

Bill Summary

SB 1094 would expand the practice of nonmedical switching of prescription drugs for patients who have already been approved for coverage of a prescription drug. The bill would allow:

- Pharmacists to substitute biologics to biosimilars.
- Health plans, insurers, and UROs to substitute brand-name drugs to AB-rated generic drugs; biologics to biosimilars or interchangeable biological products.

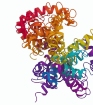
Context

Most pharmaceutical products are either:



Small molecule drugs

- Small, simple, chemically synthesized
- Substitutes: AB-rated generics (therapeutically equivalent by FDA) for brand-name drug.



Biologics

- Large, complex, produced in living organisms
- Substitutes: biosimilars or interchangeable biological products from reference product (brand-name biologic)

Nonmedical switching: Substitution of prescription drugs by non-prescribers to increase cost savings.

Medical Effectiveness

The FDA has determined there are no clinically significant safety concerns for switching between reference products and biosimilars. There is **very strong evidence** that approved biosimilars do not introduce new or greater harms than their reference product.

Utilization and Expenditures

Factors that impact how often total nonmedical switching occurs include the frequency of:

- Pharmacist switching
- Plan/insurer/URO switching
- Prescriber "do not substitute" orders
- Patient requests for exceptions



CHBRP estimates that **24,700** people would be switched from a brand-name reference product to a lower-cost biosimilar. The impact of small-molecule switches would be negligible due to high rates of nonmedical switching at baseline.

Insurance Subject to the Mandate

All 22.8M enrollees in state-regulated health insurance in California have insurance subject to SB 1094.

- CDI and DMHC-Regulated (Commercial and CalPERS)
- Medi-Cal



-\$87.7 million in total annual premiums paid by employers and enrollees



-\$92 to -\$310 in annual cost sharing for patients whose drugs switched (varies by market segment)

California Health Benefits Review Program (**CHBRP**), California Department of Insurance (**CDI**), California Department of Managed Health Care (**DMHC**), U.S. Food and Drug Administration (**FDA**), Out-of-pocket (**OOP**), Senate Bill (**SB**), Utilization Review Organization (**URO**)

Public Health Impacts

No short-term public health impact because nonmedical switching does not impact health outcomes. Some enrollees may experience decreased financial burden on enrollees due to a decrease in OOP costs.

Long-Term Impacts

- Increased biosimilar competition may lead to a reduction in their net prices
- Substitution of lower-cost drugs may become the norm, which would alleviate enrollee financial burden