoid Arthritis, Adults (NHANES,2020) [Foster et al., 2025]	10.6	4.1 (3.5-4.8)	1,271.8
Psoriatic Arthritis, Adults (NHANES, 2020) [Foster et al., 2025]	1.0	0.3 (0.2-0.5)	93.1

Source: California Health Benefits Review Program, 2026.
Note: *Numbers estimated using the US Census, 2020 American Community Survey, 1-year estimates. California adult (18 years and older) population of 31,019,925 times the percentage of U.S. population with prevalent condition.
Key: CA = California; CI = confidence interval; IBD = inflammatory bowel disease; NHIS = National Health Interview Survey; NHANES = National Health and Nutrition Examination Survey.

Disparities[8] in Access to Biologics, Biosimilars, and Generics in California

Disparities are noticeable and preventable or modifiable differences between groups of people. Health insurance benefit mandates or related legislation may impact disparities. Where intersections between health insurance benefit mandates and social determinants or systemic factors exist, CHBRP describes relevant literature.

CHBRP found literature identifying disparities by age and race in patient access to, and subsequent use of, reference biologics and biosimilars. These disparities are dependent on the reference biologic or biosimilar in question. In addition to the studies described below that examined the U.S. reference biologics and biosimilars market, disparities in age and race were also found in studies of various reference biologics and biosimilars in European markets, which have a significantly greater number of these products available to patients (Farrukh and Mayberry, 2015; Putrik et al., 2016).

CHBRP did not find literature identifying disparities for access to generic small-molecule drug products. CHBRP has assumed that there are no disparities in the access to and use of small-molecule drugs between groups of people that would be impacted by the provisions of the proposed bill.

Race or Ethnicity

CHBRP found one study that concluded Black women with breast cancer are 25% less likely to receive the appropriate biologic within 1 year of diagnosis than White women (Reeder-Hayes et al., 2016). Similar disparities have been found in the patient population with rheumatoid arthritis. Jin and colleagues (2017) found that Black patients with early untreated and prevalent rheumatoid arthritis were 40% and 30%, respectively, less likely to initiate a biologic compared to White patients (Jin et al., 2017). Another study analyzed rheumatoid arthritis therapies for patients in the Ethnic Minority Rheumatoid Arthritis Consortium and the Veteran Affairs Rheumatoid Arthritis Registry and found that non-White patients with rheumatoid arthritis were less likely to use biologics than White patients (Yip and Navarro-Millán, 2021). Large reviews have suggested that there are differences in the use of biological disease-modifying antirheumatic drugs among races with 49.3% of Black patients receiving biologics compared to 53.3% of White and 60.9% of Latino patients with

[8] Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population (Wyatt et al., 2016).

rheumatoid arthritis, which may correlate with clinical access, low socioeconomic status, and difficulty with high out-of-pocket costs (Yip and Navarro-Millán, 2021). In a multistate retrospective review of Medicaid claims data for newly diagnosed patients with psoriatic arthritis with at least 12 months of follow-up, 33.6% of Black patients received biologic treatments compared to 42.6% of White patients, and Black patients had significantly longer wait times to initiate any biological disease modifying agents (Patel et al., 2023).

In a scoping review of the literature of biologic use in diabetes, there is *strong evidence* of the influence of race and ethnicity on outcomes of diabetes, such as glycemic control and adherence to medications, but there has been no assessment of any differences in access to biosimilar long-acting insulin found in literature searches (Walker et al., 2016). The prevalence of ulcerative colitis and Crohn's disease has been increasing among Black, Latino, and Asian persons, but there have been no consistent differences in the use of biologic therapies among patients of different races or ethnicities (Afzali and Cross, 2016; Barnes et al., 2021).

Age

CHBRP found studies demonstrating that older patients are less likely to have access to and initialize use of reference biologics or biosimilars. Jin and colleagues (2017) observed that older patients have a decreased chance of initiating disease-modifying antirheumatic drugs (DMARDs) for rheumatoid arthritis. With a 10-year increase in age, the odds of starting a biologic DMARD was reduced by 13% in patients with early untreated rheumatoid arthritis, and reduced by 29% in those with prevalent rheumatoid arthritis (Jin et al., 2017). Kim and colleagues (2015) analyzed Texas Medicaid prescription and medical claims database and found for patients aged 18 to 63 years with rheumatoid arthritis, patients were 1.6% less likely to start a biologic DMARD for each year increase in age (Kim et al., 2015). Age disparities are also found in the use of other biologics. A study by Reeder-Hayes et al. showed older patients have less access to Herceptin (trastuzumab), a biologic commonly used to treat breast cancer (Reeder-Hayes et al., 2016). Approximately one half of patients aged 65 years and older with stage I to III human epidermal growth factor receptor 2 (HER2)-positive breast cancer do not receive trastuzumab (Reeder-Hayes et al., 2016).

Barriers to Accessing Biosimilars and Generic Prescription Drugs

In the United States, fewer than 2% of Americans use biologics, yet it is estimated these drugs account for around 40% of all pharmaceutical spending (Mulcahy et al., 2018; Zhai et al., 2019). With sales reaching between $5.1 and nearly $20 billion, biologics were 11 out of the top 15 selling drugs in the United States in 2018 (Dabrowska, 2019). Biosimilars are often listed at a discounted price in comparison to reference biologics. Lower-price biosimilars can decrease the cost of treating patients and there is significant market pressure to reduce list prices for these drugs (Falit et al., 2015; Rompas et al., 2015). Researchers have estimated the potential cost savings from biosimilars would be $44.2 billion dollars between 2017 to 2026 (Mulcahy et al., 2018). However, in reality, there have been substantial barriers that have prevented a more widespread adoption of biosimilars than what was predicted (Chen et al., 2018; Crespi-Lofton and Skelton, 2017; Prasad et al., 2017; Zhai et al., 2019). These obstacles include gaps in acceptance and knowledge regarding biosimilars among patients and providers, and potential financial incentives (such as rebates and discounts) for the payer and PBMs for the coverage of reference biologics over biosimilars (Mulcahy et al., 2018). In addition, reimbursement for physician-administered biosimilars may be complicated under the Centers for Medicare and Medicaid Services guidelines or under pharmacy contracts negotiated by pharmacy benefits managers. Reimbursement is based on the average sales price plus a surcharge (4-6%) to cover acquisition and inventory costs. Financial differences between lower-priced biosimilars may not be significant enough to encourage physicians to support switching, especially if there is uncertainty about acceptability of a newly approved biosimilar as a therapeutic substitute (Nabhan et al., 2018).

Patient access to lower-cost generic drugs may be limited by the prescriber when they specify "Do Not Substitute" for certain narrow therapeutic index drugs like levothyroxine, where the intent is to maintain patient on a stable long-term treatment. Payers may also have different levels of cost sharing for specialty drugs, so that patients may have to pay substantial out-of-pocket costs even for AB-generic drugs if treatment is long-term and expensive, and the patients must meet high-deductible costs. In a recent survey by KFF using National Health Interview Survey data through 2024, 8% of

American adults reported delaying, rationing, or going without prescription drugs due to cost (Rakshit et al., 2026). There may be no clear financial advantages to patients for switching products when filling prescriptions for long-term treatments, or when formulary options may be limited and still exceed affordability (CHBRP, 2022).

While the accumulated experience with biosimilars over the last 15 years has confirmed that switching between reference products and biosimilars should not present significant changes in safety or effectiveness, prescribers and patients are still hesitant because of misinformation about the differences between biosimilars and interchangeable biological products and reference products, and concerns about disrupting stable treatment regimens (Lang et al., 2023). The nocebo effect has been suggested as a barrier to the acceptance of biosimilars based on gaps in knowledge and acceptance by patients. Negative perceptions regarding the safety or effectiveness of biosimilars may lead a patient to discontinue the biosimilar product, even if objective measures of disease activity are unchanged. Participants in switching trials and in large registries dropped out in higher rates in the biosimilar groups than in the groups receiving the reference biological product, even though disease activity was not measurably different. Thus, a nocebo effect arises when a patient expects a negative outcome when switching, they develop new or worsening symptoms on the biosimilar and the symptoms are relieved when the patient is switched back to the reference biologic, even though the pharmacologic action of the two products are the same (Canter et al., 2021; Gonczi and Lakatos, 2019; Odinet et al., 2018; Pineles et al., 2018; Pouillon et al., 2018; Rossmann and Cross, 2020; Smeeding et al., 2019; Stebbing et al., 2020; Whalen, 2020).

Research on the uptake of infliximab biosimilars shows an example of the impact financial incentives have on biosimilar uptake. Despite the availability of biosimilars for the reference biologic and the offering of these biosimilars at discounts of between 15% and 40% off the list price for the reference biologic, most major payers in the United States continue to name the reference biologic (Remicade, infliximab) as the preferred medication (Nabhan et al., 2018). While biosimilars are often listed at a discounted price in comparison to reference biologics, this third-party preference for a specific biologic has limited their uptake by enrollees (Mulcahy et al., 2018). For enrollees who have a coinsurance for medications covered under the medical benefit, this means an enrollee could have higher cost sharing if they are being prescribed a reference biological product over a biosimilar.

Societal Impact of Biosimilars and Generic Prescription Drug Switching in California

Patient access to and use of biosimilars and generic prescription drug products in California has direct and indirect economic and societal costs. In dollar terms, the societal impact can be indirect (lost wages, etc.), as well as direct (medical care, etc.). CHBRP is unable to find data that displays the larger societal impact of the ability for patients to access biologics and biosimilars specifically. However, the high costs of prescription drug products, including biological products, may cause financial toxicity to health care systems, leading to restricted access to effective treatments for cancer and inflammatory diseases (Rodriguez et al., 2023). The potential to facilitate competition among multiple options for biosimilars and AB-rated generic drugs may lead to substantial reduction in costs to patients and health care systems for prescription treatments (Canter et al., 2021).

Safety and Harms Considerations

As discussed in the *Policy Context* section, the FDA confirmed in 2024, based on 15 years of data, that substituting between reference products and their biosimilars version is safe and effective, with no significant health risks (FDA, 2024b; Herndon et al., 2023). CHBRP reviewed findings from evidence[9] on the safety, side effects, or potential harms of **switching** from a reference biologic to a biosimilar.

Research Approach and Methods

CHBRP relied on FDA regulatory guidelines and a systematic review published in 2023 for findings from studies published prior to 2023. The conclusions below are based on the best available evidence from peer-reviewed and grey literature.[10] Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports. In addition, major society clinical practice guidelines related to substitution or switching of biosimilars are presented.

Key Questions

1. Are there any differences in safety profiles or effectiveness between reference biologics and biosimilars?
2. When **switching** from a reference biologic to a biosimilar, do biosimilars pose increased or alternative side effects or harms?

Methodological Considerations

Most of the data for switching has been from studies of adult patients. Therefore, the guidelines for switching in pediatric patients recommend only switching between products that have been specifically studied in pediatric patients (de Ridder, 2019).

Outcomes Assessed

The primary outcomes of interest are side effects or harms when switching from a reference biologic to a biosimilar. These include adverse events, immunogenicity (defined as an immune response leading to the production of anti-drug antibody formation), allergic reactions (e.g., injection site reactions or anaphylaxis), and medication discontinuation.

Study Findings

This following section summarizes CHBRP's findings regarding the safety, side effects, or potential harms of switching from a reference biologic to a biosimilar. Definitions of CHBRP's grading scale terms are included in the box below.

The following terms are used to characterize the body of evidence regarding an outcome:

Very strong evidence (formerly called *clear and convincing evidence*) indicates that there are multiple studies of a treatment and the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective. Conclusions are unlikely to be altered by additional evidence.

[9] Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence in the Medical Effectiveness Analysis and Research Approach document, in the absence of peer-reviewed literature on well-designed randomized controlled trials (RCTs) that is fully applicable to the analysis, CHBRP's hierarchy of evidence allows for the inclusion of other evidence.
[10] Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. See CHBRP's website for more information.

Strong evidence (formerly called *preponderance of evidence*) indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective. Conclusions could be altered with additional strong evidence.

Some evidence (formerly called *limited evidence*) indicates that a small number of studies have limited generalizability to the population of interest and/or the studies have a serious methodological concern in research design or implementation. Conclusions could be altered with additional evidence.

Conflicting evidence (formerly called *inconclusive evidence*) indicates that of the studies of equal quality, the number suggesting the treatment is effective is similar to the number of those suggesting the treatment is not effective.

Not enough research (formerly called *insufficient evidence*) indicates that (1) there are no studies of the treatment **or** (2) the available studies are not of high quality, meaning there is not enough evidence available to know whether or not a treatment is effective. *Not enough research* does not indicate that a treatment is not effective.

Biosimilars Safety and Effectiveness

CHBRP is relying on the FDA regulatory standards, which require a biosimilar to demonstrate "no clinically meaningful differences" in safety, purity, or potency compared with the reference biologic before approval (FDA, 2022). This determination relies on extensive testing to demonstrate similarity in structure and function and clinical comparative studies that consistently show statistically similar safety outcomes. Across many therapeutic areas (e.g., oncology, rheumatology, gastroenterology), head-to-head comparison randomized controlled trials (RCTs) repeatedly show no difference in overall adverse events, including serious adverse events, as well as no difference in immunogenicity.

Summary of findings regarding the safety and effectiveness of biosimilars: There is *very strong evidence* that there are no differences in safety profiles and effectiveness between biosimilars and their reference biologic based on FDA regulatory standards.

Effects of Switching to a Biosimilar from a Reference Biologic

Large systematic reviews and meta-analyses, including over 5,000 patients who switched therapies, find no increased risk of side effects, no new or different types of adverse events, no increased immunogenicity and no difference in discontinuation rates.

A systematic review and meta-analysis (Herndon et al., 2023) examined safety outcomes when switching between biosimilars and reference biologics. The analysis included data from 31 RCTs and extension studies with a switch treatment period (STP) for 21 different biosimilars. These included biosimilars used to treat a wide range of conditions including rheumatoid arthritis, plaque psoriasis, Crohn's disease, ulcerative colitis, chronic kidney disease, breast cancer, type 1 diabetes, and follicular lymphoma. A total of 5,252 patients who were switched to or from a biosimilar and its reference biologic were included in the meta-analysis. The safety outcomes assessed included deaths, serious adverse events, treatment discontinuation, immunogenicity, and immune-related adverse events. The study results showed no difference in risk of death of -0.00 (95% confidence interval [CI]: -0.00, 0.00), serious adverse events of 0.0 (95% CI: -0.01, 0.01), or treatment discontinuation of -0.0 (95% CI: -0.01, 0.00) across studies. Immunogenicity and immune-related adverse events including anaphylaxis, hypersensitivity reactions, and injection site reactions were also not significantly different between patients who were switched and those who remained on a reference biologic.

Additionally, pharmacovigilance data (i.e., real-world data from continuous monitoring of biosimilars after they are available to the public), which now includes millions of patient exposures, has not indicated any new safety concerns and no differences in adverse events patterns (Nikitina et al., 2025; Sagi et al., 2023). Because of this accumulation of real-world data, the FDA no longer mandates switching trials for interchangeability, stating that the cumulative data on switching to biosimilars supports no risk to safety (FDA, 2024b, 2026). While the accumulated experience with biosimilars

over the last 15 years has confirmed that switching between reference products and biosimilars should not present significant changes in safety or effectiveness, prescribers and patients are still hesitant because of misinformation about the differences between biosimilars and interchangeable biological products and reference products and concerns about disrupting stable treatment regimens (Lang, 2023).

Summary of findings regarding the effects of switching to a biosimilar: There is *very strong evidence* that there is no difference in safety or side effects when switching between reference biologics and their biosimilar based on 31 RCTs and comparative effectiveness studies and over 15 years of extensive pharmacovigilance data.

Summary of Findings

There is *very strong evidence* that approved biosimilars do not introduce new or greater harms than their reference biologics. Biosimilars match the reference biologic's safety profile in clinical trials and real-world use, including post switching.

Clinical Practice Guidelines Related to Substitution or Switching

Major medical specialty groups have created practice guidelines to assist physicians by outlining the general principles for switching products but making the decision based on individual patient condition, care setting, and specific health risks. The American Society of Clinical Oncologists recommendations for switching biosimilars during the treatment of cancers include ensuring equitable access, including financial counseling and access to financial assistance programs for low-income individuals to cover the costs of biosimilars; patient education on biosimilar products to ensure confidence in the safety and efficacy of biosimilars; discussions between physicians and patients on any proposed switching options and shared decision-making on treatments; and communication between pharmacists, physicians, and patients when switching is planned (Rodriguez et al., 2023). FDA-approved biosimilars used to treat cancers include rituximab (a monoclonal antibody used to treat lymphoma and blood cancers), trastuzumab (a monoclonal antibody used to treat HER-2 positive early stage breast cancer), filgrastim and pegfilgrastim (granulocyte colony stimulating factors, used to treat low white blood cell counts resulting from chemotherapy), and erythropoietin-alpha (used to stimulate red blood cell production to counteract low counts due to chemotherapy, chronic kidney disease, or treatment of HIV/AIDS) (Canter et al., 2021).

The American Association of Clinical Endocrinologists and American College of Endocrinology clinical position statement on the use of biosimilars for long-acting insulin products included similar statements, supporting physician-led switching decisions (Fonseca et al., 2017). Because there are important differences between insulin dosing forms and administration devices (autoinjectors vs. "pens" that have separate needles, multi-dose vials in differing concentrations, dosing syringes with different scales), there is a special need for coordination of care and patient education and counseling when nonmedical switches occur. There has been a published review of significant outpatient adverse events due to mix-up errors (wrong doses) between different insulin delivery forms showing that it is important for there to be coordination between the pharmacist, physician, and patient or their caregivers during any switching in order to provide adequate education (Geller et al., 2021). The American Thyroid Association, along with the American Association of Clinical Endocrinologists and The Endocrine Society, also issued a joint statement on the use and interchangeability of thyroxine products. These products are considered to have narrow ranges for treating low thyroid hormone levels (so that thyroid hormone effect is not too high or too low). Several brand-name levothyroxine preparations are FDA-approved as therapeutic equivalents but there may be differences in clinical potency between brands, so that switching from one brand to another brand may not keep a patient in the narrow therapeutic range. The joint statement recommends that patients use the same brand-name thyroxine product throughout treatment, and that any switching is coordinated with a physician, who may need to repeat blood tests or adjust doses if a new brand is substituted (AACE-ATA-TES, 2004).

A Task Force on the Use of Biosimilars to Treat Rheumatological Diseases (diseases affecting skin, gastrointestinal system, and/or joints) also created evidence-based recommendations for switching. The guidelines state that switching from a reference product to a biosimilar requires awareness of the patient and the treating health care provider, and switching between biosimilar products for the same reference product would not be expected to have different clinical outcomes (Kay et al., 2018). In this specialty field, the most prominent product class are monoclonal antibodies to act against Tumor Necrosis Factor alpha, and include infliximab, adalimumab, and etanercept (Reese et al., 2024). Most of the data supporting switching has been from studies of adult patients, so that the guidelines for switching in pediatric patients recommend only switching between products that have been specifically studied in pediatric patients (de Ridder et al., 2019).

Cost Impact Analysis: Data Sources, Caveats, and Assumptions

Analytical Assumptions

In addition to the assumptions described in the *Analytical Approach and Assumptions* section of CHBRP's Analysis of California SB 1094, CHBRP made the following assumptions:

Pharmacy Benefit Coverage

For this analysis, CHBRP considered self-administered biological drugs, which are relevant to pharmacy benefit coverage, and biological drugs administered under the supervision of a physician (generally in a hospital, a provider's office, infusion center, or similar medical facility), which are generally covered through a medical benefit. Pharmacy benefits cover outpatient prescription drugs by covering scripts that are generally filled at a retail pharmacy, a mail-order pharmacy, or a specialty pharmacy.

Almost all (95.3%) commercial/CalPERS enrollees have an outpatient pharmacy benefit that is regulated by DMHC or CDI and covers both generic and brand-name outpatient prescription medications.[11] Of the remaining commercial/California Public Employees' Retirement System (CalPERS) enrollees, 0.99% do not have a pharmacy benefit and 3.7% have a pharmacy benefit that is not regulated by DMHC or CDI.

For Medi-Cal beneficiaries, the pharmacy benefit is separate and administered by the Department of Health Care Services (DHCS) under the Medi-Cal Rx program; therefore, it is not subject to DMHC regulation. Because SB 1094 would not require creation of a pharmacy benefit, baseline benefit coverage for enrollees is compliant if they are either without a pharmacy benefit or the pharmacy benefit is not regulated by DMHC or CDI. Being compliant with SB 1094 at baseline does not necessarily mean that these Medi-Cal plans have a pharmacy benefit that includes coverage for all reference biological drugs, as CHBRP did not survey the administrator of the Medi-Cal pharmacy benefit.

Additional Assumptions

This analysis reports the estimated incremental impact of full-scale implementation of SB 1094 on benefit coverage, utilization, and cost for a single year.[12] Full-scale implementation typically requires a "ramp up" period which may include educating enrollees, providers, and insurance carriers on the new benefits or coverage; updating procedures and policies; and increasing provider capacity for marginal utilization resulting from SB 1094. Furthermore, some policies may have staggered implementation or longer-term changes in utilization. The incremental impact estimates below assume there is no "ramp up" period and represent ongoing annual costs at full-scale implementation of SB 1094, including potential short-term offsets. CHBRP further assumes that state and industry policies and provider and patient behaviors would remain constant throughout the time period it takes for the full impact of the bill to be realized.[13]

The impact of SB 1094 on premiums depends on two factors: The extent to which health plans and/or pharmacists switch patients to biosimilar products and the cost savings that arise from switch (i.e., the difference between the net cost of the reference biological product and the net price of the biosimilar product). These issues are related in that the greater the cost savings from switching, the more incentive there will be for health plans to switch patients to the lower-priced

[11] For more detail, please see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance*.
[12] For some analyses, impacts as a result of changes to health insurance benefits may occur over multiple years (e.g., impacts in pregnancy and childbirth rates resulting from changes to utilization of fertility services, staggered implementation, or long-term changes in utilization). CHBRP's estimates represent the full impact of the mandate in one year even if changes in coverage, utilization offsets, and costs may be realized in more than one year.
[13] CHBRP's Cost and Coverage Model also assumes enrollees maintain one form of health insurance for the entire calendar year. Examples of state and industry policies and behavior include medications that may be developed or approved in the future, health insurance market changes beyond what is known at the time of publication of this analysis, and statutory changes resulting from other health benefit mandates.

alternative. Previous studies reported switches ranging from 3.4% to 99% (Chang et al., 2023; Roberts et al., 2025; Saxby et al., 2019; Waterhouse et al., 2021). Closed, integrated health systems in California have switched patients on some drugs to a biosimilar 90% of the time (Lang et al., 2023); this rate is taken to be the upper bound of the changes that might arise as a result of SB 1094.

Previous studies found that prescribers were hesitant to switch patients to a biosimilar product, raising the possibility that there might be a marked increase in "do not substitute" orders on prescriptions. Furthermore, although substitution rates for small-molecule generics in the United States approach 90% when a generic is available, pharmacists appear to be more hesitant to switch a biological product with a biosimilar (Feyman et al., 2024; Herndon et al., 2024).

For the purposes of this analysis, CHBRP assumes that the division of any market share shifting from the reference products to its interchangeable biological product and biosimilar alternatives will adhere to the current market share division between the interchangeable biological product and the biosimilars. If the interchangeable biological product has 80% of the market share not assigned to the reference drug (with the biosimilar[s] having the remaining 20%), then CHBRP assumes that 80% any additional market share resulting from SB 1094 would go to the interchangeable biological product.

Because of the uncertainty regarding the degree to which patients will be switched by either the pharmacist or the health plan from a reference biological product to a biosimilar or interchangeable, the potential impact on premiums was estimated for three scenarios:

- **Scenario 1: Large Impact –** Using experience of closed, integrated health systems as an upper bound, this scenario assumed that SB 1094 would see 90% of the reference products at baseline replaced with a biosimilar or interchangeable postmandate (Lang et al., 2023).
- **Scenario 2: Moderate Impact –** To facilitate the comparison of the range of the impact of SB 1094, the impact on premiums was estimated using the assumption that 50% of the reference products at baseline would be replaced with a biosimilar or interchangeable postmandate. This is the scenario presented in CHBRP's Analysis of SB 1094.
- **Scenario 3: Low Impact –** To reflect the possibility that SB 1094 would result in only minimal switching of patients, the low impact scenario used the assumption that only 10% of the reference products at baseline would be replaced with a biosimilar or interchangeable postmandate (Chang et al., 2023).

As mentioned above, the impact of premium depends not only on the degree of substitution of the biosimilars for the reference biological products, but also the difference in the net cost that health plans pay for each drug. However, it is generally not possible to observe the net cost of a drug — be it a reference product or a biosimilar — to the health plan. The net cost for biological products, like other drugs, is generally determined by the wholesale or list price of the product reduced by a contractual discount less any rebates that the health plan or insurer receives from the pharmaceutical company (either directly or indirectly through a pharmacy benefits manager). These rebates are negotiated between the drug companies and the PBMs on behalf of the health plans/insurers and are not generally made public. Based on a few cases where rebates have been made public, they can be substantial (Rome et al., 2024). In some cases, the published list prices for some biosimilars are significantly below the list price of the reference biological drug, which suggests that the level of rebates for some biosimilar and interchangeable products may be small or zero (Fein, 2023). As described in the Detailed Cost Notes Regarding Analysis-Specific Caveats and Assumptions methodology section below, the analysis assumed a cost offset due to rebates for reference biological products, but not for interchangeable biological products or biosimilar products.

A further complicating factor in determining the net cost is the source of the prescription. Biological prescription drug treatments are self-administered biologics — typically subcutaneous injections that patients give themselves at home, like adalimumab (Humira) or etanercept (Enbrel) for rheumatoid arthritis, or insulin products. These are processed through the pharmacy benefit, are dispensed at a retail or specialty pharmacy, and are what SB 1094's pharmacist substitution provision directly acts on. Biologic infusions are administered intravenously in a clinical setting — an infusion center,

hospital outpatient department, or physician's office. Examples include infliximab (Remicade) for Crohn's disease, rituximab for cancer, trastuzumab (Herceptin) for breast cancer, and bevacizumab for various cancers. These typically go through the medical benefit rather than the pharmacy benefit, are billed per infusion episode, and are administered by clinical staff rather than dispensed to the patient. To show the price differences that can arise between the reference biological products and the biosimilars/interchangeable biological products based on the source of the prescription, Table 4 in CHBRP's analysis of Senate Bill 1094 reports the two settings separately (CHBRP, 2026). Thus, the cost savings from switching from a reference biological product to a biosimilar/interchangeable biological product were calculated by estimating the cost savings for each drug multiplied by the number of scripts for biological prescription drug treatments plus the cost savings for each infusion multiplied by the number of infusions for each drug administered in a medical setting.

Sensitivity Analysis

As mentioned above, one of the key areas of uncertainty regarding SB 1094 is the extent to which pharmacists, health plans, and prescribers will switch from the reference products to biosimilars or interchangeable biological products. To identify the impact that this factor will have on cost savings and hence premiums, CHBRP analyzed sensitivities associated with the assumed shift rate.

Table 2 summarizes the range of premium reductions that could result from SB 1094. If SB 1094 does not have a large impact on the market (only a 10% shift from the reference drug as described in the low-impact assumption described above), then premiums would be expected to fall 0.01%. If SB 1094 resulted in a large shift from the reference drug (90% as described above in the high-impact scenario), total premiums would be estimated to decrease by 0.09%.

Table 2. SB 1094 Comparison of Impacts on Premiums by Market Shift, 2027

	Baseline	10% Market Shift	50% Market Shift	90% Market Shift
Non-enrollee premiums				
Employer-sponsored (a)	$75,730,916,000	-0.01%	-0.07%	-0.12%
CalPERS employer (b)	$8,611,855,000	-0.01%	-0.05%	-0.09%
Medi-Cal (c)	$42,982,384,000	0.00%	0.00%	-0.01%
Enrollee premiums				
Enrollees, individually purchased insurance	$25,775,325,000	-0.01%	-0.06%	-0.11%
Outside Covered California	$9,551,761,000	-0.01%	-0.06%	-0.12%
Through Covered California	$16,223,564,000	-0.01%	-0.06%	-0.11%
Enrollees, group insurance (d)	$21,828,135,000	-0.01%	-0.07%	-0.12%
Total premiums	$174,928,615,000	-0.01%	-0.05%	-0.09%

Source: California Health Benefits Review Program, 2026.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

Postmandate Administrative and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

State Health Care Spending Target

In 2024, in an effort to slow health care spending growth and improve health care affordability for California families, California's Office of Health Care Affordability (OHCA) under the Department of Health Care Access and Information (HCAI) approved a statewide target for maximum annual growth in health care spending for certain health care entities. The targets apply to per capita spending to specific entities, including health plans and insurers, provider organizations with at least 25 physicians, and hospitals (HCAI, 2022). The state is implementing this target with a phased-in approach, with a spending target of 3.5% for 2026, lowered to 3.2% in 2027 and 2028, and will be at 3% for 2029 and beyond (HCAI, 2025). Since health insurance benefit mandates may increase health care spending, such as increases to insurance premiums, administrative costs, and out-of-pocket costs, OHCA spending targets may be relevant considerations in benefit mandate policy decisions.

Postmandate Changes in the Number of Uninsured Persons

CHBRP assumes that if premiums increase by more than 1.7% in the small- or large-group market segments or 0.6% in the individual market, some enrollees will lapse their coverage. Because CHBRP projects premiums in all market segments subject to SB 1094 would decrease, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 1094.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of SB 1094.

Bill-Specific Factors

It should be noted that the following additional factors may affect the fiscal impact of SB 1094, if enacted:

- **Sharing of cost savings:** Previous studies have suggested that because of the nature of pharmaceutical pricing, it is possible for some savings to be retained as profits — either by the PBMs, the health plans, or a parent company to the health plans — rather than passed along in the form of lower premiums. The analysis here assumes that 100% of any cost savings will be passed along due to the competitive pressures within the industry to lower costs.
- **Reference product pricing:** Another factor is the possibility of greater cost savings if the price of reference biological products falls as a result of SB 1094. At issue is the extent to which the drug manufacturer making the reference biological products would lower their price in order to maintain their market share. In theory, this could lower the price of the reference biological product to the same as, or comparable to, the biosimilar, in which case SB 1094 would result in lower premiums even if the degree of switching was minimal. Because the pricing of reference biological products depends on several factors that CHBRP cannot measure (such as the strength of the brand name), CHBRP

assumes that all the cost savings would result from switching to a biosimilar and that the price of the reference product would remain unchanged.

- **Demand for pharmaceutical products:** Patient demand for pharmaceutical products subject to SB 1094 may also change due to lower copayments. At issue is the degree to which some patients might currently be choosing not to take any of the drug or to reduce the amount they take due to their cost-sharing responsibility for the reference biological product. A reduction in cost sharing as a result of SB 1094 (due to either a switch to a biosimilar or a reduction in the price of the reference drug) could lead to more demand for the products, which may lead to an increase in total expenditures. While this could also be accompanied by an increase in health status because of the increased access to medications, it would limit any impact on premiums. For the purposes of this analysis, CHBRP assumes any increase in demand will be minimal, in part because many patients will reach the deductible limits on their plans regardless of the lower prices.[14] However, should drug prices fall significantly in the future, there may be an increase in demand and utilization of large-molecule drugs.
- **New biosimilars:** A final factor that could influence the impact of SB 1094 is the impact from having other biosimilar drugs introduced into the market. At present, there are 20 reference biological products and 41 interchangeable biological products and 90 biosimilars. However, over the next decade, 118 biologics are expected to lose patent protection, presenting an opportunity for biosimilars to be introduced (IQVIA, 2025). At present, only 12 of those molecules had biosimilars in development as of mid-2024, leaving 106 biologic patents expired. To the extent to which new biosimilars are introduced into the market, the net savings will likely increase. However, because the degree of new product introduction is unclear, especially in the short term, the analysis estimates the cost savings only based on existing reference products with biosimilars.

Analysis-Specific Data Sources

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc., the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.[15] Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses, are available on CHBRP's website.[16]

This section describes analysis-specific data sources, estimation methods, caveats, and assumptions used in preparing this cost impact analysis.

CHBRP surveyed several of the largest (by enrollment) providers of health insurance in California to assist in assessing the impact of SB 1094. Responses to this survey represented 84% of commercial enrollees with health insurance that can be subject to state benefit mandates. In addition, CalPERS and DHCS were queried regarding related benefit coverage.

Health Cost Guidelines

The Health Cost Guidelines (HCGs) are a health care pricing tool used by actuaries in many of the major health plans in the United States. The guidelines provide a flexible but consistent basis for estimating health care costs for a wide variety of commercial health insurance plans. It is likely that these organizations use the HCGs, among other tools, to determine the initial premium impact of any new mandate. Thus, in addition to producing accurate estimates of the costs of a mandate, we believe the HCG-based values are also good estimates of the premium impact as estimated by the HMOs and insurance companies.

[14] CHBRP assumes that patients who need to be prescribed biologics face more complex disease states. As a result, these patients generally need more frequent medical care and a higher number of prescriptions, and therefore often meet their annual deductible.
[15] CHBRP's authorizing statute requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[16] See CHBRP's Cost Impact Analysis landing page; in particular, see *Cost Impact Analyses: Data Sources, Caveats, and Assumptions*.

The highlights of the commercial HCGs include:

- Specific major medical, managed care, and prescription drug rating sections and guidance with step-by-step rating instructions.
- Other helpful analysis resources, such as inpatient length of stay distribution tables, Medicare Severity-Adjusted Diagnosis Related Group (MS-DRG) models, and supplementary sections addressing EHBs and mandated benefits, experience rating, and individual and small-group rating considerations.
- Presentation of loosely and well-managed nationwide utilization and cost information by Milliman benefit-aligned service categories used throughout the Rating Structures — inpatient hospital services for both loosely and well-managed are also supported by DRG level utilization and cost benchmarks.
- Annual updates address emerging regulatory considerations such as health care reform and mental health parity requirements.
- Annually updated benefit descriptions used in the HCG service categories.
- Annually updated medical trend assumptions and considerations.
- Presentation of two sets of nationwide area factors to facilitate development of area-specific claim costs, including separate utilization and charge level factors by type of benefit, state and Metropolitan Statistical Area for first-dollar coverage, and composite factors by deductible amount.
- Claim Probability Distributions (CPDs) by type of coverage that contain distributions of claim severity patterns for unique combinations of benefits and member types (adult, child, composite member).
- The Prescription Drug Rating Model (RXRM), an automated rating tool that provides a detailed analysis of prescription drug costs and benefits.

Consolidated Health Cost Guidelines Sources Database

Milliman maintains benchmarking and analytic databases that include health care claims data for nearly 60 million commercial lives and over 3 million lives of Medicaid managed care data. This dataset is routinely used to evaluate program impacts on cost and other outcomes.

Detailed Cost Notes Regarding Analysis-Specific Caveats and Assumptions

The analytic approach and key assumptions are determined by the subject matter and language of the bill being analyzed by CHBRP. As a result, analytic approaches may differ between topically similar analyses, and therefore the approach and findings may not be directly comparable.

Methodology and Assumptions for Baseline Benefit Coverage

- The population subject to the mandated offering includes individuals covered by DMHC-regulated commercial insurance plans, CDI-regulated policies, CalPERS, and Managed Medi-Cal plans subject to the requirements of the Knox-Keene Health Care Service Plan Act.
- CHBRP assumed that this bill would only impact biological prescription drugs and physician-administered drugs that are (1) covered and (2) have an interchangeable biological product and/or biosimilar alternative. As a result:
    - CHBRP assumed that 100% of enrollees would have coverage for the biological reference products and associated interchangeable biological product and biosimilar products in physician administered settings.

- CHBRP assumed that 100% of enrollees with an outpatient prescription drug benefit covering generic and brand-name medications would have coverage for the biological reference products and associated interchangeable biological products and biosimilar products via the outpatient pharmacy benefit.

Methodology and Assumptions for Baseline Utilization

Biological reference product identification

- CHBRP used FDA purple book data as of January 2026 to identify biological reference products with at least one licensed interchangeable biological product or biosimilar drug (FDA CDER, 2026b). The identified drugs were: tocilizumab (Actemra), bevacizumab (Avastin), etanercept (Enbrel), aflibercept (Eylea), trastuzumab (Herceptin), adalimumab (Humira), insulin glargine (Lantus), ranibizumab (Lucentis), pegfilgrastim (Neulasta), filgrastim (Neupogen), insulin aspart (Novolog), pertuzumab (Perjeta), epoetin alfa (Procrit), denosumab (Prolia/Xgeva), infliximab (Remicade), rituximab (Rituxan), eculizumab (Soliris), ustekinumab (Stelara), natalizumab (Tysabri), and omalizumab (Xolair).
  - Enbrel, Xolair, and Perjeta do not have a licensed interchangeable biological product or biosimilar that was marketed in the United States as of January 2026. Therefore, they were excluded from our analysis.
  - Epoetin alfa was excluded from the analysis for the Managed Medi-Cal population. This drug is commonly used to treat patients with chronic kidney disease who also qualify for Medicare due to having end-stage renal disease. Most of the physician-administered drug costs for such patients would be paid for by Medicare, rather than the Medi-Cal Managed Care plan.
- CHBRP identified interchangeable biological product and biosimilar products for each reference product using the FDA purple book data as of January 2026. CHBRP assumed the biologic license application information contained in the purple book would correspond to how it is treated by the proposed legislation SB 1094.

Prescription drug utilization

- Baseline utilization for biological reference products and their associated interchangeable biological product and biosimilar alternatives was estimated using Milliman's proprietary 2024 Consolidated Health Cost Guidelines Sources Database (CHSD). The data was limited to California commercial enrollees. The drugs relevant to SB 1094 were identified using the product names in the MediSpan® Master Drug Database v2.5.
- Utilization for prescription drugs was trended to 2027 at 2.5% per year.

Physician-administered drugs

Baseline utilization for physician-administered drugs in an outpatient setting was identified using Health Care Common Procedure Coding System (HCPCS) codes. CHBRP included the codes displayed in

- Table 3, below, in the analysis.
- Utilization for physician-administered drugs in an outpatient setting was trended to 2027 at 1.0% per year.

Table 3. Procedure Codes for Drugs Analyzed in SB 1094.

Drug	Procedure Codes for Reference Products, Interchangeable Biological Products, and Biosimilars
Tocilizumab	J3262, Q0237, Q0249, Q5133, Q5135, Q5156
Ustekinumab	J3357, J3358, Q5098, Q5099, Q5100, Q5137, Q5138, Q9989, Q9996, Q9997, Q9998, Q9999
Filgrastim	J1442, Q5101, Q5110, Q5125, Q5148
Infliximab	J1745, Q5102, Q5103, Q5104, Q5109, Q5121
Bevacizumab	J9035, Q5107, Q5118, Q5126, Q5129, Q5160
Pegfilgrastim	J2505, J2506, Q5108, Q5111, Q5120, Q5122, Q5127, Q5130
Trastuzumab	J9355, Q5112, Q5113, Q5114, Q5116, Q5117, Q5146
Rituximab	J9310, J9312, Q5115, Q5119, Q5123
Ranibizumab	J2778, Q5124, Q5128
Adalimumab	J0135, J0139, Q5131, Q5132, Q5140, Q5141, Q5142, Q5143, Q5144, Q5145
Natalizumab	J2323, Q5134
Denosumab	J0897, Q5136, Q5157, Q5158, Q5159
Epoetin Alfa	J0885, J0886, Q4081, Q5105, Q5106
Eculizumab	J1299, J1300, Q5139, Q5151, Q5152
Aflibercept	J0177, J0178, Q5147, Q5149, Q5150, Q5153, Q5155
Omalizumab	J2357, Q5154

Source: California Health Benefits Review Program, 2026.

Methodology and Assumptions for Baseline Cost

- CHBRP estimated the average gross cost per 30-day prescription and the average cost per infusion for biological reference products using 2024 CHSD data.
- CHBRP assumed that biological reference products would receive rebates that would offset plan cost amounts.
    - 0% Rebates: CHBRP assumed 0% rebates on branded insulin products. Manufacturers of branded insulin products decreased their list prices significantly in response to the American Rescue Plan Act of 2021. As a result, it is widely believed that insulin manufacturers no longer provide any significant pricing concession through a rebate (Fein, 2025).
    - 70% Rebates: CHBRP assumed 70% rebates on biological reference products that have biosimilar or interchangeable biological product alternatives with both a high list price option and a low list price option. The 70% implied rebate was determined by comparing the list price differential between the high list price alternatives and the low list price alternatives.
    - 20% Rebates: CHBRP assumed 20% rebates on all other drugs.

- CHBRP estimated the average gross cost per 30-day prescription and the average cost per infusion for interchangeable biological product and biosimilar drugs for each biological reference products by multiplying the average cost for the reference product by an adjustment factor. The adjustment factors were determined based on the average list price differential between each respective reference product and their associated interchangeable biological product and biosimilar alternatives. For interchangeable biological product and biosimilar alternatives that had both high list price options and low list price options, only the low list price was considered for the purpose of this adjustment.
- CHBRP assumed that interchangeable biological product and biosimilar products would not receive rebates that would offset plan cost amounts.
- CHBRP applied annual unit cost trends of 9.75% for prescription drugs (pharmacy benefit) and 4.5% for physician administered drugs (medical benefit).

Methodology and Assumptions for Baseline Cost Sharing

- CHBRP assumed the cost sharing for biological reference products and their associated interchangeable biological product and biosimilar alternatives is the same as major medical cost sharing. Major medical cost sharing was estimated based on metal tier actuarial values and sample plans. CHBRP assumed a maximum $250 copayment per prescription and per physician administered infusion.

Methodology and Assumptions for Postmandate Utilization

- CHBRP assumed that the passing of this bill would result in a shift of utilization from the biological reference product to interchangeable biological product and biosimilar alternatives, due to increased flexibility in legislative rules for dispensing biosimilars and increased awareness of interchangeable biological product alternatives to biological reference product.
- CHBRP assumed that 50% of baseline biological reference product utilization would shift to interchangeable and/or biosimilar alternatives postmandate. This shift assumption represented the total rate of switching from any possible party (i.e., pharmacists, health plans, insurers, and UROs) as a result of SB 1094.

  Note, in practice, SB 1094 may only drive switches from a reference product to a biosimilar or interchangeable biological product drug when the biosimilar or interchangeable biological product drug is covered on the formulary. CHBRP did not adjust the switch rate to reflect current formulary coverage of biosimilar and interchangeable biological product drugs (or reduce the switching percentage to account for plans that only currently cover the reference product). This is consistent with CHBRP's assumption that there would be no "ramp up" period when modeling savings from this legislation.
- As mentioned in the Sensitivity Analysis section above, there is uncertainty in how prescribing patterns may change because of SB 1094. As a result, CHBRP modeled two additional scenarios to assess the potential variation in the results driven by the assumed switching rate:
  - Low: 10% of baseline biological reference product utilization would shift to interchangeable biological product and/or biosimilar alternatives postmandate.
  - High: 90% of baseline biological reference product utilization would shift to interchangeable biological product and/or biosimilar alternatives postmandate.
- CHBRP applied a dampening factor to the shift based on feedback in the carrier survey to account for the fact that some carriers do not expect prescribing patterns to change as a result of SB 1094.
- The proportion of the shift from the reference product to the interchangeable biological product or biosimilar equivalent products was assumed to be proportional to the relative utilization of such products in the 2024 CHSD data. If there was no utilization for interchangeable biological product or biosimilar alternatives for a reference product in the 2024

CHSD, then CHBRP assumed that utilization would be split uniformly between currently licensed and marketed interchangeable biological product and biosimilar products.

Methodology and Assumptions for Postmandate Cost

- CHBRP assumed the average cost per prescription for each drug would not change as a result of SB 1094. Average cost displayed in Table 4 in CHBRP's analysis of SB 1094, changes relative to the baseline to the extent that the mix of interchangeable biological product and biosimilar alternatives changes. However, CHBRP assumes the cost per script for each drug is the same as baseline.

Methodology and Assumptions for Postmandate Cost Sharing

- CHBRP assumed the average cost sharing per script for enrollees with coverage would be the same for each drug postmandate as baseline.

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CHBRP is an independent program administered and housed by the University of California, Berkeley, under the Office of the Vice Chancellor for Research. A group of faculty, researchers, and staff complete the analysis that informs CHBRP reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing researchers and analysts who are **Task Force Contributors** to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** works with Task Force members in preparing parts of the analysis, and manages external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with an independent actuarial firm, **Milliman, Inc.**, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit. The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. Information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications, are available at chbrp.org.

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CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at chbrp.org.

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Please direct any questions concerning this document to: California Health Benefits Review Program, MC 3116, Berkeley, CA 94720-3116; info@chbrp.org; or chbrp.org.

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The California Health Benefits Review Program (CHBRP) was established in 2002. CHBRP's mission is to inform and support policymaking in California through the creation of impartial, evidence-based resources. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit-related legislation. CHBRP is dedicated to providing academic rigor on a Legislature's timeline.

The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. An independent actuarial firm helps to estimate the financial impact. Content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

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This analysis is based on existing literature and public sources identified through systematic search methods. This evidence informs the California Legislature about potential impacts of proposed health benefit legislation and does not constitute a policy recommendation from CHBRP.

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