



Abbreviated Analysis

California Senate Bill 70: Prescription Drug Coverage

Report to the 2023–2024
California State Legislature
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SUMMARY

The California Senate Committee on Health requested that the California Health Benefits Review Program (CHBRP)¹ conduct an evidence-based assessment of California Senate Bill 70 Prescription Drug Coverage, a bill that would alter two current health insurance benefit mandates.

The term *off-label* refers to use of a drug in a way that differs from the specifications explicitly approved by the Food and Drug Administration (FDA). Although the FDA's specifications may include particular drug dosages (a measurement, often in milligrams) or particular dosage forms (oral vs. inhaled, extended vs. immediate release, ocular vs. oral, etc.), off-label use of drugs is not uncommon.

The current Off-Label mandate requires that most plans regulated by the California Department of Managed Health Care (DMHC) and all policies regulated by the California Department of Insurance (CDI) that include a pharmacy benefit not exclude a drug from coverage because the drug is being prescribed off-label when (1) the drug is prescribed by a contracting prescriber and (2) when specified criteria are met. The current Off-Label mandate also requires coverage of any medically necessary services associated with the administration of the drug for which the Off-Label mandate would require coverage. SB 70 would alter the Off-Label mandate to:

- Expand the requirement from “drug” to “drug, dose of the drug, or dosage form.”

The current Continuity mandate² requires that all plans regulated by DMHC and some policies regulated by CDI³ that include an outpatient prescription drug pharmacy benefit not limit or exclude coverage for a drug for an enrollee when (1) the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and (2) the plan's prescribing provider continues to prescribe the drug for the medical condition, (3) provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition. SB 70 would alter the Continuity mandate to:

- Expand the requirement from “drug” to “drug, dose of the drug, or dosage form”;
- Clarify that the requirement applies to off-label use of a drug, so long as the criteria in the Off-Label mandate are met; and
- Prohibit cost-sharing changes if the drug had already been covered.

Background. Plans and policies that include a pharmacy benefit may apply utilization management techniques (including prior authorization, step therapy, and formulary requirements) to off-label use of a drug, dosage, or dosage form and may do so for a new use or for a continuing use. When utilization management requirements are present, prescribers may submit medical documentation along with a prior authorization request for an enrollee seeking to fill a prescription (script) for a drug. Should a plan or insurer review a prior authorization request and then deny coverage,

an enrollee, with assistance from the prescriber, may appeal the decision to the plan or insurer. Should a plan or insurer review an appeal and uphold their denial, an enrollee, with assistance from the prescriber, may appeal the second denial to the appropriate regulator – DMHC or CDI – for state-regulated health insurance.

Analytic Approach. The current Off-Label mandate applies to the health insurance of all enrollees in CDI-regulated policies as well as to the health insurance of commercial/CalPERS enrollees in DMHC-regulated plans. It does not

¹ Refer to CHBRP's full report for full citations and references.

² HSC 1367.22.

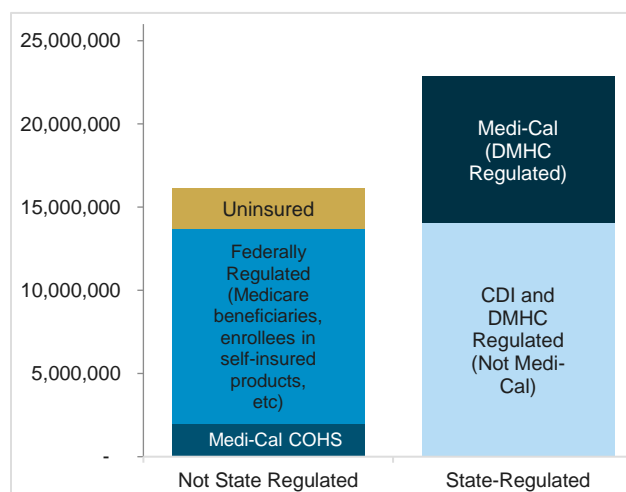
³ Due to its incorporation by reference in the Insurance Code section 10112.27(a)(2)(A)(iv)

apply to the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans. SB 70 would not alter the applicability of the Off-Label mandate.

The current Continuity mandate applies to the health insurance of all enrollees in DMHC-regulated plans (commercial/CalPERS enrollees and enrolled Medi-Cal beneficiaries) as well as to the health insurance of almost all enrollees in CDI-regulated individual and small-group policies. It does not apply to the health insurance of enrollees in CDI-regulated large-group policies. SB 70 would make the Continuity mandate applicable to the health insurance of enrollees in all CDI-regulated policies. This would make the mandate applicable to the health insurance of an additional 427,000 enrollee.

As SB 70 would alter them, the mandates would not be applicable to identical sets of health insurance. Both mandates would be applicable to the health insurance of commercial/CalPERS enrollees, but the Off-Label mandate would still not be applicable to the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Figure A. Health Insurance in CA



Source: California Health Benefits Review Program, 2023.

⁴ For more on outpatient prescription drug coverage among Californians with state-regulated health insurance, see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at: https://chbrp.org/other_publications/index.php.

As the number of outpatient prescription drugs for which SB 70 could change access to coverage would be extremely large, no analysis of medical effectiveness (and so no estimates of Public Health impacts) could be completed within CHBRP's 60-day analytic period. However, this abbreviated analysis presents SB 70's expected impacts on benefit coverage, utilization, and cost.

For this analysis, CHBRP has made a number of analytic assumptions, including:

- Benefit coverage of enrollees without a pharmacy benefit regulated by CDI or DMHC⁴ are compliant with the current Off-Label and Continuity mandates, and would be compliant with these mandates as SB 70 would alter them. In other words, CHBRP assumes SB 70 would have no impact for plans without a regulated pharmacy benefit.
- For the Continuity mandate as SB 70 would alter it, the prohibition on cost-sharing change:
 - Would be applicable only within a plan/policy year; and
 - Would not apply if the enrollee changed to another plan or policy.

Should the prohibition on cost sharing (a prohibition on cost sharing not already imposed) be applicable on a year-over-year basis⁵ – and/or should it be applicable after an enrollee changes plan or policy – impacts on premiums could, in the long term, become orders of magnitude greater than what is projected in this analysis.

Benefit Coverage. There would be variation as to how many enrollees' benefit coverage would have to change to become compliant with SB 70.

⁵ CHBRP has assumed the contrary – that health plans and policies would continue to have the ability to modify deductibles, copays, coinsurance, and maximum out-of-pocket values each year.

Under the altered Off-Label mandate, for which applicability would be unchanged:

- 5,173,000 enrollees would have enhanced coverage for off-label use of dosages and dosage forms of prescription drugs.

Under the altered Continuity mandate which would be applicable to the health insurance of 427,000 more enrollees:

- 5,173,000 enrollees would have enhanced coverage for continuing use of dosages, dosage forms, and off-label use of prescription drugs; and
- 13,404,000 enrollees would have new limits on cost sharing (so long as they do not change to another plan or policy).

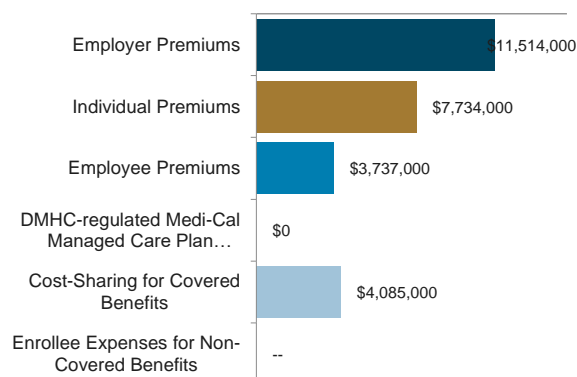
Utilization. At baseline, the total number of scripts filled for drugs impacted by SB 70 – predominantly non-preferred brand and specialty drugs prescribed for off-label use – would be 551,000. Postmandate, 4,000 additional scripts are projected to be filled, resulting from 18,000 fewer generic and preferred brand scripts filled and 22,000 more non-preferred brand and specialty scripts filled.

Unit Cost. At baseline, the average unit cost of a 30-day supply for a drug with coverage impacted by SB 70 is estimated to be approximately \$2,908. Within this average, unit costs for particular drugs range from less than \$750 to more than \$6,000. Postmandate, the average unit costs of impacted scripts would be 0.76% higher, not because the unit costs of the drugs would change, but because the postmandate mix of covered scripts filled would include a smaller proportion of generic and preferred brand drugs and a greater proportion of specialty and non-preferred brand drugs, which are generally more expensive.

Expenditures. As noted in Figure B, SB 70 would increase total net annual expenditures by

\$27,070,000 (0.02%) for enrollees with health insurance subject to state-level benefit mandates. Although the altered Continuity mandate would limit cost sharing, the Off-Label mandate, which would be connected to the majority of additional filled scripts, would not alter applicable cost sharing. Under the altered Off-Label mandate, CHBRP projects increased utilization of specialty and non-preferred brand drugs, as well as off-formulary drugs (all of which are often associated with greater per-fill cost sharing) and therefore an increase in total enrollee cost sharing due to greater use of scripts to which greater cost sharing is applicable. Although CHBRP cannot estimate the frequency at which some enrollees may have self-paid for scripts at baseline, the high unit costs for many of the drugs would have limited self-pay at the population-level level due to affordability.

Figure B. Expenditure Impacts of SB 70



Source: California Health Benefits Review Program, 2023.

Number of Uninsured in California. The impacts of SB 70 on expenditures would not be great enough to expect any change in the number of uninsured.

Essential Health Benefits. As SB 70 would not require coverage for a new benefit mandate, the bill would not appear to exceed the definition of essential health benefits (EHBs) in California.

Table 1. Impacts of SB 70 on Benefit Coverage, Utilization, and Cost, 2024

	Baseline (2024)	Postmandate Year 1 (2024)	Increase/ Decrease	Change Postmandate
Benefit Coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	22,842,000	22,842,000	0	0.00%
Enrollees with health insurance subject to SB 70 Off-Label mandate (b)	14,025,000	14,025,000	0	0.00%
Enrollees with health insurance coverage fully compliant with SB 70 Off-Label mandate	8,852,000	14,025,000	5,173,000	58.44%
Enrollees with health insurance subject to SB 70 Continuity mandate (b)	22,415,000	22,842,000	427,000	1.90%
Enrollees with health insurance coverage fully compliant with SB 70 Continuity mandate's cost-sharing provisions	9,438,000	22,842,000	13,404,000	142.02%
Enrollees with health insurance subject to SB 70 Continuity mandate (b)	22,415,000	22,842,000	427,000	1.90%
Enrollees with health insurance coverage fully compliant with SB 70 Continuity mandate's dosage and dosage form and off-label use provisions	17,669,000	22,842,000	5,173,000	29.28%
Utilization and Cost				
Number of impacted scripts filled	551,000	555,000	4,000	0.73%
Average unit cost of impacted scripts filled (g)	\$2,908	\$2,930	\$22	0.76%
Total cost	\$1,602,287,000	\$1,626,237,000	\$23,950,000	1.49%
Expenditures				
<i>Premiums</i>				
Employer-sponsored (b)	\$57,647,993,000	\$57,659,197,000	\$11,204,000	0.02%
CalPERS employer (c)	\$6,158,262,000	\$6,158,572,000	\$310,000	0.01%
Medi-Cal (excludes COHS) (d)	\$29,618,383,000	\$29,618,383,000	\$0	0.00%
<i>Enrollee Premiums (expenditures)</i>				
Enrollees, individually purchased insurance	\$21,229,233,000	\$21,236,967,000	\$7,734,000	0.04%
Outside Covered California	\$4,867,955,000	\$4,869,825,000	\$1,870,000	0.04%
Through Covered California	\$16,361,278,000	\$16,367,142,000	\$5,864,000	0.04%
Enrollees, group insurance (e)	\$18,263,775,000	\$18,267,512,000	\$3,737,000	0.02%
<i>Enrollee out-of-pocket expenses</i>				
Cost-sharing for covered benefits (deductibles, copayments, etc.)	\$14,210,326,000	\$14,214,411,000	\$4,085,000	0.03%
Expenses for noncovered benefits (f) (g)	—	—	—	—
Total Expenditures	\$147,127,972,000	\$147,155,042,000	\$27,070,000	0.02%

Source: California Health Benefits Review Program, 2023.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.6

(b) In some cases, a union or other organization. Excludes CalPERS.

(c) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.1% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.7 CHBRP has projected no impact

⁶ For more detail, see CHBRP's resource *Sources of Health Insurance in California* available at: http://chbrp.org/other_publications/index.php.

⁷ For more detail, see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at: http://chbrp.org/other_publications/index.php.

for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(d) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(e) Enrollee premium expenditures include contributions by enrollees to employer (or union or other organization)-sponsored health insurance, health insurance purchased through Covered California, and any contributions to enrollment through Medi-Cal to a DMHC-regulated plan.

(f) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance. For the expenses related to SB 70, at baseline some enrollees may have self-paid for scripts filled for which coverage would have been denied. However, others may have accepted coverage for the scripts filled of an alternative drug and so incurred no enrollee expense for a noncovered drug. CHBRP is unable to estimate baseline or postmandate amounts, but would expect such enrollee expenses to decline, postmandate.

(g) Within this average, unit costs for particular drugs range from less than \$750 to more than \$6,000.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)⁸ conduct an evidence-based assessment of SB 70 Prescription Drug Coverage, which would alter two current health insurance benefit mandates.

Background

Almost all enrollees in plans and policies regulated by the California Department of Managed Health Care (DMHC) and the California Department of Insurance (CDI) have pharmacy benefit coverage.⁹ Pharmacy benefits cover outpatient prescription drugs by covering prescriptions (scripts) that are generally filled at a retail pharmacy, a mail-order pharmacy, or a specialty pharmacy.

Plans and policies that include a pharmacy benefit may apply utilization management techniques, (including prior authorization, step therapy, and formulary requirements) to off-label use of a drug, dosage, or dosage form. All enrollees in a single plan or policy have uniform pharmacy benefit coverage, but utilization management techniques, when present, influence whether a particular enrollee at a particular moment may access their benefit coverage for assistance in paying for (or otherwise acquiring) a script filled for a particular drug. Utilization management techniques are generally applied to new prescriptions, but they may also be applied if there is a change in dose or dosage form (inhaled vs. oral, immediate vs. extended release, etc.) for a recurring prescription. Additionally, they may be applied to recurring prescriptions, should the enrollee's plan or policy alter applicable utilization management techniques or if an enrollee switches from one plan or policy to another.

Prescribers submit medical documentation along with a prior authorization request for an enrollee seeking to fill a script for a drug when utilization management requirements are present, as may be the case for off-label use of a drug or continued coverage for a drug that is no longer expected to be covered for the enrollee. Plans and insurers regulated by DMHC and CDI must complete utilization review for a completed prior authorization request within 72 hours (within 24 hours in emergency circumstances) or coverage for the script is required.¹⁰ Utilization review may result in the plan or insurer covering the drug or denying coverage.

Should a plan or insurer review a prior authorization request and then deny coverage, an enrollee, with assistance from the prescriber, may appeal the decision to the plan or insurer. Plans and insurers regulated by DMHC and CDI generally must review and respond to completed appeals within 30 days.^{11,12} The plan or insurer may agree to the appeal and cover the drug or may uphold their original denial.

Should a plan or insurer review an appeal and uphold their denial, an enrollee, with assistance from the prescriber, may appeal the second denial to the appropriate regulator – DMHC or CDI – for state-regulated health insurance. The regulator may uphold the denial or may require the plan or insurer to cover the drug.

⁸ CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.

⁹ For more on outpatient prescription drug coverage among Californians with state-regulated health insurance, see CHBRP's resource *Estimates of Pharmacy Benefit Coverage in California*, available at: <https://www.chbrp.org/other-publications/resources>.

¹⁰ H&S 1367.241, INS 10123.191.

¹¹ H&S code 1368.

¹² CDI-regulated insurers must generally respond to an appeal within 30 days of receipt, unless urgent, and then within 72 hours of receipt. However, shorter time limits apply under state law to internal appeals of adverse benefit determinations for prescription drugs. Insurance Code section 10123.191(b)(2) provides that appeals of prior authorization and step therapy exception request denials must be decided within 72 hours of receipt, or within 24 hours if urgent. The same time limits apply to exception/PA requests for off-formulary drugs under 45 CFR § 156.122(c), which is incorporated by reference at subdivision (i).

Relevant Populations

The two mandates that SB 70 would alter are not applicable to identical sets of health insurance.

The current Off-Label mandate applies to the health insurance of all enrollees in CDI-regulated policies as well as to the health insurance of commercial/CalPERS enrollees in DMHC-regulated plans. It does not apply to the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans. So the current Off-Label mandate is applicable to the health insurance of 14.0 million enrollees (36% of all Californians). This represents 61% of the 22.8 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law, SB 70 would not alter the applicability of the Off-Label mandate.

The current Continuity mandate applies to the health insurance of all enrollees in DMHC-regulated plans (commercial/CalPERS enrollees and enrolled Medi-Cal beneficiaries) as well as to the health insurance of almost all enrollees in CDI-regulated individual and small-group policies.¹³ It does not apply to the health insurance of enrollees in CDI-regulated large-group policies or to the health insurance of enrollees in CDI-regulated grandfathered small-group or individual market policies. So, the current Continuity mandate is applicable to the health insurance of 22.4 million enrollees (57% of all Californians). This represents 98% of the 22.8 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law. SB 70 would make the Continuity mandate applicable to the health insurance of enrollees in all CDI-regulated policies. This would make the mandate applicable to the health insurance of an additional 427,000 enrollees.

As SB 70 would alter them, the mandates would still not be applicable to identical sets of health insurance. Both mandates would be applicable to the health insurance of commercial/CalPERS enrollees, but the Off-Label mandate would still not be applicable to the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Bill Language

The term *off-label* refers to use of a drug in a way that differs from the specifications explicitly approved by the Food and Drug Administration (FDA). Off-label use of drugs is not uncommon and is discussed by the FDA on a webpage intended for patients.¹⁴ The FDA's specifications may include particular drug dosages (a measurement, often in milligrams) or particular dosage forms (oral vs. inhaled, extended vs. immediate release, ocular vs. oral, etc.).

The current Off-Label mandate¹⁵ requires that plans and policies that include a pharmacy benefit not exclude a drug from coverage because the drug is being prescribed off-label when (1) the drug is prescribed by a contracting prescriber and (2) when specified criteria are met. The current Off-Label mandate also requires coverage of any medically necessary services associated with the administration of the drug for which the Off-Label mandate would require coverage.

SB 70 would alter the Off-Label mandate to:

- Expand the requirement from “drug” to “drug, dose of the drug, or dosage form.”

The current Continuity mandate¹⁶ requires that plans regulated by DMHC or CDI that include a pharmacy benefit not limit or exclude coverage for a drug for an enrollee when (1) the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and (2) the plan's prescribing

¹³ Due to its incorporation by reference in the Insurance Code section 10112.27(a)(2)(A)(iv)

¹⁴ See <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label>. Accessed on February 12, 2023.

¹⁵ HSC 1367.21, INS 10123.195.

¹⁶ HSC 1367.22.

provider continues to prescribe the drug for the medical condition, (3) provided that the drug is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition.

SB 70 would alter the Continuity mandate to:

- Expand the requirement from “drug” to “drug, dose of the drug, or dosage form”;
- Specify that the requirement apply to off-label use of a drug, so long as the criteria in the Off-Label mandate are met; and
- Prohibit cost sharing changes if the drug had already been covered.

The full text of SB 70 can be found in Appendix A.

Additional information about cost sharing can be found in Appendix B.

Analytic Approach and Key Assumptions – Bill Language

For this analysis, CHBRP has assumed that mandates that reference plans and policies “that cover prescription drugs,” such as the mandates addressed by SB 70, are relevant to pharmacy benefit coverage. Drugs that are physician-ordered and administered under the supervision of a physician (generally in a hospital, a provider's office, infusion center, or similar medical facility) are generally covered through a medical benefit, along with the hospital stay or office visit. 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.

For this analysis, for the current mandates and the mandates as SB 70 would alter them, CHBRP has assumed that:

- The benefit coverage of enrollees without a pharmacy benefit regulated by CDI or DMHC is and would be compliant.¹⁷ In other words, CHBRP assumes SB 70 would have no impact for plans without a regulated pharmacy benefit.
- A generic-only pharmacy benefit regulated by CDI or DMHC is not and would not be required to cover brand-name drugs.

For this analysis, for the current Continuity mandate and the Continuity mandate as SB 70 would alter it, CHBRP has assumed that:

- Coverage of any medically necessary services associated with the administration of the drug for which the Off-Label mandate would require coverage is and would be required (as is specified in the Off-Label mandate).

For this analysis, for the Continuity mandate as SB 70 would alter it, CHBRP has assumed that:

- The prohibition on changing cost sharing:
 - Would during a plan/policy year, prohibit application of not yet imposed cost sharing.
 - Would not apply if the enrollee changed to another plan or policy.

¹⁷ For more on outpatient prescription drug coverage among Californians with state-regulated health insurance, see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at https://chbrp.org/other_publications/index.php.

Should the prohibition on cost sharing (a prohibition on cost sharing not already imposed) be applicable on a year-over-year basis¹⁸ – and/or should it be applicable after an enrollee changes plan or policy – impacts on premiums could, in the long term, become orders of magnitude greater than what is projected in this analysis.

Interaction With Existing State and Federal Requirements

Health benefit mandates may interact with state and federal mandates or provisions.

California Policy Landscape

California law and regulations

As noted, SB 70 would amend California's existing Off-Label¹⁹ and Continuity²⁰ mandates.

The current Off-Label and Continuity mandates – and the mandates as SB 70 would alter them – do and would interact with existing California laws that address plan and insurer turnaround time regarding prior authorization requests. Such requests would typically be the way in which a provider would request coverage for off-label use of a drug or continued use of a drug, submitting with the request the documentation specified by the Off-Label or Continuity mandate. Plans and insurers regulated by DMHC and CDI are required to complete their review and respond to the prescriber regarding:

- A prior authorization request – within 72 hours (24 hours in emergency circumstances) or cover the prescription;²¹
- An appeal – generally within 30 calendar days (or faster in emergency circumstances).^{22,23}

The current mandates and the mandates as SB 70 would alter them do and would interact with existing California laws that address DMHC-regulated plan coverage of off-formulary drugs.²⁴

Similar requirements in other states

CHBRP is unaware of a Continuity mandate in another state that addresses dose or dosage form. However, Continuity mandates addressing coverage for drugs (but not dose or dosage form) do exist in multiple other states including Arizona, Illinois, Indiana, Louisiana, Maine, Nevada, New Hampshire, Tennessee, Texas, Virginia, and Washington (Johnson & Johnson, 2023).

¹⁸ CHBRP has assumed the contrary – that health plans and policies would continue to have the ability to modify deductibles, copays, coinsurance, and maximum out-of-pocket values each year.

¹⁹ HSC 1367.21, INS 10123.195.

²⁰ HSC 1367.22.

²¹ HSC 1367.241, INS 10123.191.

²² For DMHC-regulated plans, see generally Cal. Code Regs., tit. 28, §1300.68, subd. (d) (outlining specific requirements for plan grievance system). Shorter timeframes apply for expedited review of grievances in cases involving an imminent and serious threat to the health of the patient. See Health & Safety Code §1368.01, subd. (b). Plans are also required to maintain a mechanism to respond to disputes from both contracted and noncontracted providers. Generally, a plan must acknowledge a provider dispute within 15 working days and make a determination regarding the dispute within 45 working days. See Cal. Code Regs., tit. 28, §1300.71.38, subds. (e)-(f).

²³ For CDI-regulated insurers, see PHSA § 2719 (42 USC § 300gg-19) on internal claims and appeals, and the implementing regulation, 45 CFR § 147.136. PHSA § 2719 is referenced in Insurance Code sections 10123.135(h)(2) and 10123.201(e). The time limit for deciding an internal appeal under 45 CFR § 147.136 is found in the regulation it incorporates by reference, 29 CFR §2560.503-1 (health insurers must follow the rules that apply to group health plans in this regulation). Subdivision (i)(2) provides that an internal appeal determination on a pre-service claim (denied PA request) must be provided within 30 days of receipt, unless urgent, and then within 72 hours of receipt.

²⁴ HSC 1367.24.

Federal Policy Landscape

Affordable Care Act and essential health benefits

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how SB 70 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).^{25,26}

In California, nongrandfathered²⁷ individual and small-group health insurance is generally required to cover essential health benefits (EHBs).²⁸ In 2023, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs.²⁹

As SB 70 would not require coverage for a new benefit mandate, the bill would not appear to exceed the definition of EHBs in California.

²⁵ The ACA requires nongrandfathered small-group and individual market health insurance – including, but not limited to QHPs, qualified health plans sold in Covered California – to cover 10 specified categories of EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website:

www.chbrp.org/other_publications/index.php.

²⁶ Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.

²⁷ A grandfathered health plan is “a group health plan that was created – or an individual health insurance policy that was purchased – on or before March 23, 2010. Plans or policies may lose their ‘grandfathered’ status if they make certain significant changes that reduce benefits or increase costs to consumers.” Available at: www.healthcare.gov/glossary/grandfathered-health-plan.

²⁸ For more detail, see CHBRP’s issue brief *California State Benefit Mandates and the Affordable Care Act’s Essential Health Benefits*, available at: https://chbrp.org/other_publications/index.php.

²⁹ See CHBRP’s resource *Estimates of Sources of Health Insurance in California* and CHBRP’s issue brief *California State Benefit Mandates and the Affordable Care Act’s Essential Health Benefits*, both available at: https://chbrp.org/other_publications/index.php.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

The number of outpatient prescription drugs for which SB 70 could change access to coverage would be extremely large. Off-label usage occurs in up to 1 in 5 drugs prescribed in a doctor's office (Radley et al., 2006). An analysis of the medical effectiveness for the thousands of medications with off-label usage could not be completed within CHBRP's 60-day analytic period, and without an analysis of medical effectiveness, no impacts on public health can be predicted. However, this abbreviated analysis presents SB 70's expected impacts on benefit coverage, utilization, and cost.

For details on the underlying data sources and methods used in this analysis, please see Appendix C.

Baseline and Postmandate Benefit Coverage

As noted in Table 1, there would also be variation as to how many enrollees' benefit coverage would have to change to become compliant with SB 70:

- Under the altered Off-Label mandate:
 - 5,173,000 enrollees would have enhanced coverage for off-label use of dosages and dosage forms of prescription drugs.
- Under the altered Continuity mandate:
 - 5,173,000 enrollees would have enhanced coverage for continuing use of dosages, dosage forms, and off-label use of prescription drugs.
 - 13,404,000 enrollees would have new limits on cost sharing (so long as they do not change to another plan or policy).

As noted in the *Policy Context* section, CHBRP has assumed that SB 70 would not require benefit coverage change for enrollees without a pharmacy benefit regulated by DMHC or CDI.³⁰

Baseline and Postmandate Utilization

The current Off-Label and Continuity mandates, and the mandates as SB 70 would alter them, allow for the application of utilization management techniques, including formulary exclusions and step therapy protocols, which can influence less utilization of less expensive drug options (Lieberman and Roebuck, 2010).

The current Off-Label and Continuity mandate require coverage of a drug, when certain criteria are met. Both mandates, as SB 70 would alter them, would also when certain criteria are met require coverage of a drug at the dosage or dosage form that has been prescribed. Although utilization would continue to be influenced by utilization management techniques, the new requirements around dosage and dosage form would result in greater utilization of expensive drugs.³¹

³⁰ No Medi-Cal beneficiaries enrolled in a DMHC-regulated plan have a DMHC-regulated pharmacy benefit, and the same is true for a significant proportion of CalPERS enrollees in DMHC-regulated plans. The same is true for a limited number of commercial enrollees in plans and policies regulated by DMHC or CDI. For more detail, see CHBRP's resource *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at: <https://www.chbrp.org/other-publications/resources>.

³¹ Expensive drugs include some brand and some specialty drugs.

- CHBRP projects that the impacts due to the altered Off-Label mandate would be much more common than the impacts due to the Continuity mandate.³² Many enrollees seek coverage for off-label use of prescriptions drugs. Prescriptions for off-label use represent roughly one in five prescriptions. Such a large number of prescriptions offers many opportunities for utilization management techniques to be applicable – and also many opportunities for enrollees to use the current Off-Label mandate to secure coverage for an off-label prescription. The Off-Label mandate as SB 70 would alter it to include dosage and dosage form would create additional opportunities for enrollees to use the mandate to secure coverage for an off-label prescription.

Fewer enrollees experience a change in their plan's or policy's utilization management techniques such that continued coverage of a drug (for which they have had coverage) may not be available going forward. When this occurs, enrollees may use the current Continuity mandate to secure benefit coverage – and more could do so under the Continuity mandate as SB 70 would alter it to include dosage and dosage form with limits on within year cost sharing changes. However, as changes in utilization management techniques are not so frequent as is prescribed use of off-label drugs, the opportunities for an enrollee to use the Continuity mandate would be considerably less frequent than the opportunities for an enrollee to use the Off-Label mandate.

At baseline, the total number of scripts filled for drugs impacted by SB 70 – predominantly non-preferred brand and specialty drugs prescribed for off-label use – would be 551,000. This is the estimated number of drugs where the requirements of either the Off-Label or Continuity mandate would be modified. This figure is 15% of non-preferred brand and specialty scripts filled for enrollees with a pharmacy benefit regulated by DMHC or CDI that would be impacted by SB 70. Postmandate, 4,000 additional scripts are projected to be filled (see Table 1). This comes from 18,000 fewer generic and preferred brand scripts filled and 22,000 more non-preferred brand and specialty scripts filled. Although utilization management techniques can encourage the use of less expensive drugs (Lieberman and Roebuck, 2010), SB 70 would slightly decrease such impacts.

CHBRP projects a postmandate increase in filled scripts for some drugs, partly offset by fewer filled scripts for others. Postmandate utilization would be impacted for these reasons:

- At baseline, scripts written that are ultimately denied may result in scripts filled for alternative drugs. Postmandate, these scripts may be filled for the original prescription (and no longer for the alternative drug).
- At baseline, scripts written that are ultimately denied may result in no script filled. Postmandate, these scripts may be filled.
- Provider and enrollee awareness of the altered Off-Label and Continuity mandates would prompt some increase in the number of scripts written and therefore filled.

At the population level, CHBRP does not project a measurable increase in utilization due to the cost-sharing provisions of the Continuity mandate. As previously noted, the altered Continuity mandate's impact on filled scripts would be substantially less than would be expected for the altered Off-Label mandate. Also, as discussed below (see the *Enrollee Expenses* subsection), there would be common instances where the altered Continuity mandate would result in the same cost sharing or increased cost sharing.

³² Personal communication, C. Stern, February 2023.

Baseline and Postmandate Per-Unit Cost

At baseline, the average unit cost of a 30-day supply for a drug with coverage impacted by SB 70 is estimated to be approximately \$2,908. Within this average, unit costs for particular drugs range from less than \$750 to more than \$6,000.

Postmandate, the average unit costs of impacted scripts would be 0.76% higher, not because the unit costs of the drugs would change, but because the postmandate mix of covered scripts filled would include a smaller proportion of generic and preferred brand drugs and a greater proportion of specialty and non-preferred brand drugs, which are generally more expensive. The average increase in unit costs applies to all drugs that would be impacted by the mandate either by qualifying for off-label use or continuity use.

Baseline and Postmandate Expenditures

Table 2 and Table 3 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

SB 70 would increase total net annual expenditures by \$27,070,000, or 0.02%, for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a \$22,985,000 increase in total health insurance premiums and a \$4,085,000 increase in enrollee cost sharing.

Premiums

Changes in premiums as a result of SB 70 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 2, and Table 3), with health insurance that would be subject to SB 70. Such changes are also related to compliance with the two mandates at baseline as well as variation in coverage and benefit expenses for outpatient prescription drugs.

Total premiums for private employers purchasing group health insurance would increase by \$11,204,000, or 0.02%. Total premiums for purchasers of individual market health insurance would increase by \$7,734,000, or 0.04%. The greatest change in premiums as a result of SB 70 is for the individual policies (0.05% increase) in the CDI-regulated market.

Total premiums for DMHC-regulated Medi-Cal managed care plans would not be impacted by SB 70 because all of these Medi-Cal beneficiaries have a pharmacy benefit that is not regulated by DMHC³³ and because the current, and as SB 70 would alter it, Off-Label mandate exempts from compliance the benefit coverage of Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Total premiums for CalPERS enrollees in DMHC-regulated plans would increase by \$310,000, or 0.01%.

Enrollee Expenses

SB 70–related changes in total cost sharing for covered benefits (deductibles, copays, etc.) would vary by market segment (see Table 3). Variation in cost sharing is driven by baseline compliance with the two mandates as SB 70 would alter them, which varies by market segment.

Under the altered Off-Label mandate, there would be no change to copayments or coinsurance applicable to filled scripts for particular drugs (which vary from plan to plan and from policy to policy). However, CHBRP does project an increase in utilization of covered drugs and a greater utilization of non-preferred

³³ For more detail, see CHBRP's resource, *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at: <https://www.chbrp.org/other-publications/resources>.

brand drugs and specialty drugs (which are often associated with higher copays) and therefore an increase in overall enrollee cost sharing.

For the additional scripts filled under the altered Off-Label mandate, cost sharing would be similar to average cost sharing (or average coinsurance) for a typical plan design within each metal level³⁴ or deductible level limited by the maximum cost sharing as defined by applicable California law.³⁵

Under the altered Continuity mandate, new limits on cost sharing for continued use of a drug (so long as the enrollee does not change from one plan or policy to another) would be in effect. However, as discussed immediately below, in the *Per-user enrollee expenses* subsection, the impacts would vary, some enrollees' cost sharing decreasing, others' increasing, and others seeing no change. Unable to project the distribution of such impacts, CHBRP has modeled no population-level change in cost sharing due to the alterations of the Continuity mandate. Table 1 shows that overall cost sharing would increase as a result of SB 70. The cost-sharing changes projected in this analysis relate to changed and increased utilization due primarily to the changes SB 70 would make to the Off-Label mandate.

Note that cost sharing for prescription drugs varies widely across plans and policies, and generally does so between market segments. Individual market plans and policies, for instance, often have higher cost sharing for prescription drugs than do large-group plans and policies.

CHBRP is unable to estimate the baseline frequency with which enrollees self-pay for filled scripts when coverage is denied. Given the high cost of many of the drugs that would be impacted by SB 70, at baseline, noncovered drugs may be forgone by enrollees (or alternative, covered drugs used). Postmandate, enrollees who did self-pay, would have coverage and so would see a decrease in expenses for noncovered benefits (though there would be a concomitant increase in cost sharing for the now-covered filled scripts).

Per-user enrollee expenses

The impact of SB 70 on cost sharing would vary depending on a number of factors, including the coverage of the drug, applicable cost sharing, as well as an enrollee's choice to self-pay for noncovered benefits. Therefore, enrollee expense impact would be quite varied. Given the variation and the large number of potentially impacted drugs, CHBRP cannot estimate likely per-user enrollee impacts.

Example 1: Decrease in cost sharing. SB 70 may result in a reduction in cost sharing for a drug covered under the Continuity mandate. At baseline, prior to the altered Continuity mandate, some enrollees may have been required to pay additional cost sharing, which would have increased the cost sharing of drugs. For example, an enrollee may have paid the difference between the price of a non-preferred drug and the preferred drug. In other instances, an enrollee may have paid the full price of the drug, up to the plan's maximum out-of-pocket. Postmandate, such additional cost sharing cannot be required, and cost sharing would be reduced for some members.

Example 2: No cost-sharing change. Despite a change in coverage for an enrollee, SB 70 might prompt no change in cost sharing. Consider an enrollee who has routinely filled an ongoing monthly prescription for a brand maintenance drug, paying a \$100 copay for each monthly script filled. This enrollee's provider prescribes a different dosage form than what the enrollee has been

³⁴ Section 1302(d) of the ACA requires coverage within specified levels of coverage, or "metal" levels: bronze; silver; gold; and platinum. These metal levels correspond to an actuarial value for the plan or policy based on the cost-sharing features, not the benefits covered. The actuarial levels are as follows: 60% actuarial value for bronze-level plans; 70% actuarial value for silver-level plans; 80% actuarial value for gold-level plans; and 90% actuarial value for platinum-level plans.

³⁵ For most enrollees in most plans and policies regulated by DMHC or CDI, applicable copays and coinsurance is limited to \$250, or \$500 for enrollees in the "bronze plans" available from Covered California, the state's ACA marketplace (H&SC 1342.73; IC 10123.1932). Cost sharing could be higher for an enrollee in a plan or policy that includes a deductible.

using (e.g., switching from an oral form to an injectable), and the new dosage form is denied by the plan/policy. At baseline, the enrollee (not willing to self-pay) continues to use the previously prescribed dosage form. Postmandate, the enrollee would fill the script for the new dosage form and will pay the same \$100 copay (assuming both dosage forms were on the same formulary tier and so had the same cost sharing). In this example, there is no impact on this enrollee's cost sharing.

Example 3: Increase in cost sharing. For other enrollees, SB 70 may result in a cost-sharing increase. Consider an enrollee who has routinely filled an ongoing monthly prescription for a specialty maintenance drug, paying 10% coinsurance for each prescription filled, which costs \$4,000, that is, cost sharing of \$400. This enrollee's provider prescribes a higher dose than what the enrollee has been using, and the new dose costs \$5,000 per prescription filled. Suppose that at baseline, the plan/policy would have denied this increased dose. At baseline, the enrollee continues to use the previously prescribed dose and has the same copay (\$400). Postmandate, the enrollee would fill the script for the higher dose and will pay a \$500 copay.

In all of these examples, the presence of a deductible not yet met for the year³⁶ could result in the enrollee paying the full unit cost, but hitting the annual out-of-pocket maximum³⁷ would result in the enrollee having no further cost sharing.

Postmandate Administrative Expenses and Other Expenses

For this analysis, CHBRP has estimated an increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies 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. All health plans and insurers include a component for administration and profit in their premiums.

However, CHBRP notes that in some circumstances, additional initial year administrative costs could be incurred for implementation of the altered Continuity mandate's cost sharing limit. Any current data systems without the ability to make enrollee-specific exemptions to standard cost sharing would have to be updated. Therefore, it is possible that the total administrative expense may be higher than has been projected for this analysis.

Potential Cost Offsets or Savings in the First 12 Months After Enactment

When analyzing mandates, CHBRP often considers offsets or reductions in cost that may arise from a mandate.

Offsets would occur when enrollees, postmandate, access coverage for off-label use of a drug or access coverage for continued use of a drug and so do not fill a script for an alternative drug (such as a generic or preferred brand drug). However, as the postmandate filled scripts are frequently for non-preferred brand or specialty drugs, which generally have a higher unit cost, the average unit cost would still increase postmandate.

Another type of offset is also possible, though it would not be expected to occur often. An enrollee could respond better to a newly covered dosage or dosage form and so have improved health outcomes and reduced use of health care services. An enrollee could also have improved medication adherence as a

³⁶ For estimates of enrollees in plans and policies with deductibles, see CHBRP's resource *Deductibles in State-Regulated Health Insurance*, available at: https://chbrp.org/other_publications/index.php.

³⁷ For most enrollees in most plans and policies regulated by DMHC or CDI, applicable copays and coinsurance is limited to \$250, or \$500 for enrollees in the "bronze plans" available from Covered California, the state's ACA marketplace (H&SC 1342.73; IC 10123.1932). Cost sharing could be higher for an enrollee in a plan or policy that includes a deductible.

result of SB 70. However, the current financial incentives for plans/policies encourage coverage when there is a measurable health impact.³⁸ For this reason, and because research suggests that formulary changes have little impact on medication adherence (Sullivan et al., 2015), CHBRP does not anticipate measurable offsets for other health care services.

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 Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 2, and Table 3), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 70.

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 70.

³⁸ Personal communication, C. Stearn, February 9, 2023.

Table 2. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2024

	DMHC-Regulated						CDI-Regulated			Total
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS (b)	Medi-Cal (excludes COHS) (c) Under 65	65+	Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Total enrollees in plans/policies subject to SB 70	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	0	35,000	71,000	22,415,000
Premiums										
Average portion of premium paid by employer (e)	\$473.17	\$417.10	\$0.00	\$581.85	\$254.61	\$543.16	\$490.57	\$517.32	\$0.00	\$93,424,638,000
Average portion of premium paid by enrollee	\$122.17	\$180.13	\$645.33	\$113.49	\$0.00	\$0.00	\$180.61	\$168.99	\$626.90	\$39,493,008,000
Total premium	\$595.34	\$597.23	\$645.33	\$695.34	\$254.61	\$543.16	\$671.18	\$686.31	\$626.90	\$132,917,646,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	\$44.58	\$127.50	\$168.90	\$49.17	\$0.00	\$0.00	\$99.37	\$184.48	\$208.51	\$14,210,326,000
Expenses for noncovered benefits (f)	—	—	—	—	—	—	—	—	—	—
Total expenditures	\$639.92	\$724.73	\$814.23	\$744.50	\$254.61	\$543.16	\$770.55	\$870.80	\$835.40	\$147,127,972,000

Source: California Health Benefits Review Program, 2023.

Notes: (a) Includes enrollees with grandfathered and non-grandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.1% are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.³⁹ CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.

(d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.⁴⁰

(e) In some cases, a union or other organization – or Medi-Cal for its beneficiaries.

(f) Includes only those expenses that are paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance. For the expenses related to SB 70, at baseline some enrollees may have self-paid for scripts filled for which coverage would have been denied. However, others may have accepted coverage for the scripts filled of an alternative drug and so incurred no enrollee expense for a noncovered drug. CHBRP is unable to estimate baseline or postmandate amounts, but would expect such enrollee expenses to decline, postmandate.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

³⁹ For more detail, see CHBRP's resource *Estimates of Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at: http://chbrp.org/other_publications/index.php.

⁴⁰ For more detail, see CHBRP's resource *Sources of Health Insurance in California*, available at: http://chbrp.org/other_publications/index.php.

Table 3. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2024

	DMHC-Regulated						CDI-Regulated			Total
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	Small Group	Individual	CalPERS (b)	Medi-Cal (excludes COHS) (c) Under 65 65+		Large Group	Small Group	Individual	
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Total enrollees in plans/policies subject to SB 70	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Premiums										
Average portion of premium paid by employer (e)	\$0.0694	\$0.1579	\$0.0000	\$0.0293	\$0.0000	\$0.0000	\$0.1060	\$0.1433	\$0.0000	\$11,514,000
Average portion of premium paid by enrollee	\$0.0179	\$0.0682	\$0.2315	\$0.0057	\$0.0000	\$0.0000	\$0.0390	\$0.0468	\$0.3039	\$11,471,000
Total premium	\$0.0873	\$0.2261	\$0.2315	\$0.0350	\$0.0000	\$0.0000	\$0.1451	\$0.1901	\$0.3039	\$22,985,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	\$0.0066	\$0.0460	\$0.0615	\$0.0025	\$0.0000	\$0.0000	\$0.0214	\$0.0605	\$0.1081	\$4,085,000
Expenses for noncovered benefits (f)	—	—	—	—	—	—	—	—	—	—
Total expenditures	\$0.0940	\$0.2721	\$0.2930	\$0.0375	\$0.0000	\$0.0000	\$0.1664	\$0.2506	\$0.4120	\$27,070,000
Percent change										
Premiums	0.0147%	0.0379%	0.0359%	0.0050%	0.0000%	0.0000%	0.0216%	0.0277%	0.0485%	0.0173%
Total expenditures	0.0147%	0.0376%	0.0360%	0.0050%	0.0000%	0.0000%	0.0216%	0.0288%	0.0493%	0.0184%

Source: California Health Benefits Review Program, 2023.

Notes: (a) Includes enrollees with grandfathered and non-grandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.71 are state retirees, state employees, or their dependents. About one in five of these enrollees has a pharmacy benefit not subject to DMHC.⁴¹ CHBRP has projected no impact for those enrollees. However, CalPERS could, postmandate, require equivalent coverage for all its members (which could increase the total impact on CalPERS).

(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.

(d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.⁴²

(e) In some cases, a union or other organization – or Medi-Cal for its beneficiaries.

(f) Includes only those expenses that are paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance. For the expenses related to SB 70, at baseline some enrollees may have self-paid for scripts filled for which coverage would have been denied. However, others may have accepted coverage for the scripts filled of an alternative drug and so incurred no enrollee expense for a noncovered drug. CHBRP is unable to estimate baseline or postmandate amounts, but would expect such enrollee expenses to decline, postmandate.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

⁴¹ For more detail, see CHBRP's resource Pharmacy Benefit Coverage in State-Regulated Health Insurance, available at: http://chbrp.org/other_publications/index.php.

⁴² For more detail, see CHBRP's resource *Sources of Health Insurance in California*, available at: http://chbrp.org/other_publications/index.php.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of SB 70 which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Because high-cost drugs are anticipated to account for an increasing share of US prescription drug spending (Mulcahy et al., 2022), and because SB 70 may restrict the ability of plans/policies to reduce overall expenditure for high-cost drugs, the impact of SB 70 on utilization and cost could be substantially higher in future years than in the first 12 months after implementation.

APPENDIX A TEXT OF BILL ANALYZED

On January 20, 2023, the California Senate Committee on Health requested that CHBRP analyze SB 70 as introduced on January 9, 2023. On February 23, 2023, the Senate Health Committee asked CHBRP to analyze the bill with proposed amendments. The amendments became final on March 8, 2023. That language, which appears below, is what CHBRP analyzed.

AMENDED IN SENATE MARCH 08, 2023

CALIFORNIA LEGISLATURE— 2023–2024 REGULAR SESSION

SENATE BILL

NO. 70

Introduced by Senator Wiener

January 09, 2023

An act to amend Sections 1367.21 and 1367.22 of the Health and Safety Code, and to amend Section 10123.195 of, and to add Section 10123.190 to, the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

SB 70, as amended, Wiener. Prescription drug coverage.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care, and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law generally authorizes a health care service plan or health insurer to use utilization review, under which a licensed physician or a licensed health care professional who is competent to evaluate specific clinical issues may approve, modify, delay, or deny requests for health care services based on medical necessity. Existing law prohibits a health care service plan contract that covers prescription drug benefits or a specified health insurance policy from limiting or excluding coverage for a drug on the basis that the drug is prescribed for a use that is different from the use for which it was approved by the federal Food and Drug Administration if specified conditions are met. Existing law also prohibits a health care service plan that covers prescription drug benefits from limiting or excluding coverage for a drug that was previously approved for coverage if an enrollee continues to be prescribed that drug, as specified.

This bill would ~~expand the above described prohibitions to additionally prohibit limiting or excluding coverage of a drug, dose of a drug, or dosage form, and would apply these~~

~~prohibitions to a prescription form of a drug that is prescribed for off-label use. use if the drug has been previously covered for a chronic condition or cancer, regardless of whether or not the drug, dose, or dosage form is on the plan's or insurer's formulary. The bill would prohibit a health care service plan contract or health insurance policy from requiring additional cost sharing not already imposed for a drug that was previously approved for coverage. Because a willful violation of these provisions by a health care service plan would be a crime, the bill would impose a state-mandated local program. The bill would also prohibit a disability insurer that covers prescription drug benefits from limiting or declining coverage for a drug or dose of a drug as prescribed if specified criteria are met.~~

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1367.21 of the Health and Safety Code is amended to read:

1367.21. (a) A health care service plan contract that covers prescription drug benefits shall not be issued, amended, delivered, or renewed in this state if the plan limits or excludes coverage for ~~a drug, dose of a drug, or dosage form drug~~ on the basis that the ~~drug, dose of the drug, or dosage form drug~~ is prescribed for a ~~use, dose, or dosage form use~~ that is different from the ~~use, dose, or dosage form use~~ for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), ~~provided that~~ if all of the following conditions have been met:

- (1) The drug is approved by the FDA.
- (2) One of the following is true:
 - (A) The drug is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition.
 - (B) The drug is prescribed by a participating licensed health care professional for the treatment of a chronic and seriously debilitating ~~condition and condition~~, the drug is medically necessary to treat that ~~condition~~, ~~condition~~, and the drug is on the plan formulary. *If the drug is not on the plan formulary, the participating subscriber's request shall be considered pursuant to the process required by Section 1367.24.*
- (3) The drug has been recognized for treatment of that condition by any of the following:
 - (A) The American Hospital Formulary Service's Drug Information.

(B) One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(i) The Elsevier Gold Standard's Clinical Pharmacology.

(ii) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(iii) The Thomson Micromedex DrugDex.

(C) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) A health care service plan contract that covers prescription drug benefits shall not be issued, amended, delivered, or renewed in this state if the plan limits or excludes coverage for a drug, dose of a drug, or dosage form of a drug on the basis that the drug, dose of a drug, or dosage form is prescribed for a use, dose, or dosage form that is different from the use, dose, or dosage form for which the drug has been approved for marketing by the FDA if all of the following conditions have been met:

(1) The drug is approved by the FDA.

(2) One of the following is true:

(A) The drug, dose, or dosage form is prescribed by a participating licensed health care professional for the treatment of a life-threatening condition.

(B) The drug, dose, or dosage form is prescribed by a participating licensed health care professional for the treatment of a chronic and seriously debilitating condition and the drug, dose, or dosage form is medically necessary to treat that condition.

(3) The drug has been recognized for treatment of that condition by any of the following:

(A) The American Hospital Formulary Service's Drug Information.

(B) One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(i) The Elsevier Gold Standard's Clinical Pharmacology.

(ii) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(iii) The Thomson Micromedex DrugDex.

(C) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(4) The drug has been previously covered pursuant to Section 1367.22 for a chronic condition or cancer.

~~(b)~~

(c) It shall be the responsibility of the participating prescriber to submit to the plan documentation supporting compliance with the requirements of ~~subdivision (a)~~, subdivisions (a) and (b), if requested by the plan.

~~(e)~~

(d) Any coverage required by this section shall also include medically necessary services associated with the administration of a drug, subject to the conditions of the contract.

~~(d)~~

(e) For purposes of this section, “life-threatening” means either or both of the following:

- (1) Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.*
- (2) Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.*

~~(e)~~

(f) For purposes of this section, “chronic and seriously debilitating” means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

~~(f)~~

(g) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the plan.

~~(g)~~

(h) This section does not prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is

prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA.

~~(h)~~

(i) If a plan denies coverage pursuant to this section on the basis that its use is experimental or investigational, that decision is subject to review under Section 1370.4.

~~(i)~~

(j) Health care service plan contracts for the delivery of Medi-Cal services under the Waxman-Duffy Prepaid Health Plan Act (Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code) are exempt from the requirements of this section.

SEC. 2. Section 1367.22 of the Health and Safety Code is amended to read:

1367.22. (a) 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, or require additional cost sharing not already imposed, for a drug, dose of a drug, or dosage form for an enrollee if the drug previously had been approved for coverage by the plan for a medical condition of the enrollee and the plan's prescribing provider continues to prescribe the drug for the medical condition, provided that the drug, dose of the drug, or dosage form is appropriately prescribed and is considered safe and effective for treating the enrollee's medical condition. 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 drug substitutions as authorized by Section 4073 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) 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.

(c) 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.

(d) This section applies to a prescription drug that is prescribed off-label in accordance with Section 1367.21.

~~SEC. 3. Section 10123.190 is added to the Insurance Code, to read:~~

~~10123.190. (a)(1) Notwithstanding Sections 10123.13, 10123.191, and 10123.201, or another section of this code to the contrary, a disability insurer that provides coverage for prescription drugs shall not limit or decline to cover a drug or dose of a drug as prescribed, or impose additional cost sharing for covering a drug as prescribed, if all the following apply:~~

~~(A) An insured is undergoing a current course of treatment with the prescription drug for a covered medical condition or is seeking an authorization for continued coverage within a month of the date of expiration of the last prescription or refill.~~

~~(B) The drug was previously covered by the insurer or the insured's prior private or public health care coverage for the insured's medical condition.~~

~~(C) A prescribing provider prescribed the drug for the insured's medical condition, and the drug is appropriately prescribed and considered safe and effective under generally accepted standards of medical care for treating the insured's medical condition.~~

~~(2) An insurer that verifies that a condition in paragraph (1) is satisfied shall not delay or deny coverage during the verification process, except if a drug is unsafe as prescribed. If a drug is unsafe as prescribed, an insurer shall notify the provider of its coverage determination, as provided by Section 10123.191. If an insurer determines that another condition in paragraph (1) is unsatisfied, it shall comply with Section 10123.13.~~

~~(3) This subdivision does not do any of the following:~~

~~(A) Preclude a provider from prescribing another drug that is clinically appropriate for an insured.~~

~~(B) Prohibit generic drug substitutions under Section 4073 of the Business and Professions Code.~~

~~(b) This section applies to a prescription drug that is prescribed off label in accordance with Section 10123.195.~~

~~(c) This section applies to a disability insurer and disability insurance policy that provides coverage for hospital, medical, surgical, or prescription drug benefits. This section does not apply to the insurance listed in paragraphs (1) through (8) of subdivision (b) of Section 106, a specialized health insurance policy that provides coverage only for dental or vision benefits, or a Medicare supplement policy.~~

SEC. 3. Section 10123.190 is added to the Insurance Code, to read:

10123.190. *(a) A health insurance policy that covers prescription drugs that is issued, amended, or renewed on or after January 1, 2024, shall not limit or exclude coverage, or require authorization or additional cost sharing that is not generally applicable to drugs covered by the policy, for a drug, dosage of a drug, or dosage form of a drug if a plan or insurer had previously*

approved coverage of the drug for a health condition, and a participating provider continues to prescribe the drug for the condition, if the drug, dosage, or dosage form of the drug was prescribed appropriately and is considered safe and effective for an insured's health condition under current generally accepted standards of care.

(b) A prescription drug is prescribed appropriately if a provider is authorized to prescribe or furnish the drug within the provider's scope of practice. This section does not preclude a participating provider from prescribing or furnishing another drug that is clinically appropriate for an insured or prohibit generic drug substitution as authorized by Section 4073 of the Business and Professions Code.

(c) This section applies to a prescription drug that was prescribed off-label, including in accordance with Section 10123.195. This section does not apply to a Medicare supplement policy or a specialized health insurance policy that covers only dental or vision benefits.

(d) The commissioner may promulgate regulations subject to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to implement and enforce this section. In addition to any other remedies that are available to the commissioner for a violation of this code, the commissioner may enforce this article pursuant to Chapter 4.5 (commencing with Section 11400) or Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. This subdivision does not impair or restrict the commissioner's authority pursuant to another provision of this code or the Administrative Procedure Act.

SEC. 4. Section 10123.195 of the Insurance Code is amended to read:

10123.195. ~~(a) A group, blanket, or individual disability~~ *An individual or group health insurance policy issued, delivered, or renewed in this state or state, or a certificate of group or blanket disability insurance issued, delivered, or renewed in this state pursuant to a master group policy issued, delivered, or renewed in another state that, as a provision of hospital, medical, or surgical services, state, that directly or indirectly covers prescription drugs shall not limit or exclude coverage for a drug, dose of a drug, or dosage form drug on the basis that the drug, dose of the drug, or dosage form drug is prescribed for a use, dose, or dosage form use that is different from the use, dose, or dosage form use for which that drug has been approved for marketing by the federal Food and Drug Administration (FDA), provided that if all of the following conditions have been met:*

(1) The drug is approved by the ~~FDA~~ *FDA or is legally marketed without FDA approval.*

(2) One of the following is true:

(A) The drug is prescribed by a contracting licensed health care professional for the treatment of a life-threatening condition.

(B) The drug is prescribed by a contracting licensed health care professional for the treatment of a chronic and seriously debilitating condition, the drug is medically necessary to treat that condition, and the drug is on the insurer's formulary, if any.

(3) The drug has been recognized for treatment of that condition by any of the following:

(A) The American Hospital Formulary Service's Drug Information.

(B) One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(i) The Elsevier Gold Standard's Clinical Pharmacology.

(ii) The National Comprehensive Cancer Network Drug and Biologics Compendium.

(iii) The Thomson Micromedex DrugDex.

(C) Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

(b) An individual or group health insurance policy issued, delivered, or renewed in this state, or a certificate of group insurance issued, delivered, or renewed in this state pursuant to a master group policy issued, delivered, or renewed in another state, that directly or indirectly covers prescription drugs shall not limit or exclude coverage for a drug, dose of a drug, or dosage form of a drug on the basis that the drug, dose of a drug, or dosage form is prescribed for a use, dose, or dosage form that is different from the use, dose, or dosage form for which the drug has been approved for marketing by the FDA if all of the following conditions have been met:

(1) The drug is approved by the FDA or is legally marketed without FDA approval.

(2) One of the following is true:

(A) The drug, dose, or dosage form is prescribed by a contracting licensed health care professional for the treatment of a life-threatening condition or health condition as provided by Section 10123.1961.

(B) The drug, dose, or dosage form is prescribed by a contracting licensed health care professional for the treatment of a chronic and seriously debilitating health condition and the drug, dose, or dosage form is clinically appropriate to treat that condition. If the prescription drug is not covered or not covered off-label, then clinical appropriateness shall be determined solely in accordance with paragraph (3).

(3) *The drug has been recognized for treatment of that condition by any of the following:*

(A) *The American Hospital Formulary Service's Drug Information.*

(B) *One of the following compendia, if recognized by the federal Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:*

(i) *The Elsevier Gold Standard's Clinical Pharmacology.*

(ii) *The National Comprehensive Cancer Network Drug and Biologics Compendium.*

(iii) *The Thomson Micromedex DrugDex.*

(C) *Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.*

(4) *The drug has been previously covered pursuant to Section 10123.190 for a chronic condition or cancer.*

~~(b)~~

(c) *It shall be the responsibility of the contracting prescriber to submit to the insurer documentation supporting compliance with the requirements of ~~subdivision (a)~~, subdivisions (a) and (b), if requested by the insurer. With respect to a request for coverage of a prescription drug pursuant to Section 10123.191, it shall be the responsibility of the health insurer to determine whether or not this section applies to the request, and to request any additional or omitted information that is needed to make a coverage determination pursuant to the request under the requirements of this section and Section 10123.191.*

~~(e)~~

(d) *Any coverage required by this section shall also include medically necessary services associated with the administration of a ~~drug subject to the conditions of the contract~~ drug.*

~~(d)~~

(e) *For purposes of this section, "life-threatening" means either or both of the following:*

(1) *Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.*

(2) *Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.*

~~(e)~~

(f) For purposes of this section, “chronic and seriously debilitating” means diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.

~~(f)~~

(g) The provision of drugs and services when required by this section shall not, in itself, give rise to liability on the part of the insurer.

~~(g)~~

(h) This section shall not apply to a policy of ~~disability~~ insurance that covers ~~hospital, medical, or surgical expenses which~~ *health care expenses* and that is issued outside of California to an employer whose principal place of business ~~is and majority of employees are~~ located outside of California.

~~(h) This section does not prohibit the use of a formulary, copayment, technology assessment panel, or similar mechanism as a means for appropriately controlling the utilization of a drug that is prescribed for a use that is different from the use for which that drug has been approved for marketing by the FDA.~~

(i) If an insurer denies coverage pursuant to this section on the basis that ~~its use is experimental or off-label use of a prescription drug is experimental, investigational, or not clinically appropriate, or for any other reason,~~ that decision is subject to review under the Independent Medical Review System of Article 3.5 (commencing with Section 10169).

(j) This section is not applicable to vision-only, dental-only, ~~Medicare or Champus supplement, disability income, long-term care, accident-only, specified disease or hospital confinement indemnity insurance, or Medicare supplement insurance policies.~~

(k) The commissioner may promulgate regulations subject to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to implement and enforce this section. In addition to any other remedies that are available to the commissioner for a violation of this code, the commissioner may enforce this article pursuant to Chapter 4.5 (commencing with Section 11400) or Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code. This subdivision does not impair or restrict the commissioner’s authority pursuant to another provision of this code or the Administrative Procedure Act.

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.

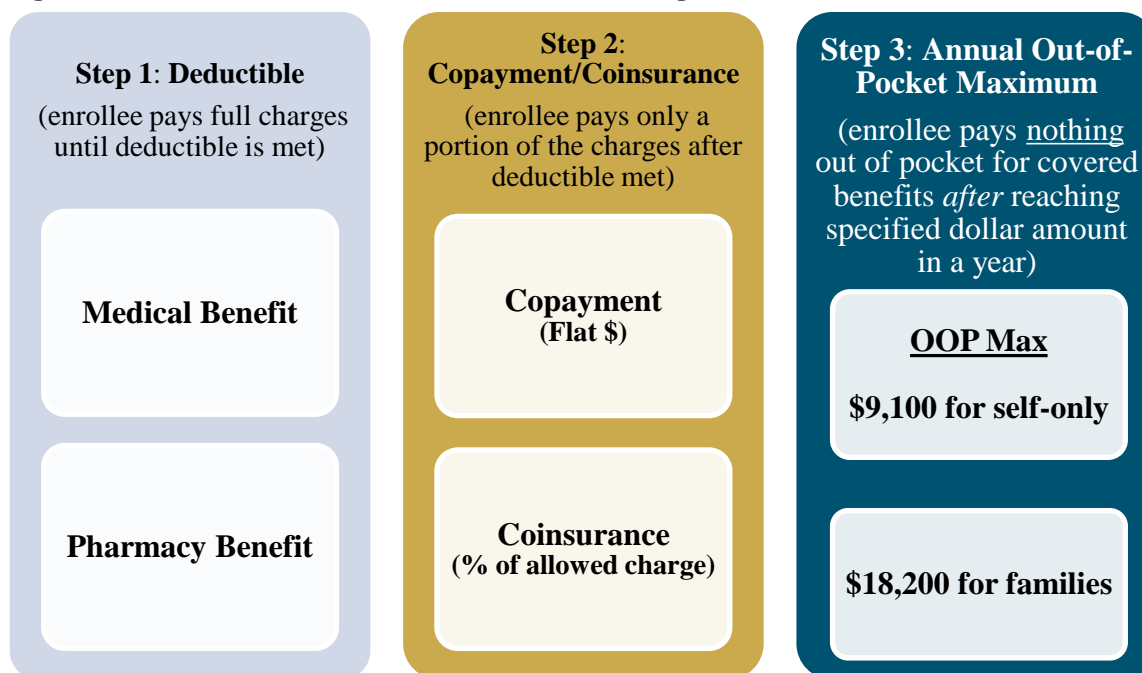
APPENDIX B COST SHARING

This appendix provides an overview of cost sharing that may be applicable to covered benefits, including coverage of prescription drugs through a pharmacy benefit.

Payment for use of covered health insurance benefits is shared between the payer (e.g., health plan/insurer or employer) and the enrollee. Common cost-sharing mechanisms include copayments, coinsurance, and/or deductibles (but do not include premium expenses⁴³). There are a variety of cost-sharing mechanisms that can be applicable to covered benefits (Figure 1). Some health insurance benefit designs incorporate higher enrollee cost sharing in order to lower premiums. Reductions in allowed copayments, coinsurance, and/or deductibles can shift the cost to premium expenses or to higher cost sharing for other covered benefits.⁴⁴

Annual out-of-pocket maximums for covered benefits limit annual enrollee cost sharing (medical and pharmacy benefits). After an enrollee has reached this limit through payment of coinsurance, copayments, and/or deductibles, insurance pays 100% of the covered services. The enrollee remains responsible for the full cost of any tests, treatments, or services that are not covered benefits.

Figure 1. Overview of the Intersection of Cost-Sharing Methods Used in Health Insurance



Source: California Health Benefits Review Program, 2023; CMS, 2022.

Note: Steps 1 and 2 are not mutually exclusive. Under certain circumstances (i.e., preventive screenings or therapies), enrollees may pay coinsurance or copayments prior to their deductible being met; also copayments and coinsurance may be applied against the deductible in some circumstances. The figure assumes that the enrollee is in a plan with a deductible. If no deductible, then enrollee pays a coinsurance and/or a copayment beginning with the first dollar spent (Step 2).

⁴³ Premiums are paid by most enrollees, regardless of their use of any tests, treatments, or services. Some enrollees may not pay premiums because their employers cover the full premium, they receive premium subsidies through the Covered California, or they receive benefits through Medi-Cal.

⁴⁴ Plans and policies sold within Covered California are required by federal law to meet specified actuarial values. The actuarial value is required to fall within specified ranges and dictates the average percent of health care costs a plan or policy covers. If a required reduction in cost sharing impacts the actuarial value, some number of these plans or policies might have to alter other cost-sharing components of the plan and/or premiums in order to keep the overall benefit design within the required actuarial value limits.

The annual out-of-pocket maximums listed in Step 3 increase each year according to methods detailed in CMS' Notice of Benefit and Payment Parameters (CMS, 2022).

Key: OOP Max = annual out-of-pocket maximum.

High deductible health plans

Both DMHC-regulated plans and CDI-regulated policies may be designated high deductible health plans (HDHPs).⁴⁵ HDHPs are a type of health plan with requirements set by federal regulation.⁴⁶ As the name implies, these plans include a deductible – but they are not allowed to have separate medical and pharmacy deductibles. For the 2023 plan year, the Internal Revenue Service (IRS) defines an HDHP as any plan with a deductible of at least \$1,500 for an individual and \$3,000 for a family.⁴⁷ Annual out-of-pocket expenses for coverage of in-network tests, treatments, and services, which would result from cost sharing⁴⁸ applicable after the deductible is met, are not allowed to be more than \$7,500 for an individual and \$15,000 for a family.⁴⁹

Health savings account–qualified HDHPs

To be eligible to establish a health savings account (HSA) for taxable years beginning after December 31, 2003⁵⁰ (and so to be eligible to make tax-favored contributions to an HSA), a person must be enrolled in an HSA-qualified HDHP.

In order for a HDHP to be HSA qualified, it must follow specified rules regarding cost sharing and deductibles, as set by the IRS. Generally, an HDHP may not provide benefits for any year until the deductible for that year is satisfied – but federal law provides a safe harbor for the absence of a deductible applicable to preventive care.⁵¹ Therefore an HDHP may cover preventive care benefits without any deductible or with a deductible below the minimum annual deductible – but is not required to do so for a specified list of preventive services. The list of preventive services for which application of a deductible is not required includes treatments for chronic conditions.⁵²

Allowed Cost Amounts for Medical Services

Insurers usually negotiate how much they will pay for the costs of covered health care services with health care providers and suppliers (Center on Budget and Policy Priorities, 2022). These negotiated amounts are known as the “allowed cost amount.” Health care providers, including hospitals and physicians, participating in a plan’s network agree to accept these payment amounts when an enrollee covered by the plan uses covered services. The cost-sharing charges the enrollee owes (for example, a 20% coinsurance rate) are based on this allowed cost amount. If an enrollee uses a service that is not covered or sees a provider that is not within the insurer’s network, the overall charge, including an enrollee’s cost sharing, could be higher than the allowed amount.

⁴⁵ For enrollment estimates, see CHBRP’s resource *Deductibles in State-Regulated Health Insurance*, available at: https://chbrp.org/other_publications/index.php.

⁴⁶ HealthCare.gov. Glossary: High Deductible Health Plan (HDHP). Available at: www.healthcare.gov/glossary/high-deductible-health-plan/#:~:text=For%202019%2C%20the%20IRS%20defines,or%20%2413%2C500%20for%20a%20family. Accessed March 5, 2021.

⁴⁷ IRS Revenue Procedure 2022-24. Available at: www.irs.gov/pub/irs-drop/rp-22-24.pdf.

⁴⁸ Such as copays and coinsurance applicable to the covered test, treatment, or service.

⁴⁹ There is no annual out-of-pocket expenses limit for coverage of out-of-network tests, treatments, and services.

⁵⁰ Section 1201 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, added section 223 to the Internal Revenue Code.

⁵¹ For more information on screening services, see Notice 2004-23, 2004-15 I.R.B. 725. Available at: www.irs.gov/irb/2004-15_IRB#NOT-2004-23. For additional guidance on preventive care, see Notice 2004-50, 2004-2 C.B. 196, Q&A 26 and 27, available at: www.irs.gov/irb/2004-33_IRB#NOT-2004-50; and Notice 2013-57, 2013-40 I.R.B. 293, available at: www.irs.gov/pub/irs-drop/n-13-57.pdf.

⁵² For information on preventive care for chronic conditions, see Notice 2019-45, 2019-32 I.R.B. 593, available at: www.irs.gov/pub/irs-drop/n-19-45.pdf.

APPENDIX C: COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

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.⁵³ 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 at CHBRP's website.⁵⁴

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

Analysis-Specific Data Sources

Current coverage of the Continuity and Off-Label mandate as SB 70 would alter them for commercial enrollees was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represented 93.5% of commercial enrollees with health insurance that can be subject to state benefit mandates. As necessary, CHBRP extrapolated from responses of similarly situated plans/policies.

Detailed Cost Notes Regarding Analysis-Specific Caveats and Assumptions

General assumptions are noted in the body of this report. Additional assumptions are noted below.

The analysis of SB 70 was developed using research on how efforts by plans/policies to control costs impact the overall utilization and unit costs of drugs.

SB 70 would partially restrict the ability of plans and policies to limit utilization of certain drugs. Although neither the current mandates nor the mandates as SB 70 would alter them prohibit prior authorization (or other forms of utilization management), CHBRP assumed that the combined effect of SB 70 for the Continuity and Off-Label mandates as SB 70 would alter them would be equivalent to removing prior authorization requirements for one to two drug therapy classes. A drug therapy class or therapeutical class is a group of drugs that work by a similar mechanism. These drugs are related by their pharmaceutical properties. Examples of therapeutic classes include sodium-glucose co-transporter 2 (SGLT2) inhibitors and antiretrovirals. Utilization management techniques may encourage the use of less expensive drugs (Lieberman and Roebuck, 2010).

Rebates were modeled as an offsetting cost for SB 70. CHBRP assumed that rebates were \$200 per brand script at retail and \$600 per brand script at mail. CHBRP assumed all brand drugs would receive rebates and did not make any assumptions about reduced rebate revenue associated with nonformulary utilization or revised utilization management efforts.

"Off-label use", otherwise known as prescribing without an FDA indication, occurs where there is prescribing for a medication for a nonapproved FDA condition or not in accordance with the package insert (the FDA label). Medically necessary services that would be associated with SB 70 are substantially included in the underlying research on outpatient prescription drug costs. The research includes administration fees and other services reimbursed through outpatient prescription drug claims.

⁵³ CHBRP's authorizing statute, available at: https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

⁵⁴ See method documents posted at: <https://www.chbrp.org/about/analysis-methodology/cost-impact-analysis>; in particular, see *2023 Cost Impact Analyses: Data Sources, Caveats, and Assumptions*.

For this analysis, CHBRP has assumed that under both the current Off-Label mandate and the mandate as SB 70 would alter it, plans and policies can and could, when medically appropriate, cover generic drugs instead of brand-name drugs. CHBRP has also assumed that plans and policies can and could, when medically appropriate, cover a biosimilar drug instead of the original biological medication from different manufacturer.⁵⁵

Methodology and Assumptions for Baseline Utilization

CHBRP estimated the number of prescription drugs per 1,000 commercial/CalPERS enrollees that occurred in 2023 using Milliman's Health Cost Guidelines™ Prescription Drug Rating Manual (RxRM) calibrated to a gold copay benefit design available on Covered California. The RxRM is developed using a database of commercial prescription drug claims, along with published research on pharmacy trends, brand patent losses, pipeline products, and other reference data sources.

CHBRP assumed that plans and policies generally had several drug programs features in place to manage the cost of prescription drugs. These features include use of a formulary, prior authorization, and step therapy requirements. Responses from plan or policy surveys and consultation with a content expert⁵⁶ indicated that these program features were generally consistent across the large-group, small-group, and individual markets. The starting actuarial model, RxRM Model #1 may be found in Table 4 below.

CHBRP assumed 15% of non-preferred brand and specialty drugs were off-label and would be impacted by SB 70.

For each market segment, CHBRP further adjusted utilization to match our survey of plan and policy premiums. CHBRP assumed that pharmacy expenses totaled 18% of total health benefits.

Methodology and Assumptions for Baseline Cost

CHBRP estimated baseline unit costs after rebates as discussed in the utilization section above. See Table 4 below for more details.

Formulary tiers with predominantly generic and preferred brand drugs had average unit costs of \$57 for each script filled. CHBRP expect postmandate utilization to slightly decrease in these formulary tiers.

Formulary tiers with predominantly non-preferred brand or specialty drugs had average unit costs of \$2,908 for each script filled. CHBRP expect postmandate utilization to increase in these formulary tiers.

Methodology and Assumptions for Baseline Cost Sharing

CHBRP assumed the cost sharing for prescription drugs is the same as major medical cost sharing as prescription drugs are a major component of health plans. Enrollee cost share is equal to one minus the line of business paid-to-allowed ratio multiplied by the prescription drug cost.

CHBRP assumed that there were minimal expenses for noncovered benefits in the baseline.

Methodology and Assumptions for Postmandate Utilization

CHBRP assumed the utilization rate for enrollees *with coverage* postmandate is equal to the utilization rate for enrollees *with coverage* at baseline.

⁵⁵ A biosimilar is a biological medication. It is highly similar to a biological medication already approved by the FDA – the original biologic (also called the reference product) (FDA, Biosimilar Basics for Patients, 2023).

⁵⁶ Personal communication, C. Stern, February 2023.

As noted above, the postmandate utilization assumes a level of utilization that would occur if prior authorization requirements were removed from one to two drug classes.

To estimate this level of utilization, Models #1 and #2 were developed (see Table 4). RxRM model #2 reflects the impact of removing prior authorization requirements from two to four therapeutic classes using the Milliman's Health Cost Guidelines™ Prescription Drug Rating Manual (RxRM) and otherwise identical underlying assumptions as RxRM model #1. The RxRM allows direct modeling of such utilization management techniques as a direct input into the rating manual.

Although neither the current mandates nor the mandates as SB 70 would alter them prohibit prior authorization (or other forms of utilization management), CHBRP projects that the impact of the mandate, for all enrollees for whom there was not compliant benefit coverage at baseline, would be equivalent to removing prior authorization requirements on one to two therapeutic classes. In such circumstances, the impact of the mandate would be approximately 50% of the difference between RxRM model #1 and RxRM model #2.

Table 4. Starting Models, 2024

	RxRM Model #1	RxRM Model #2*	Increase / Decrease	Change
Non-preferred Brand and Specialty				
Utilization per 1,000 members	209	215	6	3.05%
Total allowed claims cost PMPM	\$51.00	\$51.10	\$0.10	0.19%
Average cost per script	\$2,933	\$2,852	-\$81	-2.77%
Generic and Preferred Brand				
Utilization per 1,000 members	7,298	7,293	-5	-0.07%
Total allowed claims cost PMPM	\$34.39	\$34.88	\$0.49	1.41%
Average cost per script	\$56.55	\$57.39	\$0.84	1.48%

Source: California Health Benefits Review Program, 2023.

Notes: *RxRM model #2 reflects a difference of removing prior authorization requirements from two to four therapeutic classes.

Key: PMPM = per member per month.

As discussed above, CHBRP further adjusted these models based upon a survey of carrier premiums and compliance with SB 70 at baseline.

Methodology and Assumptions for Postmandate Cost

CHBRP assumed the average cost per service would not change as a result of SB 70. CHBRP assumed the altered Continuity and altered Off-Label mandates will cause a shift to more expensive non-preferred brand and specialty drugs, resulting in a higher average cost per script.

Methodology and Assumptions for Postmandate Cost Sharing

CHBRP assumed the cost sharing for prescription drugs is the same as major medical cost sharing because prescription drugs are a major component of health plans.

Determining Public Demand for the Proposed Mandate

CHBRP reviews public demand for benefits by comparing the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage that complies with the dosage and dosage forms SB 70 would require, but cost sharing for continued use of a drug, dosage, or dosage form is not different from other cost sharing.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask plans and insurers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. CHBRP asked the same questions of the content expert recruited for this analysis, who has general familiarity with the benefit coverage of enrollees in self-insured products.⁵⁷ The responses indicated that:

- Coverage for use of off-label drugs, dosages, or dosage forms is often limited and may require prior authorization.
- Continued coverage for a drug, dosage, or dosage form is not uncommon.
- Cost sharing for continued use of a drug, dosage, or dosage form is not different from other cost sharing.

Second-Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of SB 70 would have a substantially different impact on utilization of pharmacy benefits for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second-year impacts and determined the second year's impacts of SB 70 would be substantially the same as the impacts in the first year (see Table 1), notwithstanding industry trends in high-cost drug expenditures. Minor changes to utilization and expenditures are also expected due to population changes between the first year postmandate and the second year postmandate.

⁵⁷ Personal communication, C. Stern, February 2023.

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ABOUT CHBRP

The California Health Benefits Review Program (CHBRP) was established in 2002. 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. The state funds CHBRP through an annual assessment on health plans and insurers in California.

A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (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 a certified actuary, **Milliman**, 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 www.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 www.chbrp.org.

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